The Society of MSK Campaign 2025–2026

Finding Tomorrow's Treatments Today



Nearly every cancer treatment available today is the result of a clinical trial, a study that evaluates the safety and efficacy of new therapies.

Memorial Sloan Kettering Cancer Center (MSK) runs one of the most extensive clinical trial programs for cancer in the United States, with nearly 2,000 active trials at any given time and approximately 5,000 people enrolled in trials that test new treatments each year. These studies provide our patients with access to the most advanced cancer treatments, sometimes years before they are available anywhere else. Research by MSK investigators has played a pivotal role in more than 40 FDA drug approvals since 2019, with 11 approvals in 2024 alone.

MSK was one of the first comprehensive cancer centers to provide significant access to clinical trials outside of its main campus. Today, more than half of our trials are available at our regional sites, a share markedly higher than that of our peers. We also work collaboratively with more than 250 other sites in the United States and conduct multisite clinical trials internationally, ensuring that leading-edge clinical trials are broadly available to patients worldwide.

MSK has made extraordinary strides in translating laboratory discoveries into life-changing cancer care, and we are committed to doing even more. Under the leadership of **Paul Sabbatini**, **MD**, Senior Vice President of Clinical Research, and **Ross Levine**, **MD**, Senior Vice President of Translational Research and Edward P. Evans Endowed Chair for MDS, we are expanding our efforts to accelerate the pace of discovery in our labs and increase the enrollment of patients into MSK clinical trials, factors that are crucial to the delivery of new treatments to people with cancer.

The Society of MSK has long championed scientific research that has transformed patient care. This year's Society Campaign presents a powerful opportunity to build on that legacy. With your support, MSK will expand our clinical trial offerings, extend our reach, and bring renewed hope to people with cancer around the world.

Dr. Ross Levine, Senior Vice President of Translational Research and Edward P. Evans Endowed Chair for MDS



Turning Pioneering Discovery Into Life-Changing Care

Scientific discovery is the foundation beneath every bold and lifesaving decision in cancer care. At MSK, this pursuit is powered by an extraordinary research infrastructure that spans cancer and cell biology, genomics, computational oncology, immunotherapy, tumor immunology, and precision oncology. The institution houses an unmatched wealth of information that represents decades of tumor sample analyses, genome sequencing, imaging, and records of treatment outcomes.

Clinical trials are the keys that unlock the benefits of these discoveries for patients and represent the central goal of MSK's efforts to see state-of-the-art science deliver meaningful impact to people with cancer. At MSK, we leverage scientific discoveries and world-leading expertise in genomics and data science to ensure that our trials test the right innovative medicines in the patients most likely to benefit. This precision approach accelerates the translation of research into clinical practice and speeds the approval of new treatments for molecularly defined patient subgroups. It's a strategy that sets MSK apart and demonstrates how matching the right treatments to the right patients can transform clinical research and deliver meaningful results faster than ever before.





Clinical research generates new knowledge and directly guides patient care. By analyzing tumor and blood samples from trial participants, we gain insights that inform and improve future studies — creating a continuous cycle of innovation. This work is made possible by a robust clinical research infrastructure that includes investigators, research nurses and support staff, scientists, laboratory core services, and technology.

Some of the most transformative breakthroughs in cancer treatment, including the first targeted cancer therapies and the development of cancer immunotherapy, began as ideas in MSK's laboratories. One of our most recent and notable advances supported by last year's Society Campaign — was overseen by Andrea Cercek, MD, Section Head of Colorectal Cancer, Co-Director of the Center for Young Onset Colorectal and Gastrointestinal Cancer, and The Ford Family Chair. Her groundbreaking clinical trial tested an immunotherapy called dostarlimab (Jemperli) for a specific type of rectal cancer and achieved an unprecedented 100% success rate among participants. In December 2024, this treatment received the FDA's Breakthrough Therapy designation, a status granted to expedite the development and review of drugs that show substantial improvement over existing therapies for serious or life-threatening conditions. Our program supports many other practice-changing treatments, based on innovative MSK science and led by our clinical investigators and their teams.

Another milestone was reached in 2024 with the accelerated FDA approval of afamitresgene autoleucel (Tecelra®, also known as afami-cel) for the treatment of synovial sarcoma, a rare and aggressive form of the disease that typically arises in the soft tissues near the joints. Sarcoma medical oncologist and cellular therapist **Sandra D'Angelo, MD**, played a pivotal role in the early clinical trials of this therapy at

MSK, which became the first genetically engineered T cell receptor therapy to receive FDA approval for a solid tumor. Using the clinical research infrastructure at MSK, the team employed samples from the earlier trials to inform new ways to moderate the immune system, determine the optimal dose and schedule, and identify the right time to apply the therapy for best results.

Most recently, **Alison Schram**, **MD**, a gynecologic medical oncologist and early drug development specialist, tested the drug zenocutuzumab (Bizengri®) for people with any cancer that had an alteration called an *NRGI* gene fusion and had stopped responding to other treatments. The drug was effective for many people in the trial, and based on the results, the FDA granted accelerated approval to zenocutuzumab to treat advanced pancreatic and lung cancers with *NRGI* gene fusions. This trial exemplifies how tailoring treatments for people with molecularly defined cancers can accelerate access to more effective therapies.

"An NRGI gene fusion is found in less than 1% of all cancers, but for those who have it, zenocutuzumab provides significant benefit," explains Dr. Sabbatini. "These patients, who had limited treatment options, gained access to this remarkable drug thanks to our ability to screen for this rare mutation and offer them a clinical trial. Our goal at MSK is to bring that hope and that opportunity to more people, both locally and worldwide. We want to give every person with cancer another chance at a potentially lifesaving treatment."

Extending Our Reach

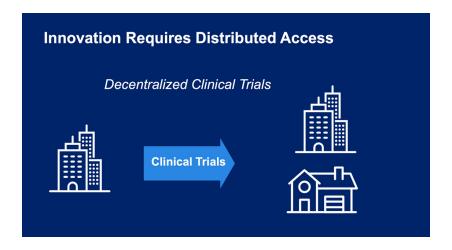
While about 22% of patients at MSK enroll in some form of clinical trial, only about 7% of patients nationwide enroll specifically in clinical trials testing new treatments. When studies are limited to a single site, enrollment can be slow, sometimes taking years to complete, which delays access to potentially lifesaving treatments. This challenge is even more pronounced for rare cancers, for which finding enough eligible participants is especially difficult, further prolonging the development of new therapies.

To advance MSK's mission of ending cancer for life, we must invest in a robust and growing program of clinical research that matches innovative therapies to the people most likely to benefit.

"With The Society of MSK's support, our investigators will continue to increase their ability to understand drug and tumor resistance and deliver the right drug to the right patient at the right time," says Dr. Levine. "As a result, MSK will improve the precision of clinical trials and open more of these optimized studies at our regional sites and at organizations across the country, giving countless people with cancer access to the best options for survival."

Establishing Decentralized Clinical Trials

To make advanced treatments more available and strengthen our science, MSK is opening research studies beyond our own healthcare system through an approach known as decentralized clinical trials. This model, which is a top priority of MSK and of the National Cancer Institute, reduces or eliminates the need for patients to travel to a central research facility for every procedure. Instead, participants may be able to visit a hospital close to their home or connect



with their care team remotely, making it easier for more people to benefit from leading-edge therapies, regardless of where they live.

MSK already has access to such groups through our robust partnerships with hundreds of sites, but since each location has its own researchers, research assistants, and data managers, these partnerships create staffing and infrastructural redundancies. By providing the infrastructure needed for MSK to assume the bulk of the regulatory and management activities, decentralized clinical trials will enable MSK to serve as the coordinating site, cutting down on duplicative efforts and streamlining the process of opening external trials. As a result, patients in rural or underserved areas will be able to access clinical trials without the burden of long-distance travel, local providers can focus more on care with reduced administrative demands, and MSK will benefit from more robust and diverse data. strengthening the evidence for treatment effectiveness across broader populations.

Speeding the Development of Novel Drugs

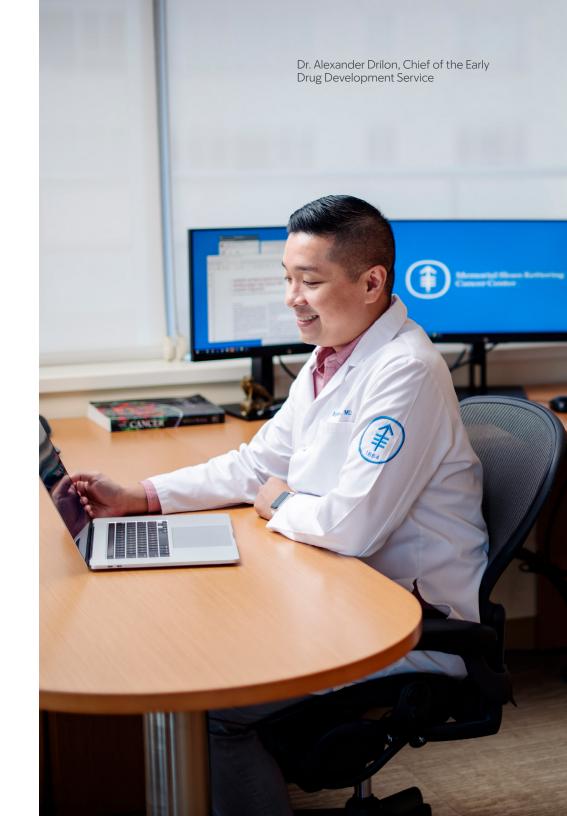
Alongside our decentralized clinical trial model, MSK boasts the area's largest infrastructure for early-phase clinical trials through the Early Drug Development (EDD) Service, led by **Alexander Drilon, MD**. The EDD Service conducts phase 1 trials of novel therapies for adult and pediatric patients with solid tumors — often those who have exhausted standard treatment options. These trials offer access to leading-edge therapies that may extend or save lives.

The EDD Service plays a critical role in accelerating drug development by identifying safe and effective doses early and employing innovative trial designs such as basket trials, which target specific genetic mutations across multiple tumor types. Over the past five years, the EDD Service has contributed to nine FDA drug approvals and three Breakthrough Therapy designations, opened 73 clinical trials and enrolled more than 800 patients, and authored or contributed to more than 160 scientific publications.

To further speed the delivery of promising therapies, MSK is launching Accelerated Advantage, a new initiative aimed at streamlining the clinical trial activation process within the EDD Service. By removing administrative barriers and optimizing trial start-up workflows, this program will enable faster access to innovative treatments and serve as a model for broader implementation across MSK.

Supporting investigator-initiated clinical trials is also a top priority for the EDD Service and MSK.

These studies, designed and led by MSK's own physician-scientists, leverage deep clinical insight and research expertise to explore bold, patient-centered treatment strategies. Unlike industry-sponsored trials, investigator-initiated studies allow researchers to pursue novel ideas with the greatest potential to transform cancer care and often lay the groundwork for larger, paradigm-shifting discoveries.





Your Support Will Transform Patient Care

For many people with cancer, especially those with limited treatment options, clinical trials offer the best opportunities for healing and survival. A gift to The Society of MSK's 2025–2026 Campaign, "Finding Tomorrow's Treatments Today," will support the work of MSK leaders and investigators who are working to expand access to pioneering clinical trials and accelerate the development of life-changing cancer therapies.

Thank you for your thoughtful consideration and continued support of advancing MSK's mission of ending cancer for life.



When you're facing cancer, options matter. Clinical trials offer access to tomorrow's treatments today. By supporting MSK, you're not just backing a center that conducts clinical trials — you're investing in a world-class institution with the scientific depth and infrastructure to bring more precise and effective studies to more people and translate discoveries into therapies that restore hope.

I am grateful to The Society of MSK for its commitment to this effort and for its longtime dedication to improving the lives of people with cancer."

— **Dr. Paul Sabbatini**, Senior Vice President of Clinical Research



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