This year, Perlmutter Cancer Center welcomed exceptional faculty and produced leading-edge cancer research that, in several cases, will alter cancer care worldwide.

We have continued to expand our portfolio of cutting edge clinical trials, including an increasingly robust Phase I program.

The number of transplants performed at Perlmutter Cancer Center’s Blood and Marrow Transplant Program increased dramatically in the last year, and we obtained certification from the Foundation for the Accreditation of Cellular Therapy (FACT) for allogeneic transplants.

Our faculty continue to advance cancer diagnosis and treatment, including new therapeutic breakthroughs in the treatment of intractable lung and triple negative breast cancers, the identification of three oral bacteria tied to esophageal cancer risk, a new laser ablation technique for intractable brain tumors, and the development of a 580-gene diagnostic panel for cancer-associated mutations.

We look forward to another year of continued growth for new understanding of cancer and pathways to treatment.

BENJAMIN G. NEEL, MD, PHD
Professor of Medicine
Director, Laura and Isaac Perlmutter Cancer Center
Perlmutter Cancer Center Expands Clinical Trials Programs

Over the last five years, Perlmutter Cancer Center’s Clinical Trial Office (CTO) has tripled in size. With shortened opening times, expanded biobanking, a budding Phase I Trial Drug Development Program, new metric-tracking tools, and increased patient accrual across a growing clinical network, the CTO team has steadily grown and strengthened its relationships with pharmaceutical and biotech companies—solidifying the center’s status as a go-to site for cancer research trials.

TRACKING EFFICIENCY WITH ENHANCED METRICS

With a formalized process for tracking metrics, the reorganized CTO is relying on new, more advanced tracking tools and data management systems. Many of these IT instruments were developed in-house at NYU Langone to streamline the review and approval process and assist investigators in managing data and meeting reporting requirements once trials are activated. The CTO can now provide trial sponsors with quantitative metrics demonstrating that NYU Langone’s program operates with extreme efficiency. “We now get our studies activated within 100 days. We’ve lowered the number of deviations, we’re running studies with higher acuity and complexity, and we significantly increased accrual rates,” says Deirdre J. Cohen, MD, associate professor of medicine and medical director of the Clinical Trials Office at Perlmutter Cancer Center.

The phase I program has been particularly successful at enrolling patients, thanks to an operational culture that encourages collaboration. “Where many centers are more siloed with only a select number of investigators participating in trials, here we run a very open program where just about every investigator can be on our protocols,” explains Daniel C. Cho, MD, assistant professor and director of the rapidly expanding Phase 1 Drug Development Program. “Downstream, this openness leads to robust patient accrual, a key metric for drawing in more trials.”

EXPANDING TO SATELLITE SITES

That collaborative culture is now extending to investigators at NYU Winthrop Hospital, an affiliate of NYU Langone Health, all of whom have been assigned to disease management groups at Perlmutter Cancer Center, going forward, they will be part of the vetting process for all new trials under consideration. “With representatives from NYU Winthrop in each group, we can determine early on if a trial suits their patient population, as well as ours, or competes with existing studies,” says Dr. Cohen.

We’ve lowered the number of deviations, we’re running studies with higher acuity and complexity, and we significantly increased accrual rates.”

—Deirdre J. Cohen, MD
A pilot program will start with five clinical trials conducted at both locations. With expansion to NYU Winthrop as the first phase, the center is also working to extend trials to NYU Langone Hospital—Brooklyn and other network sites. An earlier initiative aimed at increasing clinical trial access for the patient population at NYU Health's Hospitals/Bellevue, where NYU Langone Health has an academic affiliation, resulted in a fivefold accrual increase in the past year. “We want to mimic that model at NYU Winthrop and future sites,” notes Dr. Cohen.

**GROWING THE TRIAL PORTFOLIO**

High-growth program areas include studies and phase I drug trials initiated by Perlmutter Cancer Center, and that momentum is feeding opportunity throughout the center. “This past year has seen the launch of several trials originated by investigators at the cancer center, and the phase I program—launched within the past five years—became our fastest-growing trial unit at the center,” says Dr. Cohen.

In one ongoing trial, Mohammad Maher Abdul Hay, MD, assistant professor of medicine at NYU Langone and associate director for research at Bellevue’s Cancer Center, is currently recruiting patients with myelodysplastic syndrome (MDS) for research stemming from preclinical work conducted by Benjamin G. Neel, MD, PhD, professor of medicine and director of the Perlmutter Cancer Center and Iannis Aifantis, PhD, professor of pathology and chair of the Department of Pathology. The Neel/Aifantis team showed that in TET2-deficient mice, high-dose vitamin C restored TET2 function, induced stem cells to mature into healthy blood cells, and suppressed leukemia stem cell growth. The findings, published in August 2017 in Cell, suggest that high-dose vitamin C might effectively treat blood diseases caused by TET2-deficient leukemia stem cells, most likely in combination with other targeted therapies.

In light of these laboratory studies, Dr. Hay launched an open label phase Ib/IIa study to evaluate the safety and biological activity of intravenous vitamin C infusions in MDS patients who are at intermediate or high risk of acute myeloid leukemia and also have a mutation in the TET2 gene, found in 30 percent of MDS patients. This the first FDA-approved clinical trial to use a continuous vitamin C infusion, a potentially promising therapy for a condition with extremely low median survival.

**MORE FIRSTS ON THE HORIZON**

Across Perlmutter Cancer Center, disease groups are expanding their trials portfolio. Among the many other notable studies currently underway: the first in-human trial of a targeted therapy for advanced non-small-cell lung cancer, a phase II study for locally advanced pancreatic cancer, and a precision oncology phase Ib trial for patients with metastatic colorectal cancer.

Meanwhile, successful results from multinational trials designed and conducted by Sybria Adams, MD, associate professor of medicine and director of clinical research, suggest that an immunotherapy–chemotherapy combination may be effective as a first-line therapy for women with advanced triple-negative breast cancer. This trial is poised to be the seventh practice-changing piece of research at Perlmutter Cancer Center in the past six years.

Deeper insights at the cellular level are helping to lead lung cancer investigators toward new pathways to stop the growth of tumor cells—giving rise to new treatment possibilities for previously intractable cancers.

NFS1 Protein Protects Lung Cancer Cells

In a recent study in Nature, Perlmutter Cancer investigators demonstrated that blocking the action of a key protein—NFS1—permits oxygen to damage a class of iron-dependent proteins in lung and breast cancer cells, slowing their growth and sensitizing them to cell death.

Human cells are known to contain 48 proteins that depend on complexes of iron and sulfur to function. These “iron-sulfur clusters” are dismantled when they encounter oxygen. In high-oxygen environments such as the lungs, these iron-sulfur clusters must be constantly replaced to sustain normal cell function. This demand for replacement increases under abnormal cell growth, as in cancer.

The current study showed that lung adenocarcinoma cells survive high oxygen levels by producing more NFS1, which harvests sulfur from the amino acid cysteine to make iron-sulfur clusters. The researchers also found that breast cancer cells that have spread to the lungs increase their NFS1 production upon arriving in this high-oxygen environment, while tumor cells remaining in the breast do not.

When the investigators injected cancer cells with blocked NFS1 function into the lungs of mice, they failed to form tumors. Consistent with these findings in mice, analysis of human datasets revealed that NFS1 levels were higher in lung adenocarcinoma cells than in nearby normal lung tissue.

“Our data support the notion that NFS1 provides a central protection for cancer cells against oxygen, and we’d like to find ways to eliminate this protective mechanism,” says lead study author Richard Possemato, PhD, assistant professor of pathology.

As a next step, the research team is screening for experimental compounds that block the ability of NFS1 to feed the production of iron-sulfur clusters.

Samantha Alvarez and Richard Possemato, PhD
COMBINATION OF PEMBROLIZUMAB AND CHEMOTHERAPY DOUBLES SURVIVAL IN LUNG CANCER PATIENTS

An international phase III clinical trial led by Perlmutter Cancer Center showed that the immunotherapy drug pembrolizumab (Keytruda®), when combined with chemotherapy, doubles survival in patients with non-squamous non-small-cell lung cancer (NSNSCLC). These results were presented at the American Association for Cancer Research in April 2018 and simultaneously published online in the *New England Journal of Medicine*.

A total of 616 patients with untreated metastatic NSNSCLC, without EGFR or ALK mutations, from nearly 120 international sites, were randomized—405 patients were treated with both pembrolizumab and platinum therapy plus Pemetrexed, and 202 received platinum therapy plus Pemetrexed with a placebo.

Response rates, overall survival, and progression-free survival were superior in the pembrolizumab and chemotherapy combination treatment group.

Of those treated with pembrolizumab and platinum plus Pemetrexed, the risk of death was reduced by 51 percent, compared with those treated with platinum plus Pemetrexed alone. Among patients treated with the combination therapy, the chance of progression or death was reduced by 48 percent. In other words, overall and progression-free survival doubled.

“For some groups of patients with NSCLC, chemotherapy has been the standard treatment for more than 30 years,” says Leena Gandhi, MD, PhD, former director of thoracic medical oncology for Perlmutter Cancer Center, and the study’s lead author. “But for patients with non-squamous NSNSCLC without EGFR or ALK mutations, this study may suggest a new standard of care.”

Pembrolizumab in combination with chemotherapy is now FDA-approved to treat metastatic NSNSCLC in adults as a result of a previous phase II trial on which Dr. Gandhi was one of the lead investigators.
Researchers Identify Bacteria Tied to Esophageal Cancer

“Our study brings us much closer to identifying the underlying causes of these cancers, because we now know that at least in some cases, disease appears consistently linked to the presence of specific bacteria in the upper digestive tract,” says study senior investigator and epidemiologist Jiyoung Ahn, PhD, associate professor of population health and environmental medicine and associate director of population science at Perlmutter Cancer Center. “Conversely, we have more evidence that the absence or loss of other bacteria in the mouth may lead to these cancers, or to gut diseases that trigger these cancers.”

That said, the researchers emphasized that their findings do not demonstrate that the bacteria directly cause or prevent esophageal cancer. Postdoctoral fellow and study lead investigator Brandilyn Peters, PhD, says the team next plans to analyze the main biological functions of some bacteria in the mouth to see how these metabolic pathways may influence cancer risk.

Perlmutter Cancer Center Names New Director of Gastrointestinal Medical Oncology

Paul E. Oberstein, MD, assistant professor of medicine, joined Perlmutter Cancer Center in 2018 as director of gastrointestinal medical oncology and assistant director of its Pancreatic Cancer Center. Prior to his new post at NYU Langone, Dr. Oberstein was a member of the Herbert Irving Comprehensive Cancer Center at Columbia University.

NYU Langone’s Pancreatic Cancer Center continues to grow under the leadership of Diane Simeone, MD, the Laura and Isaac Perlmutter Professor of Surgery. The center was recently designated as a National Pancreas Foundation Center, and is offering five clinical trials, among only several elite centers in the country to offer a Randomized Phase II Study of Losartan and Nivolumab in Combination with FOLFIRINOX and SBRT in Localized Pancreatic Cancer (Stand Up To Cancer) Clinical Study Identifier. The center also continues to lead Early Detection and Prevention efforts through its recently opened High Risk Clinic.

Pushing the Envelope of Brain Tumor Treatment with Alternative Methods and Molecular Diagnostics

Clinicians at the NYU Langone Brain Tumor Center are expanding brain tumor treatment options with a new laser-based ablation approach, while a collaborative effort to develop genetically based cancer screens is advancing the complementary fields of cancer diagnosis and research.
Laser interstitial thermal therapy (LITT), a tumor ablation technique in use at NYU Langone over the past year, offers a new approach for treating inoperable brain tumors. Stereotactic navigation guides the placement of an infrared laser probe that heats and destroys the adjacent cancerous tissue, with real-time MRI informing the precise positioning required for this treatment. “This approach gives us tremendous control over the ablation process,” notes Dimitris G. Placantonakis, MD, PhD, assistant professor in the Department of Neurosurgery. “It expands our reserve of treatments in cases that lack surgical options due to tumor location, or when a patient’s age or overall health makes a craniotomy unfeasible.”

Nine months later, the patient was, instead, doing very well. I have no doubt this treatment extended his life.”

LITT might also be indicated to counter brain swelling effects from radiation treatment, as a minimally invasive therapy for tumors unresectable with resection or radiosurgery, and for tumors that don’t respond to currently efficacious treatment options. “In addition to its use for brain tumors, we’re looking at laser ablation as a potential treatment for epilepsy and movement disorders, with clinical trials anticipated here in the near future,” adds Dr. Placantonakis.

New Expertise Refines Center’s Clinical, Research Emphasis

The Brain Tumor Center has reaffirmed its commitment to forward-thinking patient care with the addition of co-director Erik P. Sulman, MD, PhD, vice chair of research in the Department of Radiation Oncology. Dr. Sulman brings deep experience combining radiation planning with advanced imaging and immunobiology to achieve maximum treatment benefit for patients, expanding the center’s armamentarium of cutting-edge radiation treatment modalities.

Dr. Sulman will work to adapt the center’s translational research programs to target critical problems associated with brain tumor treatment, such as expanding its investigators into neurocognitive approaches to counter the effects of radiation and chemotherapy. “It is thought that there may be genetic predictors associated with these neurocognitive effects,” he explains. “Exploring these factors will allow our laboratory research with our clinical focus.”

While similar centers traditionally emphasize therapeutic outcomes, notes Dr. Sulman, the goal at NYU Langone will be to round out the patient experience with multidisciplinary services including psychologists, psychiatrists, rehabilitative medicine, integrative medicine, and palliative care. “The idea is to address the overall brain health of the patient with a combined approach focused on both tumor control and patient well-being,” he says.
Blood and Marrow Transplant Program Expands Services

On the heels of receiving new certification for performing adult allogeneic transplants from the Foundation for the Accreditation of Cellular Therapy (FACT), Perlmutter Cancer Center is significantly expanding its Blood and Marrow Transplant Program.

Maxim Kreditor, MD, and Samer Al-Homsi, MD, MBA

The program now offers haploidentical transplantation to patients, based on pioneering work done at Johns Hopkins School of Medicine. Haploidentical transplantation, in which a healthy half-matched first- or second-degree relative can serve as a donor, vastly expands the potential donor pool for patients who require a transplant.

"Conventionally, when you did a transplant, you needed to have a full tissue match between the donor and recipient, but we can now use haploidentical, or ‘half-match,’ transplants," says nationally renowned hematologist-oncologist Samer Al-Homsi, MD, MBA, who joined the Perlmutter Cancer Center in June 2017 to lead the program. "This transplant option will go a long way in overcoming the limitations of finding the right donor. Patients who have difficulty finding perfect matches will have more options, meaning that we can treat their cancer more effectively." The Blood and Marrow Transplant Program also performs autologous and matched allogeneic transplants in adults and autologous transplants in children to treat the full spectrum of blood-borne cancers, including leukemia, lymphoma, and multiple myeloma, as well as pediatric neuroblastoma.

Patients who have difficulty finding perfect matches will have more options, meaning that we can treat their cancer more effectively.”
—Samer Al-Homsi, MD, MBA

Since Dr. Al-Homsi was appointed director, more than 130 patients have received blood or marrow transplants at Perlmutter Cancer Center, which are performed in the specially designed Rita J. and Stanley H. Kaplan Stem Cell and Bone Marrow Transplant Center, located in the brand-new Kimmel Pavilion on NYU Langone’s main campus in Manhattan.

Dr. Al-Homsi also carries out research that focuses on preventing graft-versus-host disease, or GvHD, a potentially life-threatening complication of blood and marrow transplantation. He has led clinical trials examining innovative combinations of medications to prevent GvHD, including cyclophosphamide and proteasome inhibitors. Because of NYU Langone’s research, Perlmutter Cancer Center is one of the only programs in the country that offers matched-related and matched-unrelated allogeneic transplantation without using traditional GvHD preventive medications, such as cyclosporine, tacrolimus, and sirolimus. This enables people who are often denied a blood and marrow transplant, such as those with limited kidney function, to receive a transplant.

"Our understanding of hematologic malignancies has advanced greatly over the past decade, to the point that many cases are curable," says Benjamin G. Neel, MD, PhD, director of Perlmutter Cancer Center. "Bone marrow transplantation plays a critical role in these advances. Dr. Al-Homsi’s research holds tremendous promise to curtail negative interactions between host and transplanted cells and make this form of treatment safer and more effective.”

The Blood and Marrow Transplant Program is also a full member of the National Marrow Donor Program, which gives patients access to donors from across the country and around the world.
Combining the immunotherapy drug atezolizumab with the chemotherapy drug nab-paclitaxel improves overall survival for patients with metastatic triple-negative breast cancer, according to research led by Sylvia Adams, MD, associate professor of medicine and director of clinical breast cancer research at Perlmutter Cancer Center.

These are the findings of phase Ib and phase III clinical trials conducted around the world, including at Perlmutter Cancer Center. Dr. Adams was lead investigator of the phase Ib trial and a member of the steering committee of the phase III trial.

Atezolizumab belongs to a class of immunotherapy drugs called checkpoint inhibitors that boost the immune system by blocking the action of "checkpoint" proteins on the surface of T cells that blunt an immune response. Atezolizumab targets a protein called PD-L1 found in some cancers, including triple-negative breast cancer (TNBC), and prevents it from binding to the checkpoint protein PD-1. The results show that combining atezolizumab with nab-paclitaxel significantly increased survival in metastatic TNBC patients whose tumors are PD-L1 positive.

“It is exciting to see that chemotherapy combined with an immune checkpoint inhibitor can increase survival rates for TNBC patients, especially since standard therapies often result in a poor prognosis,” says Dr. Adams.

**IMPRESSIONS EVIDENCE BOLSTERS THE INNOVATIVE TREATMENT**

The phase Ib trial was the first to combine chemotherapy with an immune checkpoint inhibitor in TNBC. The results of the trial, which involved 33 patients with advanced TNBC, showed that the combination treatment was safe and clinically active. The researchers also found that patients who received this combination as a first-line treatment had a higher response rate, nearly 54 percent, compared with patients who received prior treatments (39 percent). For patients who responded to treatment, overall survival is promising. In fact, one of the first patients at Perlmutter Cancer Center is still receiving treatment four years later and remains without any evidence of cancer.

The phase III trial was a double-blind, placebo-controlled, randomized study of first-line atezolizumab plus nab-paclitaxel. The study, also known as the Impassion130 trial, involved patients at 246 sites in 41 countries; Perlmutter Cancer Center was the only site in New York City. The control arm received standard nab-paclitaxel chemotherapy, while the investigational arm received the same chemotherapy plus atezolizumab, given every two weeks.

**STRONG RESULTS INSPIRE CONFIDENCE**

The researchers found that progression-free survival improved from 5.5 months to 7.2 months with atezolizumab in the entire group of patients, and from 5 months to 7.5 months in the PD-L1-positive population, which constituted 41 percent of the overall study population. Overall survival for the entire cohort increased from 17.6 to 21.3 months and from 15.5 to 25 months in the PD-L1-positive population.

**TREATMENT IMPRESSIVE EVIDENCE BOLSTERS THE INNOVATIVE TREATMENT**

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NYU Langone Health

Tuition-Free Initiative Addresses High Student Debt

NYU School of Medicine announced in August 2018 that it will begin offering full-tuition scholarships to all current and future students in its MD degree program regardless of need or merit—a bold effort to simultaneously address the rising costs of medical education and still attract the best and brightest students to careers in medicine. “This decision recognizes a moral imperative that must be addressed, as institutions place an increasing debt burden on young people who aspire to become physicians,” says Robert I. Grossman, MD, the Saul J. Farber Dean of NYU School of Medicine and CEO of NYU Langone Health.

Visit med.nyu.edu/school for more information.

NYU Langone Health

Awards & Recognition

Dafna Bar-Sagi, PhD, won the 2018 American Association for Cancer Research (AACR) Women in Cancer Research Charlotte Friend Memorial Lectureship award, in recognition of her achievements in cancer research and her contributions to the advancement of women in science.

Abraham Chachoua, MD, the Jay and Isabel Fine Professor of Oncology, won the Chayim Aruchim award, an organization dedicated to providing religious and ethical guidance to families who have a family member who is seriously ill.

Kathie-Ann Joseph, MD, MPH, won the 2018 Caribbean Life Healthcare Award, which recognizes the contributions of Caribbean Americans as caregivers and practitioners in New York.

Basod Tibes, MD, PhD, was elected trustee of the New York City chapter of the Leukemia & Lymphoma Society.

Michelle Krogsgaard, PhD, won the ASPIRE Award from the Mark Foundation for the development of a humanized transgenic mouse model.

Douglas Levine, MD, was appointed an NRG National Cancer Institute Community Oncology Research Program representative on the NCI Cancer Prevention Steering Committee.

Daniel Makarov, MD, and David Wise, MD, won 2018 Prostate Cancer Foundation Young Investigator Awards. Recipients are dedicated to advancing critical research in developing better early detection methods, improving lifesaving treatments, and finding a cure.

Ben Noell, MD, PhD, was appointed to the board of directors of the Association of American Cancer Institutes.

Joseph Ravennell, MD, spoke about improving colorectal cancer screening in black men at the Biden Cancer Summit on September 21 in Washington, D.C.

Boris Beitzis, PhD, Co-Director, Judith and Stewart Cohen Center for Autoimmunity, won the Cancer Research Institute’s Frederick W. Alt Award for New Discoveries in Immunology, which recognizes a former CRI Irvington postdoctoral fellow whose research has had a major impact on immunology.

Neville Sanjana, PhD, won the 2018 Martin and Rose Wachtel Cancer Research Award from the American Association for the Advancement of Science. The award recognizes early-career investigators who have performed outstanding work in the field of cancer research.

Diane Simeone, MD, the Laura and Isaac Perlmutter Professor of Surgery, won the National Pancreas Foundation’s 2018 Nobility in Science Award, in recognition of her dedication to and work with patients.

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110% INCREASE IN NEW PATIENT VOLUME OVER LAST FIVE YEARS

$75 M GIFT TO ESTABLISH NEW CENTER FOR BLOOD CANCERS

Tripled SIZE OF CLINICAL TRIALS PROGRAM OVER LAST FIVE YEARS