CORPORATE NEWS

MASSIVEBIO

YEAR:2022 / ISSUE:02

BEYOND CHEMOTHERAPY
AN INTERVIEW WITH ARTURO LOAIZA-BONILLA, MD

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UPDATE ON *BREAST CANCER*

TAKING CARE
CAREGIVERS MUST CARE FOR THEMSELVES, TOO

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MASSIVEBIO

A MESSAGE FROM SELIN

Welcome to our second issue of *Massive Bio* magazine, which we offer to help you keep up with the work we're doing, the latest news in clinical trials, and recent progress in the fight against cancer. That's the focus of an interview with Arturo Loaiza-Bonilla, MD, who is much more than a co-founder and the chief medical officer for Massive Bio. Arturo is also a practicing physician who has deep and extensive experience as a scientific investigator, too, having led and authored many research studies. His background and perspective ensure that Massive Bio is guided by a high level of clinical rigor, as well as a spectacularly patient-centric approach to customer service. In this issue, he talks about how cutting-edge oncology treatments such as targeted therapies and immunotherapies have reshaped the landscape of cancer care. And Arturo—whom I have watched with admiration as he engaged my mother, and even my grandmother, in discussions of complex medical topics—does so in language that any lay reader can understand.

This autumn has been an intensely busy time for us at Massive Bio, as we work hard in pursuit of our mission to help cancer patients gain access to clinical trials of advanced treatment options. We're in contact with more patients every day and we continue to expand our network of partners in the pharmaceutical industry. We deeply value our relationships with both of these groups of critical stakeholders in the work we're doing here at Massive Bio, and want to thank them for their commitment to helping us "erase cancer from the map."

Selin Kurnaz
PhD, Co-founder and CEO

Massive Bio News Briefs

Selin Kurnaz Appears on Popular TV Show
During a recent visit to Turkey, Massive Bio's CEO and Co-founder Selin Kurnaz appeared on the television show "Tekno Hayat," hosted by Ahmet Can. "Tekno Hayat" (which means "techno life") airs on NTV and explores how new technology is improving our lives and reshaping the future. Kurnaz and Can discussed Massive Bio's mission and how the company is using artificial intelligence to match cancer patients with clinical trials of new therapies. Kurnaz was visiting Turkey to spend time with Massive Bio's rapidly growing staff in Istanbul, where she worked with our team to develop new strategies for achieving the company's goals.

'Gratitude and Grit': Massive Bio Co-Founder Traces His Journey and Origin of the Company
Amid the red mesas of Sedona, Arizona, Massive Bio Co-founder and Chief Medical Officer Arturo Loaiza-Bonilla, MD, MsED, gave a talk titled "Gratitude and Grit" at Review and Renew Sedona, an oncology-education retreat where participants met to discuss and learn about the latest research and strategies in cancer care, on August 6, 2022.

In the talk, Dr. Loaiza-Bonilla traced his life journey, which began in Bogota, Colombia, where his mother imbued him with "the ability to be grateful for the things I have, but also the grit to overcome challenges." That life philosophy guided Dr. Loaiza-Bonilla as he enrolled in medical school at age 16, continued his medical education at the University of Miami and University of Pennsylvania, and ultimately became an assistant professor of gastrointestinal oncology at Penn Medicine's Abramson Cancer Center.

"I was happy, successful, and had a big practice," said Dr. Loaiza-Bonilla. But he came to realize that there was a critical gap in medicine. The burgeoning field of genomics promised to change the practice of oncology by making it possible to identify genetic mutations that cause cancer—which can be targeted by new-generation drugs. But pharmaceutical companies have struggled to recruit enough patients to evaluate these novel therapies

in clinical trials, which has created a bottleneck in getting new treatments approved and available to people with cancer.

"Where are those patients?" Dr. Loaiza-Bonilla found himself asking. To close the gap between pharma companies seeking patients for clinical trials and people with cancer searching for new therapies, he eventually teamed up with co-founders Selin Kurnaz, PhD, and Cagatay Culcuoglu to form Massive Bio. With its artificial intelligence platform, known as SYNERGY-AI, Massive Bio rapidly identifies clinical trials of new therapies for cancer patients. Massive Bio, he said, is "really good at matching patients to clinical trials—like really, crazy good," noting that patients who receive recommendations from the company are significantly more likely to enroll in studies of these potentially life-saving treatments.

Massive Bio in the Running for Digital Health Award

Massive Bio has been named as a quarterfinalist in the annual UCSF/Health Hub: Digital Health Awards competition. These prestigious awards are given to recognize "the achievements of innovative health tech companies that are dramatically improving healthcare through the use of technology in the digital health industry." Massive Bio is one of 16 quarterfinalists in the "New Health Application of AI" category. Finalists for the awards will be announced on October 21, with the winners revealed at the grand finale of the 2022 HLTH conference in Las Vegas on November 14.

Massive Bio Named a Top Startup Company

Massive Bio was named to the StartUp100 list by *StartUp Magazine*. The StartUp100 list is based on voting by a jury of Turkey's top entrepreneurs, each of whom were asked to select their choices for the best startup companies. After their votes were pooled and tabulated, Massive Bio ranked 29th among other fast-growing startups, and was the only organization on the list with a technology platform that uses artificial intelligence to match oncology patients to clinical trials.

Educating Patients: Massive Bio Demystifies Mantle Cell Lymphoma

In an effort to help patients with mantle cell lymphoma (MCL) and their caregivers better understand this form of blood cancer, Massive Bio presented a Facebook Live event titled "Mantle Cell Lymphoma: Oncology Hour" on August 16. In the event, oncologist and hematologist Liat Dagan, MD, PhD, gave an overview of MCL that focused on three major areas: What's known about the cause of MCL, how is this cancer treated, and what are researchers learning about how to control it? Massive Bio's director of patient engagement, MaLinda Ross, hosted the presentation.

Dr. Dagan, who treats patients with blood cancer at Boca Raton Regional Hospital's Lynn Cancer Institute, in Boca Raton, Florida, began by explaining that MCL is a relatively rare cancer, accounting for about 6 to 7 percent of all cases of non-Hodgkin lymphoma (NHL), which includes several other forms of blood cancer. MCL can strike anyone, but the typical patient is a white male with a median age of 68. Some patients have no symptoms when diagnosed, but others experience fever, night sweats, and significant weight loss. Nausea and vomiting are common, too—as Dr. Dagan explained, one feature of MCL that sets it apart from other NHLs is that it often affects the gastrointestinal tract.

Doctors diagnose MCL by performing a variety of tests, including a physical exam, blood tests, and imaging tests. Lymph nodes are often removed to examine for the presence of cancer. Some patients require a bone marrow biopsy, in which a needle is used to extract a sample from the soft tissue inside bone, where blood cells are created.

While the cause of MCL is unknown, the disease is associated with mutations (or DNA alterations) in immune cells called B cells. Certain gene mutations can make MCL more aggressive and difficult to treat, while others produce a more indolent, or slow-growing, form. Patients with the latter form are often candidates for "watching and waiting," a strategy in which patients don't receive immediate treatment, and instead are monitored closely by their physicians, said Dr. Dagan, noting that some can go years without needing therapy. However, she added, "most patients with MCL are diagnosed with an advanced form of the disease.... Most are symptomatic. They have a high tumor burden and we need to decide about treatment."

The treatment a doctor recommends for MCL will depend on a variety of factors, such as the patient's age and overall health, the cancer's stage, whether they have certain genetic mutations and their personal preferences. "There are many, many options," says Dr. Dagan. Younger and healthier patients may be candidates for bone marrow transplants, in which normal stem cells from a well-matched donor are infused into the patient to replace diseased stem cells that can't produce adequate levels of blood cells. However, most MCL patients require medical therapy. For many years, chemotherapy was the main option, but the addition of new classes of drugs has changed the approach to treating MCL. That includes targeted therapies, which shrink tumors by attacking proteins and other factors that cancer cells need to survive; and immunotherapies, which boost the body's natural defenses against cancer.

Yet, MCL is a challenging opponent. "Most patients will eventually experience relapse," said Dr. Dagan. "That's why participating in clinical trials is encouraged." Dr. Dagan concluded her discussion by describing several promising recent clinical trials that could soon add to the list of treatments available for managing MCL.

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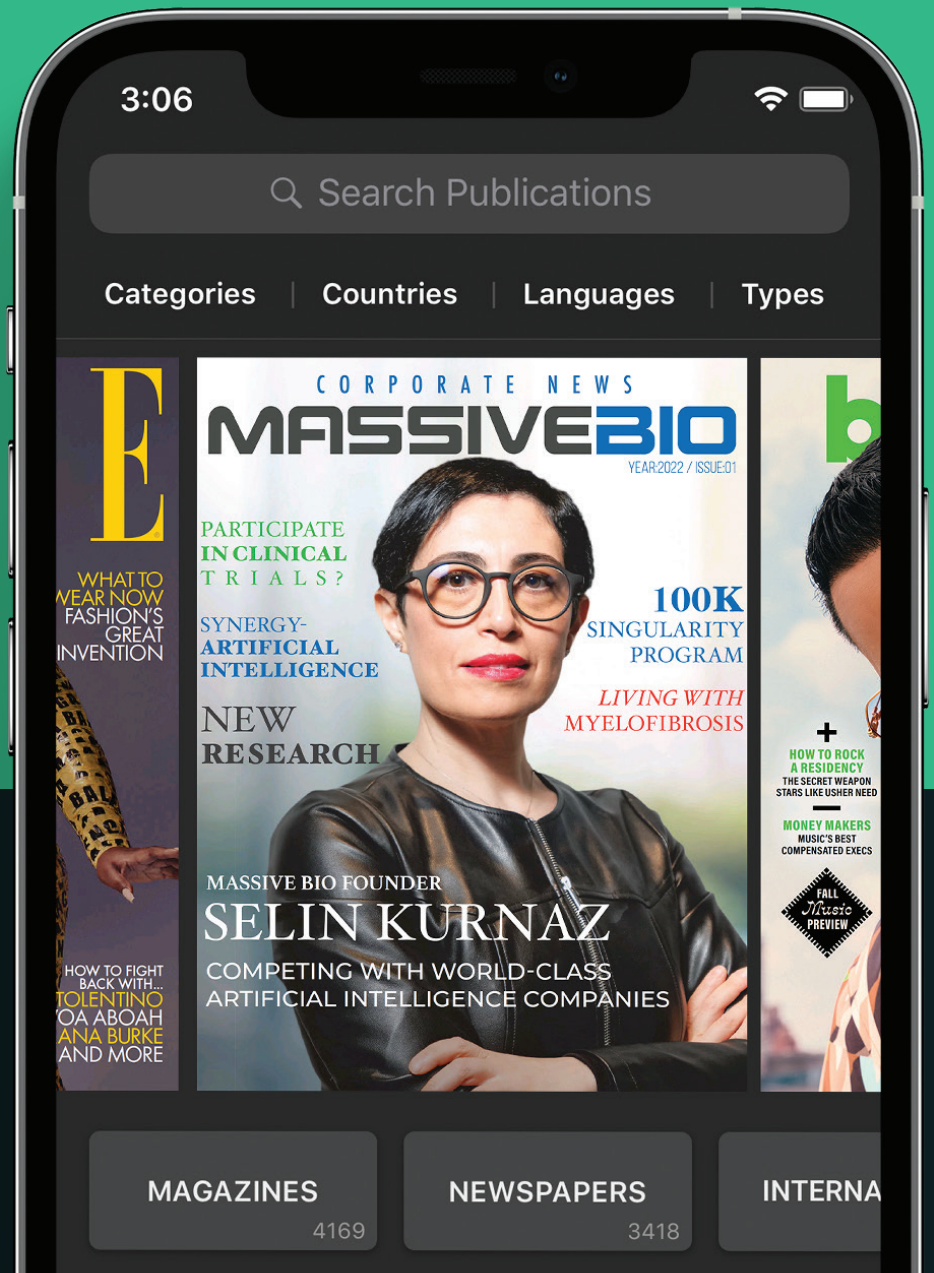


Taking Care

Helping a loved one cope with a chronic illness can bring you closer together. But caregivers must care for themselves, too.

Every cancer patient has a story, which often includes an unsung hero: A caregiver who was at his or her side throughout the journey. Caregivers of people with cancer and other disabling diseases play many roles. They take patients to medical appointments, make sure medications are taken on time, keep the house tidy, cook meals, and pay bills, all while providing critical emotional support, too.

Caring for a loved one who has cancer or any disease that requires short- or long-term assistance can be rewarding and bring you closer to that person. But many take on the role of caregiver while holding down full-time jobs, taking care of their own families, or coping with an illness of their own. And there's growing recognition that juggling these many responsibilities can exact a physical and psychological toll on caregivers.

That awareness is building as the ranks of caregivers in the United States are rising. In 2015, 43.5 million Americans provided unpaid care and support to a spouse, partner, close family member, or friend with a chronic or serious health condition, according to a survey by AARP and the National Alliance for Caregiving (NAC). By 2020, that figure had jumped to 53 million, or about one in five adult men and women in the United States.

Caregivers of people with cancer represent somewhere between 7 to 15 percent of that total, and scholars say their experiences are often distinct from those of people who care for patients with other illnesses. As a 2022 review in the journal *Cancers* observed, cancer patients are living longer than ever today, thanks to advances in early detection and treatment. That means a growing population of survivors will continue to require care as

they cope with the long-term effects of cancer and its treatment. As the latter is concerned, many caregivers find themselves administering complex medicines and performing other medical roles as cancer centers move more treatment to the outpatient setting. About half of people who assist cancer patients are also employed, according to the review, yet they also spend 32.9 hours per week providing care, on average, with about one third putting in 40 hours a week or more aiding a loved one.

A number of studies have found that the burden of caregiving can increase the risk for physical and psychological problems, such as a 2022 investigation by researchers at Massachusetts General Hospital (MGH) in Boston, Massachusetts, which was published in the journal *Blood Advances*. A survey of 127 caregivers of patients with multiple myeloma found that 44.1 percent had symptoms of clinical anxiety, which was significantly higher than rates reported by the patients themselves (22.5 percent). The MGH study also found that 24.2 percent of the caregivers had symptoms of post-traumatic stress disorder (PTSD) and that 15.8 percent had symptoms of depression. Other studies have found even higher rates of depression among caregivers.

Caregivers often report worse overall physical wellbeing than members of the general public, too. In the AARP/NAC survey, 21 percent of caregivers described their own health as poor. Nearly one quarter (23 percent) said that caregiving had made their health deteriorate. That's no surprise, since many say they eat unhealthy diets and lack time for regular exercise. A survey by the

Centers for Disease Control and Prevention found that more than one third of people who provide care for a patient with a chronic condition said they were sleep deprived.

Avoiding burnout

Women have historically borne much of the weight of caregiving, and that hasn't changed: Today, they make up 61 percent of caregivers. However, a 2019 study in the journal *Healthcare* found that many male caregivers, like their female counterparts, experience physical, emotional, and financial burdens, too. For men and women alike, that's a prescription for a problem that has become so common it's got a name: caregiver burnout. Experts say that adopting some positive strategies can help you avoid that fate.

· Ask for help. This can be difficult, especially for men, but it's the most crucial step for avoiding caregiver burnout. Ask other family members or friends to fill in for you now and then. If no one steps up or is available, your community may have volunteer groups who can find someone to spell you. An afternoon off to catch up on errands or a night out for dinner with a friend could be just what you need.

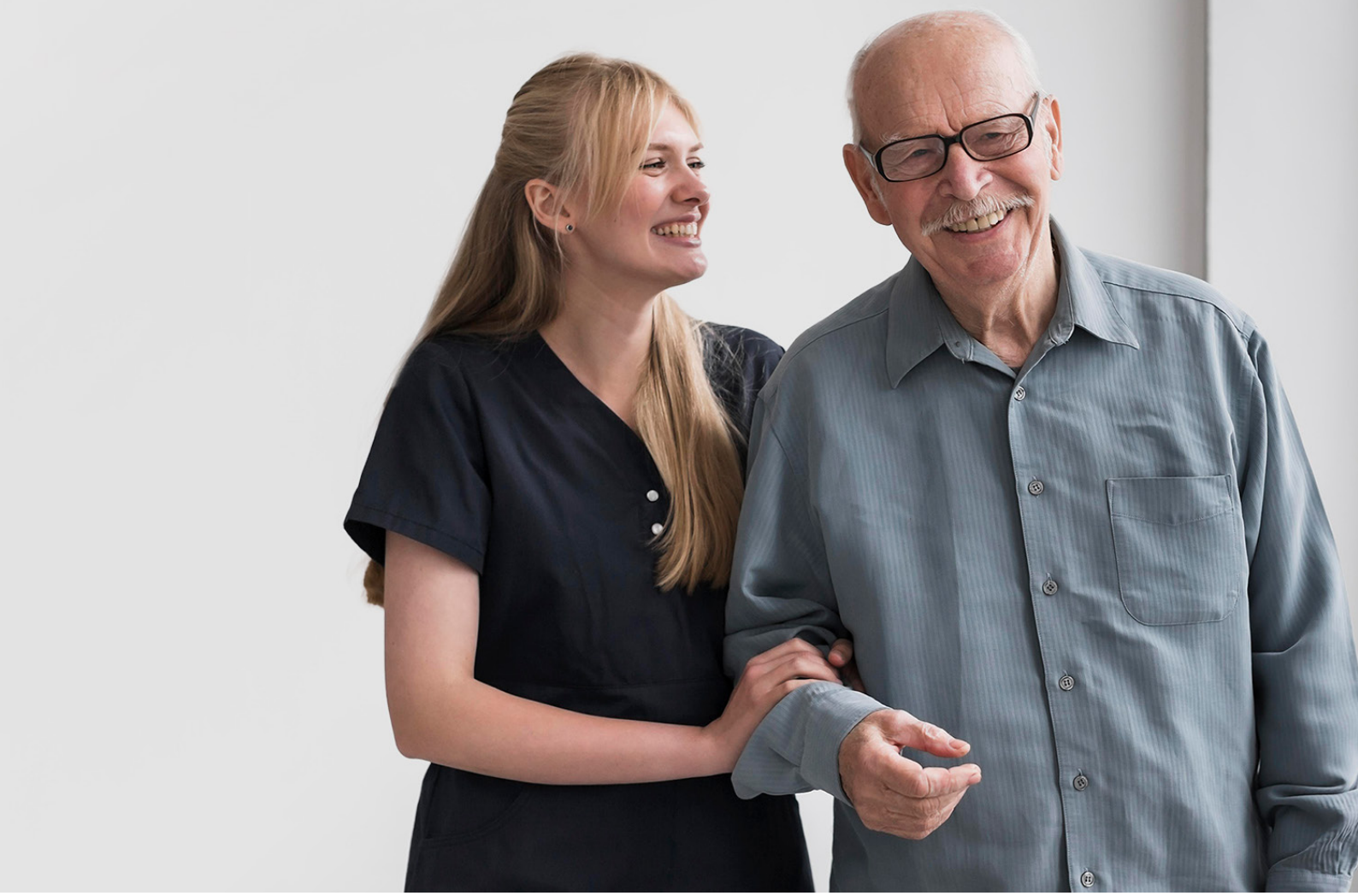
· Consider respite care. For a longer break (up to five days), find out if your loved one qualifies for respite care at a Medicare-approved facility.

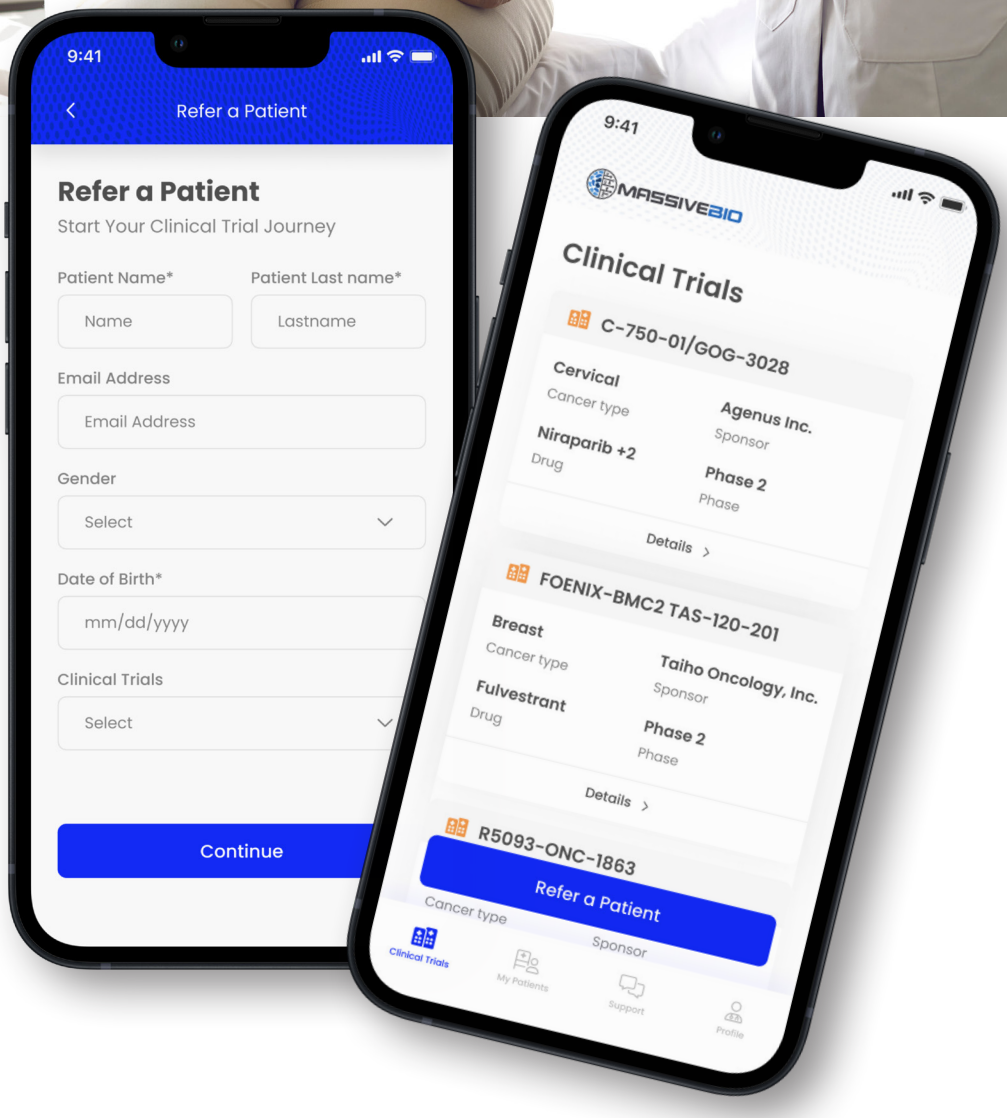
· Communicate. Often, a caregiver's perception of the care recipient's symptoms, such as nausea or pain, don't agree with what the patient is actually experiencing. Researchers at Boston College found that there's less stress and anxiety for both partners in the relationship when a caregiver and the patient "get on the same page" by communicating and listening to one another.

· Take time off. If you work, find out if your employer has a family-leave policy that would give you more time for your caregiving duties.

· Don't let your health routine slip. Try to eat a healthy diet, get some exercise, and turn in early, as much as you can.

· Prioritize. Does the laundry really need to get done today? Or can it wait until tomorrow, when you have more time to spare? Setting priorities in your caregiving schedule can make it more manageable.





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CLINICAL NEWS

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CANCER BIOMARKERS

Study Suggests Wider Role for Pralsetinib

Pralsetinib *(Gavreto)* treats certain forms of lung and thyroid cancer, but a preliminary study suggests that the drug could play a role in managing a select group of patients with several other types of malignancies.

Pralsetinib is a form of precision medicine that targets an abnormality called a *RET* gene fusion. Normally, the *RET* gene plays a role in development of the nervous system and the kidneys. However, sometimes this gene "fuses" with another gene, which can lead to production of proteins that promote cancer, as can mutations in the *RET* gene. Pralsetinib is approved for treating certain forms of non-small cell lung (NSCLC) and thyroid cancer that is positive for the *RET* fusion and a form of thyroid cancer that is positive for a *RET* mutation.

However, scientists knew that *RET* fusions occur in a small number of patients with several other kinds of malignancies, including ovarian, pancreatic, salivary, and colorectal cancers. In the early-stage ARROW trial, investigators treated 29 patients with 12 different types of solid tumor (excluding NSLC and thyroid cancer) who had previously received or were not candidates for standard therapies.

The study, published in *Nature Medicine*, included data from 23 of these patients with various tumor types and found that 57% responded to pralsetinib. The typical patient survived 14 months, though several experienced remarkable benefits. One man in his thirties with advanced pancreatic cancer who been unable to tolerate chemotherapy had his tumor disappear, which persisted for over at least 33 months, when the authors stopped collecting data. Additional studies will be necessary before pralsetinib is approved for treating other tumors that have the *RET* fusion.

LYMPHOMA

A New Treatment Option for Older MCL Patients

Mantle cell lymphoma (MCL) is often diagnosed in patients who are 65 or older, who are not typically candidates for intensive chemotherapy or stem cell transplantation, which could prove too toxic. Thankfully, a recent study confirmed the benefits of a new treatment option for older MCL patients.

Last June, the *New England Journal of Medicine* published the results of the SHINE trial, which tested a combination of the drug ibrutinib *(Imbruvica)* and chemotherapy in older MCL patients. Ibrutinib belongs to a class of drugs called BTK inhibitors, which block a protein called Bruton's tyrosine kinase, resulting in the death of malignant B cells. In the SHINE trial, 523 MCL patients aged 65 or older were randomly chosen to receive the combination of ibrutinib and the chemotherapy drug bendamustine or only chemotherapy. Patients who responded to treatment were then put on maintenance therapy with rituximab *(Rituxan)*. Patients received these treatments until their cancer progressed or side effects made them intolerable.

The SHINE trial found that patients treated with the combination of ibrutinib and chemotherapy went 80.6 months, on average, before their cancers progressed, compared to 52.9 months among patients treated with only chemotherapy. However, overall survival was similar in both groups. Patients treated with ibrutinib were slightly more likely to report side effects of treatment. The study's authors believe that ibrutinib plus chemotherapy should be the new standard of care for older MCL patients.

MELANOMA

Advanced Melanoma: New Treatment May Soon Be Approved

Doctors have few approved treatment options to offer patients with advanced melanoma who no longer respond to immunotherapy. However, that could soon change. A California-based company called Iovance Biotherapeutics has asked the U.S. Food and Drug Administration for permission to take certain steps that would expedite approval of a treatment called lifileucel, which could be good news for some patients who have few other options.

Lifileucel is a form of tumor-infiltrating lymphocyte (TIL) therapy. Lymphocytes are white blood cells that protect the body against infection and identify cells that can cause harm, including cancer cells. When cancer is detected, lymphocytes respond by penetrating, or infiltrating, the tumor. In TIL therapy, a doctor removes a sample of tissue from the tumor, which is sent to a lab. TILs are removed from the tumor tissue and grown to increase their numbers. The patient undergoes chemotherapy, then TILs are infused back into his or her bloodstream. TIL therapy is currently only available in clinical trials.

In a phase II clinical trial, lifileucel was evaluated in four groups of patients, who received slightly different versions of the treatment. An analysis of the 153 patients in two of the groups found that 31 percent responded to lifileucel. Response continued for at least 27.6 months, on average, when the authors of the study reported their findings. In one group, five patients' tumors disappeared, while 18 patients' tumors shrunk significantly.

If approved, lifileucel will be available for patients with melanoma that has spread or can't be surgically removed, and who no longer respond to immunotherapy and, if they are positive for the BRAF-mutation, who have had prior treatment with targeted therapies (known as BRAF or BRAF/MEK inhibitors).

MYELOFIBROSIS

New Drug May Reduce Anemia Risk for Myelofibrosis Patients

Anemia, which is a loss of red blood cells that can leave you feeling tired all the time, is a symptom of the form of blood cancer called myelofibrosis. Unfortunately, common medications for myelofibrosis called JAK inhibitors can worsen anemia, and some patients find the fatigue intolerable and quit treatment. A new drug under consideration for approval by the FDA called momelotinib may minimize this side effect, however.

Momelotinib blocks the same chemical signals in the body that promote myelofibrosis as JAK inhibitors (known as the JAK1 and JAK2 pathways), but the drug also inhibits another protein, called activin A receptor type 1 (ACVR1), which may help to minimize anemia.

The developers of momelotinib tested it in a clinical trial that included 195 people with symptomatic myelofibrosis and anemia who had previously been treated with a JAK inhibitor. Two thirds of the participants were given momelotinib, while the remainder received danazol, a drug sometimes used to treat anemia in myelofibrosis patients.

After six months, researchers evaluated the patients using a numeric scale that quantified their symptoms. They found that patients given momelotinib improved their symptom scores by 9.36 points, on average, compared to an improvement of 3.13 points in the danazol group. Patients in the momelotinib group were more likely to go at least 12 weeks without requiring a red blood cell transfusion (30.8 percent versus 20.0 percent). And, importantly, they were less likely to develop anemia (8 percent versus 11 percent). Patients taking momelotinib also had superior reduction in spleen volume, which is a goal of treatment, and they were less likely to quit treatment due to side effects. The FDA plans to announce its decision on whether to approve momelotinib by June 2023.

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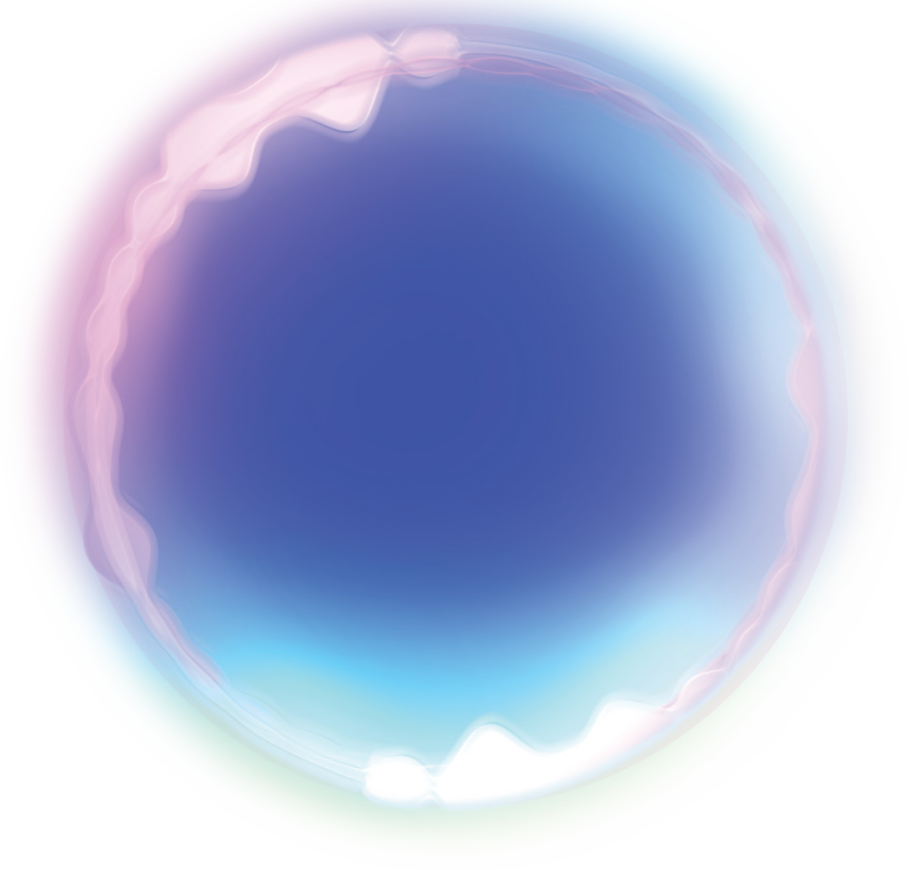


Massive Bio's Artificial Intelligence is **Talking To You!**

Watch our one-minute videos to learn about different types of cancer.

WHAT THE HECK IS **AI?**

Massive Bio uses artificial intelligence, or AI, to match cancer patients to clinical trials, but this technology is turning up everywhere these days. What exactly is AI?

Massive Bio helps people with cancer identify and enroll in clinical trials of promising new therapies. While our dedicated staff is the heart and soul of Massive Bio, the "brain" is a system known as SYNERGY-AI, which precisely identifies the clinical trials that are best suited to each patient who reaches out to us. The "AI" stands for artificial intelligence, of course, which is rapidly becoming part of everyday life. But have you ever wondered: What exactly is AI?

AI is technology that allows machines to mimic the human brain's ability to solve problems and make decisions. Scientists have been fascinated by the potential of AI since the dawn of the digital era. One of the first computer scientists, British mathematician Alan Turing, asked a provocative question in 1950: "Can machines think?"

It turns out that not only are AI-driven machines able to process huge amounts of data in a way that closely resembles human thought, but they can learn, too. Known as machine learning (ML), this form of AI allows computers to recognize and adapt to patterns in data sets. You probably encounter ML every day. For

example, streaming and music apps use it to get to know your tastes over time, which allows them to recommend new movies or artists you may enjoy. Social media apps use ML to determine what posts and ads you see on your feed. When you type a text message and your smartphone suggests a word or phrase to click, that's ML at work, too.

The business world has embraced AI in many ways. If you have ever used a chat bot when you needed customer service from an e-commerce company, for instance, then you may have come face to face with AI (though, if the chat bot had an actual face, that was just a model). If you check out a pair of shoes on an online store, but decide not to buy them, you can bet you'll see ads for those shoes the next time you log on, thanks to AI. Banks use AI for a variety of purposes, such as detecting identify theft and other forms of fraud.

AI has even found its way into the arts. For instance, in 2021, one filmmaker released a short science fiction movie called *Sunspring*, which was shot with a script written by an AI program. Some reviewers who watched the film on YouTube called it "nonsense," but others raved about its quirky brilliance, noting that the dialogue sounded a little odd, but no more so than the dialogue in many science fiction movies.

In another example, an artist won first prize for digital art at this year's Colorado State Fair's annual art competition with an AI-generated picture. Using a program called Midjourney, which converts text to images, he created a grand and mysterious image he titled "Théâtre D'opéra Spatial." Other artists accused him of cheating, but artist Jason M. Allen stood by his work. "I'm not going to apologize for it," he told the *New York Times*. "I won, and I didn't break any rules."

Other recent applications of AI have been controversial, too. For instance, facial recognition software, which uses AI, must be trained by "reading" databases of faces. Developers have been accused of bias for using too few faces of people of color to train the software. As a result, some facial-recognition systems are less accurate at identifying faces of people who don't have white skin.

However, AI is having a positive impact in other fields, including medicine. Currently, some AI-powered tools that doctors use include clinical-decision support software, which helps them make choices about

treatments and other patient needs; and software that assists in evaluating X-rays, MRIs, CT scans, and other imaging tests, which sometimes detects abnormalities that are missed by the naked eye. AI also allows researchers to analyze huge sets of patient data to identify the causes of diseases, including genetically based cancers.

And this remarkable technology is helping cancer patients find new hope through Massive Bio's SYNERGY-AI platform. The process works like this: A patient interested in enrolling in an oncology clinical trial signs a consent form, which grants Massive Bio permission to access his or her medical records. We upload that data into our system, which is analyzed by SYNERGY-AI to collect and interpret data about a long list of parameters, including the patient's gender and age, where the patient lives, his or her type and stage of cancer, what medications he or she has received, the results of blood tests, and many others.

Our AI technology then searches a database of more than 13,000 clinical trials to find research studies with protocols that match the patient's parameters. Finally, SYNERGY-AI generates a report with detailed information about the trials that a patient is eligible to enroll in. And it does all this with lightning speed and accuracy that even a team of humans could never match. AI provides Massive Bio with the crucial intelligence needed in the ongoing battle to wipe out cancer.

There's always hope!

We will help you to find treatment options if you have been diagnosed with cancer and have a specific mutation.

Find a Clinical Trial Near You

BEYOND CHEMOTHERAPY

How today's innovative new therapies, developed in clinical trials, have revolutionized cancer care. An interview with Arturo Loaiza-Bonilla, MD, chief medical officer and co-founder of Massive Bio.

Chemotherapy has long been a critical treatment for many forms of cancer, and will remain so for years to come. But the emergence of new classes of drugs, notably targeted therapies and immunotherapies, has changed the landscape of oncology. We asked Arturo Loaiza-Bonilla, MD, chief medical officer and co-founder of Massive Bio, to explain how these innovative treatments work and discuss how they're changing the outlook for cancer patients.

Dr. Loaiza-Bonilla grew up in Bogota, Colombia, where he enrolled in medical school at the National University of Colombia at age 16, continued his medical education at the University of Miami and University of Pennsylvania, and held a post as a clinical researcher at the National Institutes of Health before being named an assistant professor of gastrointestinal oncology at Penn Medicine's Abramson Cancer Center. He co-founded Massive Bio with Selin Kurnaz, PhD, and Cagatay Culcuoglu in 2015.

Q: *What are targeted therapies and how do they work?*
A: The easiest way to explain a targeted therapy is to compare it to traditional chemotherapy. Now, chemotherapy drugs are very effective treatments and they're an essential part of cancer care. But treating cancer with chemotherapy is basically a very broad, nonspecific approach. It's a little like dropping an atomic bomb on an area that kills everything. A targeted treatment is more like a sniper. With a targeted therapy, you have determined that the cancer is susceptible to this specific drug and molecule, so it's a much more refined approach in identifying cancer, finding it, and killing it.

Q: *How do these drugs select their targets?*
A: In some cases, the target is a protein on the surface of a cancer cell. One good example is the HER2 receptor in breast cancer, which can be targeted with certain drugs. The same is true of androgen receptors in prostate cancer. Another approach is to target a gene mutation that is driving cancer growth. In some cancers, there is an amplification of gene expression, and that can be targeted, too. In general, a targeted drug blocks the specific process that is making the cancer grow. Here's another way to think about how precisely they act: Imagine you were trying to enter a building that requires a passcode to open the front door. Using targeted treatments is like knowing the exact passcode so you can enter the building, instead of trying a gazillion different random codes to see which one opens the door.

Q: *Immunotherapy has provided another important breakthrough in cancer treatment. How does it work?*

A: Immunotherapy is a way of leveraging the intelligence of our own bodies, which are very smart. Through millions of years of evolution, the human body has developed the natural ability to get rid of things like viruses, bacteria, and other bad things. For example, in a very basic sense, if you eat spoiled food, the body has diarrhea and vomiting as a way of saying, "This is not good, I need to get rid of it."

Obviously, cancer cells are bad agents, but the immune system faces challenges in getting rid of them. For starters, cancer cells are made of our own cells, so initially the immune system doesn't recognize them. A cancer cell is like a rogue spy that starts working against the body, attacking tissue and growing out of control. But even if the immune system recognizes cancer cells, they can modify themselves so that they are not reachable by the immune system. For example, some cancer cells have a protein on the surface called PD-L1, which acts like a fake ID that says to the immune system, "I'm family, so don't get rid of me." A

lot of today's immune therapies work by covering up the fake ID that's making the cancer cells go undetected, and also by saying to the immune system, "Hey, it's war time and you have been drafted." That's the basic way that immune therapy works.

Q: *Lately there has been a lot of talk about CAR T-cell therapy. Can you explain what it is?*
A: Sometimes the immune system doesn't understand that a specific cancer biomarker needs to be attacked. It's like T cells—which are key immune defenders—are trying to look for Osama Bin Laden, but they don't know what he looks like or where he lives. With CAR T-cell therapy, we can harvest a patient's T cells and train them to identify cancer by changing their receptors, which act like their "eyesight." We grow these modified T cells in a lab, then infuse them back into the patient, which is like putting a SWAT team into action that will only kill a specific target. In that way, CAR T-cell therapy is almost like combining a targeted drug with immune therapy, since it makes the immune system very specific about what to attack.

Q: *What has been the impact of these new treatments on cancer care?*
A: In the past, there were certain cancers that had a horrible prognosis and chemo didn't really work for them, but that's changing. I'll give you an example: Former president Jimmy Carter is still alive, even though he had melanoma that metastasized, or spread, to his brain. When I was receiving my medical training, these patients only received dacarbazine, which is a type of chemotherapy and all we had to offer, and the patients just died—they lasted no more than a year. It was very frustrating.

But then, we realized two things. One is that half of melanomas have a mutation in a gene called BRAF, and that led to the development of effective drugs called BRAF inhibitors. What's more, we recognized that melanoma is one of those tumors in which we recognize secondary mutations, so now we not only inhibit BRAF, but we also inhibit another pathway called MEK. So we use a combination of BRAF and MEK inhibitors in these patients, and not only do they live longer and the cancer is reduced in size, but the

patient also has fewer side effects. These tumors also have a great response to immunotherapy, so we have both options available. Jimmy Carter has been off immune therapy for many years and he's alive and well, with no cancer. Patients have responded very well to these therapies.

Q: *What does the future hold for cancer treatment?*
A: I predict it will become much more personalized. The use of technologies such as artificial intelligence, deep learning, and neural networks will provide multiple data sources for individualizing treatments with even more precision and specificity. That's where we're heading and that's one of the things we're doing at Massive Bio: We're trying to analyze as much data as possible so that we can start to understand the future of oncology and beyond.

Q: *What role do clinical trials hold in shaping the future of cancer care?*
A: All of these amazing developments we've been discussing, and the developments that will happen in the future, are possible because we do clinical trials. We've done them for decades and without clinical trials we wouldn't have made a dent in cancer—we'd be living in the era of just chemo, but now we can see a glimpse of hope for a lot of patients. When you participate in clinical trials, you're not only contributing to the future of medicine, but you're helping yourself. If you have the chance, you want to be able to look back and say, I did everything in my power to fight this cancer, and clinical trials are one of those things you should always consider, so that you're not removing yourself from an option that may hold the key to you living longer.

It’s long road, but not a lonely one.

Free Clinical Trial Matching Service for Advanced Lyphoma Patients.

Find a Clinical Trial Near You

UPDATE ON BREAST CANCER

Greater awareness and better treatments mean more women are surviving breast cancer. But the search for new therapies continues.

October is National Breast Cancer Awareness Month (NBCAM), which was first observed in 1985. All those pink ribbons you'll see on lapels and hats this month are intended to remind us of loved ones lost to breast cancer, honor survivors, and call attention to the need for more research to develop new medicines for fighting this disease.

While rates of breast cancer in the United States have risen about 0.5 percent per year recently, the portion of older women who die of the disease has steadily declined by about 1 percent annually. Credit for those encouraging survival statistics goes in part to growing knowledge of the importance of practices such as breast self-exams, thanks to NBCAM and other awareness campaigns. But it's also true that research in the lab and in clinical trials has led to the growing availability of better treatments and methods for detecting tumors early, which have improved survival rates.

An important step toward developing effective new therapies for this malignancy has been the discovery of breast cancer biomarkers. A biomarker is a molecule, gene, or other substance in the body that can be measured for several purposes, such as predicting disease risk or monitoring a patient's response to treatment. A biomarker can also be a target for treatment. One key biomarker target in breast cancer is HER2, a protein that spurs the growth of breast tumors. If tests show that a patient's breast tumor is positive for HER2, it can be targeted and blocked with medicines such as trastuzumab *(Herceptin)* and others. (See "New Treatment for a New Designation" to learn about recent changes in the definition of HER2 status.)

Over time, scientists have discovered new breast cancer biomarkers, which has led to the development of additional targeted therapies that take aim at other proteins known to promote tumor growth. These include drugs that block proteins called CDK4/6, mTor, and PI3K, which can benefit the three out of four women with breast cancer who have malignancies

that are positive for hormone receptors; they're generally prescribed to patients with advanced breast cancer. Other targeted therapies for breast cancer include PARP inhibitors for patients who have *BRCA1* and *BRCA2* mutations. Some patients are candidates for immunotherapy drugs known as checkpoint inhibitors, which target certain proteins to promote a stronger response to cancer by protective T cells. Antibody conjugates combine chemotherapy with drugs designed to mimic the human body's own natural defenses, called monoclonal antibodies.

Developing all of these cutting-edge treatments required the participation of patients who volunteered to enroll in clinical trials of experimental therapies. Clinical trials have also helped improve other aspects of breast cancer management, including radiation therapy, which is commonly administered to prevent recurrence of tumors after surgery. While effective, radiation treatments can be physically and emotionally taxing, to say nothing of inconvenient, since they're usually administered daily from Monday to Friday, for multiple weeks. Traditionally, regimens of radiation treatment have taken six or seven weeks. However, the results of clinical trials showed that a technique called hypofractionation allows higher doses of radiation to be safely administered over a shorter period, such as four weeks. Partial breast irradiation can be completed in just one week. Not only do shorter radiation regimens improve quality of life for patients, but they cause fewer side effects than traditional regimens, such as inflammation, skin darkening, and fatigue.

But despite this growing knowledge of how best to control this all-too-common threat, there remains a great need for new medicines that can further improve survival rates for women with breast cancer, which can also affect men, who make up about one percent of cases. Massive Bio works closely with industry partners who are developing new treatments for breast cancer and other malignancies. If you or a loved one has breast cancer, we can help you find clinical trials of promising new therapies. Contact Massive Bio at support@massivebio.com or (844) 627 7246.

New Breast Cancer Screening Guidelines

In September, the National Comprehensive Cancer Network (NCCN) released newly revised guidelines on breast cancer screening. (NCCN is a not-for-profit alliance of 31 cancer centers dedicated to improving cancer care.) NCCN made the following recommendations:

- All people who were assigned female sex at birth should undergo a breast cancer risk assessment by age 25. This assessment will help determine when you should begin having screening mammograms.
- Some factors that place you in a high-risk category include family history, a genetic mutation, prior benign breast disease (such as atypical hyperplasia), or receiving radiation therapy to the chest at a young age.
- A woman with a higher-than-average risk of breast cancer should begin annual breast cancer screening (a mammogram or breast MRI) before age 40 and have a physical exam every six to 12 months.
- If you have one or more blood relatives who have had breast cancer, begin screening no later than when you're seven to 10 years younger than the age at which

the youngest person in your family was diagnosed.
· Women who are at average risk of breast cancer should have a physical exam and a mammogram every year starting at age 40.

Other organizations have established their own guidelines for breast cancer screening. Ask your doctor what schedule makes sense for you.

Black Breast Cancer Patients Often Not Told About Clinical Trials

Black people who develop breast cancer are more likely to die of the disease than members of any other demographic group in the United States. Yet, while Blacks make up 15 percent of U.S. cancer patients, only four to six percent of clinical trial participants are Black. Diversity is essential in clinical trials in order for drug developers to fully understand whether a new medicine is safe and effective in different populations.

To learn more about this disparity, a nonprofit organization called the Metastatic Breast Cancer Alliance launched an initiative called the BECOME (Black Experience of Clinical Trials and Opportunities for Meaningful Engagement) project. As part of the project, they surveyed 424 people with metastatic breast cancer, including 102 who self-identified as Black. They found that Black patients had very high trust in and satisfaction with their oncology care teams, and that 83 percent said they were somewhat or very likely to consider participating in a clinical trial. Unfortunately, 40 percent of Black respondents said that no one on their care team had mentioned the opportunity to enroll in a trial. What's more, nearly three quarters of Black respondents said concerns about side effects kept them from participating in a trial.

The authors of the study, which was presented at the ASCO annual meeting last May, suggest several solutions:
· Black patients should be told about clinical trials as a treatment option and offered assistance in enrolling.
· Black patients should be able to have conversations with other Black people who have been in clinical trials to hear about their experiences.
· Doctors should reassure Black patients about the potential for benefits and risk for side effects.

New Treatment for a New Designation

In September 2022, the U.S. Food and Drug Administration approved fam-trastuzumab-deruxtecan-nxki *(Enhertu)*, an IV infusion for the treatment of patients with breast cancer that can't be treated with surgery or has spread (metastasized) and is considered to be HER2-low.

If you have never heard of HER2-low breast cancer, that's not surprising. In the past, about 20 percent of women with breast cancer were designated as HER2-positive, meaning that their tumor tested positive for human epidermal growth factor receptor 2 (HER2), a protein that promotes the growth of cancer cells. All other patients were called HER2-negative.

However, doctors discovered that some breast tumors had HER2 proteins on the cell surfaces, but too few for the malignancy to be considered HER2-positive. For this reason, about 60 percent of patients who were previously classified as having HER2-negative breast cancer are now reclassified as HER2-low.

What's more, these women have a newly approved treatment option, in the form of *Enhertu*. This treatment is really a combination of two drugs that prevent breast tumor cells from dividing and growing in different ways. The FDA approved *Enhertu* for patients with HER2-low breast cancer based on the results of a clinical trial called DESTINY-Breast04. This trial included 557 patients with inoperable or metastatic HER2-low breast cancer; two thirds got *Enhertu*, while the remainder were treated with chemotherapy. On average, patients in the *Enhertu* group went 9.9 months before their cancer progressed, compared to 5.1 months in the chemotherapy group. Overall survival was 23.4 months and 16.8 months, respectively.

In addition to being diagnosed with HER2-low breast cancer, eligibility for *Enhertu* requires that a patient has already received chemotherapy for metastatic disease or the patient's cancer returned during, or within six months of completing, adjuvant chemotherapy.

Breast Cancer by Numbers

1 in 8

The number of women in the United States who develop breast cancer.

1%

The portion of breast cancer cases diagnosed in men.

62

The median age of breast cancer diagnosis.

287,850

The approximate number of new cases of invasive breast cancer to be diagnosed in the United States this year, according to the American Cancer Society.

43,250

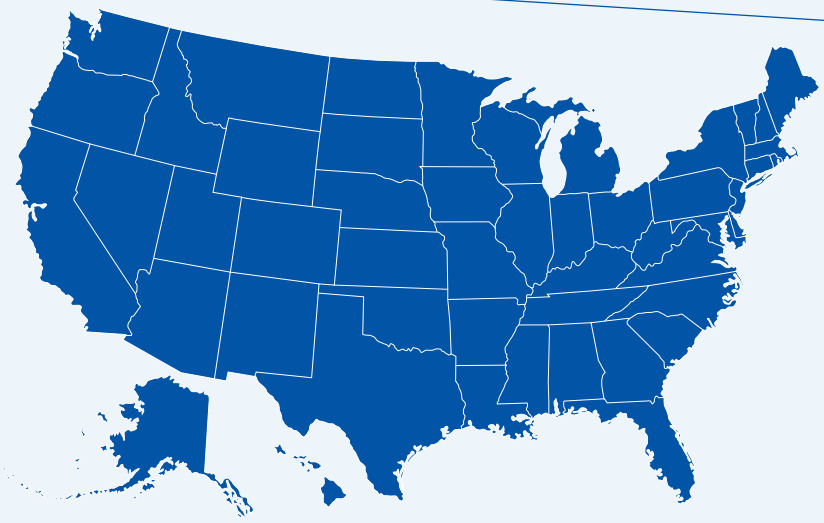
The approximate number of women who will die of breast cancer in the United States this year.

0.5%

The annual increase in rates of breast cancer diagnosed in the United States.

1%

The annual decrease in death rates from breast cancer among older women in the United States.



MASSIVE BIO AND PERTHERA.AI

PARTNER TO EMPOWER CANCER PATIENTS WITH PERSONALIZED THERAPIES AND ACCURATE TRIAL RECOMMENDATIONS

Massive Bio, a leader in AI-powered cancer clinical trial enrollment, announced a strategic partnership with Perthera.ai, a pioneer in connecting oncologists and patients with biomarker-based therapy options. Perthera.ai's patented ranked therapy recommendations complement Massive Bio's screening and analysis to empower more cancer patientsto find an appropriate clinical trial.

Less than three percent of cancer patients today are matched and enrolled in a clinical trial. By combining the advanced computational methods and artificial intelligence capabilities of both companies, more physicians and patients will be able to confidently access the benefits of investigational precision oncology treatments from FDA-approved and novel therapies that are specific to patients' unique molecular and genetic biomarkers. Perthera.ai combines multi-omic testing results (DNA, RNA, IHC and phosphoproteomics) to advise oncologists and their patients and simplify the decision-making process to increase the chance that the best therapy is used the first time.

"We are excited to partner with Massive Bio to leverage the most advanced science and technology to help as many cancer patients as possible," said Albert Kelley, CEO of Perthera.ai. "Increasing access to genomic and multi-omic testing and patient-trial matching solutions is the best way to advance cancer care for all. We believe in collaboration where it can help more patients and by combining forces with Massive Bio, we can improve data acquisition and the accuracy of patient-trial matching."

"Our mission is to create hope and empower cancer patients by helping them find their best treatment options, which often requires access to clinical trials," said Selin Kurnaz, co-founder and CEO of Massive Bio. "By combining Perthera.ai's focus on biomarker-based algorithms with our AI-powered clinical trial matching platform, we can create more options for patients and physicians to find the best trials. We can also pursue additional innovations together around real-world data, biomarker discovery, and diagnostic and commercial collaborations with industry stakeholders."

Dr. Arturo Loaiza-Bonilla, co-founder and Chief Medical Officer of Massive Bio, added: "We are excited to expand our data sets and leverage our technologies and combined networks to offer more precise treatment paths, which will have an immediate and positive impact to identify more treatment options for more patients."

MASSIVE BIO **CONTINUES TO GROW** IN EUROPE

Two senior executives join Massive Bio, which is expanding its operations in Europe with Series B investments. Massive Bio, which uses its proprietary artificial intelligence-based platform to match cancer patients to clinical trials regardless of where they live or their financial circumstances, is expanding its operations in Europe. With support from Series B investments received in the first half of this year, Massive Bio announced the hiring of two new team members who will help expand the company's global operations, intensify its marketing activities, develop new data sets and products, and expand its M&A efforts. The new recruits are Toygun Onaran, and who will serve as Head of Strategy, Mert Sarı, who will be Regional Manager.

Massive Bio's expanding presence in Europe will allow the company to continue its mission of ensuring that all cancer patients receive treatment under fair and favorable conditions, said Çağlar Demirbağ, Director of International Partnerships, which manages the company's operations outside of the United States, adding that "there are about 4 million patients diagnosed with cancer annually in Europe. With the steps we have taken in the last two years, we have been ensuring that thousands of cancer patients in Spain, Italy, France, Germany, Romania, Poland, and Greece are matched to appropriate clinical trials. This is also enabling that these patients receive the best treatment free of charge."

"The current changes we are making today will help us better reach and support more cancer patients in the future," added Erkan Terzi, Massive Bio's Vice President of Global Marketing. Terzi said, "At Massive Bio, we work on three continents in 32 different functional areas in our marketing efforts. Our recent updates, newsletters, infographics, new video production, digital-asset improvements, content writing, and advertising management continue to help us create a more comprehensive and effective patient-use case. The technologies we use and the integrated studies we create with different units enable us to work more effectively in the business focus."

Cancer and Diet

Will choosing the right foods help you defeat cancer?

Can you fight cancer with a fork? Scientists have been studying the link between diet and cancer for decades. While no single food or nutrient has emerged as the ultimate defense against malignancies, plenty of research indicates that making the right choices when you tuck in your bib can help guard against cancer and give you a boost if you're currently receiving treatment, including several recent studies.

For example, in a 2022 paper published in the journal *Menopause*, researchers found clues that women who eat plenty of fish may also gain some protection against breast cancer. In the study, 1,589 women in China with breast cancer were asked to describe their diets in great detail, as were 1,621 similarly aged women who didn't have breast cancer. The study showed that women who consumed the most fish had a 32 percent reduced risk for breast cancer compared to those who ate the least.

The authors of the study suspected that the omega-3 polyunsaturated fatty acids in fish may protect against breast cancer and some other cancers, possibly by reducing inflammation. There are well-established reasons to include more fish in your diet, such as lowering your risk for heart disease and keeping your weight under control, so swapping a cheeseburger for a salmon filet is a no-lose exchange.

And how about some broccoli with that salmon? The cruciferous vegetables are another group of foods that have garnered great interest from cancer researchers. They include not only broccoli, but also vegetables such as arugula, Brussels sprouts, cabbage, cauliflower, kale, turnips, and others. Scientists have determined that compounds in cruciferous veggies seem to rev up a gene called *P53*, which is one of several tumor suppressor genes in the human body. The job of *P53* and its mates is to control cell division and repair DNA, which helps quash the rise and spread of cancerous tumors. (Being born with mutations in *P53* increases the risk for gastric, small intestine, colon, liver, and pancreatic cancers.) Stud-

ies have found that people who eat a lot of broccoli and other cruciferous foods have reduced risks for prostate, breast, colorectal, and lung cancers.

However, rather than focusing on single "magic foods" to fight cancer, it may make more sense to adopt a general pattern of healthy eating, say scientists who study diet and cancer. For instance, there's intriguing research suggesting that vegetarian or vegan diets shield against many forms of malignancies. Some of the most-persuasive studies have involved members of the Seventh Day Adventist Church, many of whom are vegetarian; those who eat meat, tend to do so sparingly.

In a 2020 study in the journal *Cancer*, researchers found that cancer rates were 30 percent lower among Seventh Day Adventists compared with the general U.S. population, while rates of premature death from any cause were 33 percent lower. It's difficult to draw conclusions from studies like this because the lower cancer and death rates among Seventh Day Adventists are likely influenced by various factors—very few of them smoke tobacco, for instance, and they exercise more than other Americans, too. But the authors of the study argued that diet likely plays an important role in the Seventh Day Adventists' lower cancer risk.

Other research has linked plant-based diets to lower cancer risk, which appears to be due to what they include, and don't include. For starters, fruit and vegetables are rich in cancer-fighting compounds such as antioxidants, which latch onto and disarm harmful molecules called free radicals that can damage healthy cells and promote disease, including cancer. If you're eliminating meat, you're probably consuming more grains, preferably whole grains, which are

an excellent source of dietary fiber. A 2022 review in *Nutrition and Cancer* found that people who consume the most fiber are about 25 percent less likely to develop colorectal cancer than people who eat the least, while research also suggests that eating lots of roughage can limit the risk of some other cancers. There are additional chemicals in plant foods that probably protect against cancer, too, though they're less well understood.

Plant-based diets also lack some elements that make the typical American diet so unhealthy. They tend to be low in calories, for one thing, which helps you stay trim—and obesity is a known risk factor for many types of cancer. They also limit or omit meat, and diets that are rich in steaks, chops, and especially processed meats such as deli ham and salami are associated with colorectal and other forms of cancer.

You don't have to give up meat entirely to adopt a plant-based diet—simply eat modest portions, and not every day, while filling your dinner plate with vegetables and healthy grains. If you need some guidance on reducing your meat intake and including more healthful foods in your meal plan, read up on the Mediterranean diet, which includes little meat or junk food, but plenty of fish, fruit, vegetables, nuts, and olive oil. Not only has it been shown to reduce the risk for heart disease and stroke, but research also indicates that it's a cancer fighter, too.

Foods and Beverages To Limit or Avoid

Steering clear of these consumables may reduce your risk for certain types of cancer.

Alcohol

Studies show that regularly consuming alcoholic beverages increases the risk for some forms of cancers. That includes cancer of the oral cavity (that is, tissue in the mouth, other than the lips), throat, larynx (voice box), esophagus (windpipe), liver, breast, colon, and rectum. The increased risk is dose dependent, that is, the more you drink, the more likely you are to develop cancer.

Charred meat

Cooking meat with high heat, such as in a frying pan or on a grill, can cause it to char. This process produces chemicals called heterocyclic amines (HCAs) and polycyclic aromatic hydrocarbons (PAHs) that have been shown to cause cancer in laboratory animals. While their effect on humans is less clear, some evidence points to an increased risk for certain cancers, especially colon cancer. The longer you cook meat, the more HCAs it forms. Meanwhile, smoked meats also tend to have high levels of PAHs (which are found in tobacco smoke and automobile exhaust, too). HCAs and PAHs can form in beef, pork, fish, and poultry that is cooked at high temperatures. Briefly pre-cooking meat in a microwave oven or marinating it in wine or beer (which are rich sources of antioxidants) before cooking may help reduce formation of HCAs and PAHs.

Processed meats

A number of studies indicate that a diet rich in processed meats such as ham, salami, and baloney increases the risk for colorectal and stomach cancers. Consuming these deli favorites may also raise the risk for certain other cancers, including pancreatic cancer and lung cancer. If you include them in your diet at all, make them a rare treat.

Sweets

All cells in the human body require a basic form of sugar called glucose to survive. That includes cancer cells, so some people have wondered whether consuming sugar feeds the growth of tumors. Your body can get all the glucose it needs from healthy foods, such as fruit, and by making it from starch in other foods, such as grains (preferably whole grains), and both of these food groups have other nutrients to offer, too. But candy, soda, cakes, cookies, and other sweets are empty calories that do nothing but contribute to weight gain. And studies show that being overweight or obese increases the risk for colorectal, breast, ovarian, and pancreatic cancers, among others. If you have a sweet tooth, keep it in check.

The Problem Solver

Brian McCloskey is fighting prostate cancer with a formidable tool: data. Now he's helping other men do the same.

Brian McCloskey (right) getting ready to ride the waves with some friends.

Brian McCloskey had it all: A beautiful family, a job he loved, and a home just north of San Diego, which gave him easy access to the Pacific Ocean, where he loved to surf. But one day in 2016, McCloskey got a call from his doctor with jolting news: You have prostate cancer.

McCloskey had just stepped out of a meeting at AMN Healthcare, the medical staffing company where he served as senior vice president of marketing. "I had five or 10 minutes to reflect on the news, then I had to get to another meeting," recalled McCloskey, now 57, who said he initially let professional responsibilities distract him from the diagnosis. "But as the weeks unfolded, I came to understand what it meant and that I had to get smart about this. I was always in the position of solving problems at work. I viewed my cancer diagnosis as just another problem to solve," said McCloskey. "That's when my journey began."

And what an arduous journey it has been. McCloskey first underwent a radical prostatectomy (surgical removal of the prostate), plus hormone therapy and radiation. He thought he was done with cancer, but it recurred in 2017. "That was devastating," said McCloskey. Since then, he has had chemotherapy and immunotherapy, more surgery, then more hormone therapy.

Fast forward to 2022 and McCloskey is still solving problems—for himself and for other men with prostate cancer, through the Prostate Cancer Lab (prostatecancerlab.com), which he created with Brad Power and Rick Stanton last March. Both McCloskey and Stanton have stage IV prostate cancer. They established the Prostate Cancer Lab with Power, who is a lymphoma survivor, as a way to use their collective knowledge and experience in coping with the disease to help other men with prostate cancer discover their best treatment options. That includes enrolling in research studies of experimental therapies, which is why the Prostate Cancer Lab has encouraged several men to be screened by Massive Bio for potential enrollment in clinical trials—a choice McCloskey made, too.

"I realized that Massive Bio could help by matching me to clinical trials," said McCloskey in a recent video conference. He has also been in touch with a few other services that identify trials of investigational medicines for cancer patients, but feels that Massive Bio stands apart in significant ways. "Of all the organizations we've worked with, quite frankly, you provide the most complete end-to-end solution," said McCloskey.

Massive Bio's clinical trial matching service (CTMS) produced a report for McCloskey in June 2022. The report identified three trials of new treatments that CTMS's artificial intelligence determined stand the best chance of controlling his cancer and possibly even offering what he and Stanton call "a home run"—that is, a cure. McCloskey discussed those three trials, along with 18 other clinical trials that had been recommended to him, with his medical oncologist at Moores Cancer Center at UC San Diego Health, Rana McKay, MD. Together, they winnowed the list down to eight clinical trials of

systemic treatments (which are infused into the bloodstream to destroy cancer cells), then down to just two—including one trial that Massive Bio recommended.

McCloskey was still considering which of the two trials to enroll in, or whether to seek out additional radiation therapy as an alternative treatment, when we caught up with him. It would be the next in a long succession of major therapeutic choices McCloskey has faced as he battles cancer—by his count, he has had to make nine important treatment decisions along the way. To put himself in the best position to make the right choice, McCloskey has not only educated himself about prostate cancer, but has created charts, graphs, and spreadsheets that track details such as his complete treatment history, accompanied by changes in his prostate-specific antigen (PSA, a biomarker of prostate cancer) and testosterone (which feeds growth of prostate tumors) over the years.

What's more, McCloskey has taken steps to learn more about his specific form of prostate cancer, which is obviously unusual and aggressive: Not only did it strike at a young age (the typical prostate cancer patient is 66 at diagnosis), but the malignancy has behaved in unexpected ways, such as spreading to his peritoneum (the lining of the abdomen), which is highly uncommon. Not only has McCloskey undergone genomic profiling (which scans every gene in the body for mutations that can promote cancer and other diseases), but he has also had RNA sequencing (an analysis of alterations RNA, which plays an essential role in protein production). The latter testing provided key information that helped McCloskey and his doctor select one of the clinical trials Massive Bio recommended as a finalist.

McCloskey stresses that it's essential for cancer patients to educate themselves about their disease and take part in deciding what treatments they receive. "I believe there is a real difference in terms of outcomes for patients who are involved" in their care, he said. "It's important for patients to be their own advocates. And you have to recognize that there is hope."

While McCloskey mulls which treatment to choose, he continues to recommend Massive Bio as a source for men interested in enrolling in clinical trials. He was particularly impressed recently when one man who had been screened and received a CTMS report underwent a change in status that meant he needed to be re-screened. After he contacted Massive Bio about the change, oncology nurse navigator Kate Himmelsbach, RN, immediately generated a re-match report for the man. "Within a day, Massive Bio turned around and provided an updated report," says McCloskey. "It was so awesome."

Meanwhile, he, Power, and Stanton continue developing the Prostate Cancer Lab, which McCloskey has discussed in presentations for doctors and pharmaceutical company representatives at cancer conferences and symposia. He's still surfing, too, and says he finds strength and joy in spending time with his wife, Kristin, and children, Liam, 25, Jack, 23, and Grace, 17. "There's no question," said McCloskey, "I'm blessed in many ways."

The McCloskeys: Jack, Liam, Kristin, Brian, and Grace.

PATIENT ADVOCACY

PINK FUND: HELPING BREAST CANCER PATIENTS WHO FACE IMPOSSIBLE CHOICES

Every cancer patient knows all too well that treatment can have side effects, but many experience a complication they never expected: Financial toxicity, which is the term some use for getting blindsided by huge medical bills they can't afford to pay. Some patients find themselves faced with cruel choices, such as deciding between selling their homes or quitting treatment.

Molly MacDonald (second from left) at a fundraiser with two of her children, Drake and Brittany, and her husband, Tom Pettit.

But for some fortunate patients, that's when Pink Fund steps up to help. Pink Fund is a non-profit advocacy group that provides 90 days' worth of non-medical financial aid to breast cancer patients facing insurmountable bills. Recipients' bills for expenses such as housing, transportation, insurance, and utilities are paid directly to their creditors.

Pink Fund's story begins with Molly MacDonald, who in 2005 was about to start a new job with a high-end graphics company when she was diagnosed with breast cancer. "That derailed my job opportunity," says MacDonald, who didn't feel she could keep the position while facing a treatment regimen that would ultimately involve several surgeries and six weeks of radiation. "So, I was unemployed and unemployable."

And that wasn't all. MacDonald, a mother of five, already faced deep debt as a result of what she calls a "financially devastating divorce," that cost the family its home in Bloomfield Hills, Michigan. MacDonald was resourceful enough to keep her family afloat and eventually remarried, but after completing her treatment, she was haunted by

the conversations she had with other cancer patients in hospital waiting rooms. Time and again, talk turned to money—many patients said they were unable to work while undergoing cancer treatment and the bills were stacking up. Women told Molly that they were faced with cruel decisions: Sell their homes and cars, pull their kids out of college, or maybe liquidate their life savings, in order to pay their medical expenses—or quit treatment and go back to work.

Quitting treatment was like accepting a death sentence, MacDonald thought to herself. "Why isn't somebody doing something to help these women?" she asked her new husband, Tom Pettit. The two put their heads together and launched Pink Fund in 2006, seeking contributions from donors large and small. A front-page story about Pink Fund in the *Detroit Free Press*, which was picked up in several dozen other newspapers around the country, put them on the map. Then, in 2012, Pink Fund forged a partnership with its first major corporate donor, the Ford Motor Company.

"That really took us national," says MacDonald. Ford's sponsorship meant Pink Fund could help many more patients, as the group went from paying about $40,000 in patients' bills annually to $212,000 in just a year. With Ford's continued support, and the addition of other corporate sponsors, such as tool-and-equipment maker Snap-on Incorporated, the annual totals have risen: Last year, Pink Fund paid over $1 million in bills for cancer patients in need and has distributed $6.4 million in assistance since its inception.

The long list of recipients of financial assistance includes plenty of people with health insurance who never dreamed they would be diagnosed with cancer, much less that treatment-related costs would threaten their financial future. The problem is particularly acute for patients while they're receiving treatment, which often leaves them too sick and disabled to work. "We know that people can't afford their co-pays and their deductibles," says MacDonald, "but when that lost income collides with those two things, then everything falls apart."

Testimonials from patients who received assistance from Pink Fund featured on the organization's website (pinkfund.org) leave little doubt about its impact. "Nothing short of a miracle," said one. Another called the aid she received from Pink Fund "truly life changing." That patient was a 35-year-old mother of two when she was diagnosed with stage III breast cancer in 2020, just as the COVID-19 pandemic essentially closed her husband's business. But, she said, thanks to assistance they received, "we can focus on treatment and healing without having the cloud of financial doom over us. We will be forever grateful to The Pink Fund!"

It is a long road, but not a lonely one.

Use our Artificial Intelligence to match to advanced melanoma treatment options now

Find a Clinical Trial Near You

AWARENESS CALENDAR

November

- Carcinoid Cancer Awareness Month
- Lung Cancer Awareness Month
- National Family Caregivers Month
- Hospice and Palliative Care Month
- National Marrow Awareness Month
- Pancreatic Cancer Awareness Month
- Stomach Cancer Awareness Month
- World Neuroendocrine Tumor (NET) Day (Nov 10)
- Great American Smokeout Day (Nov 17)
- World Pancreatic Cancer Day (Nov 17)

December

- World Aids Day (Dec 1)
- National Influenza Immunization Week (Dec 5-9)

January

- Cervical Health Awareness Month

February

- National Cancer Prevention Month
- Gallbladder and Bile Duct Cancer Awareness Month
- World Cancer Day (Feb 4)
- International Childhood Cancer Day (Feb 5)
- National Donor Day (Feb 14)
- Rare Diseases Day (Feb 28)

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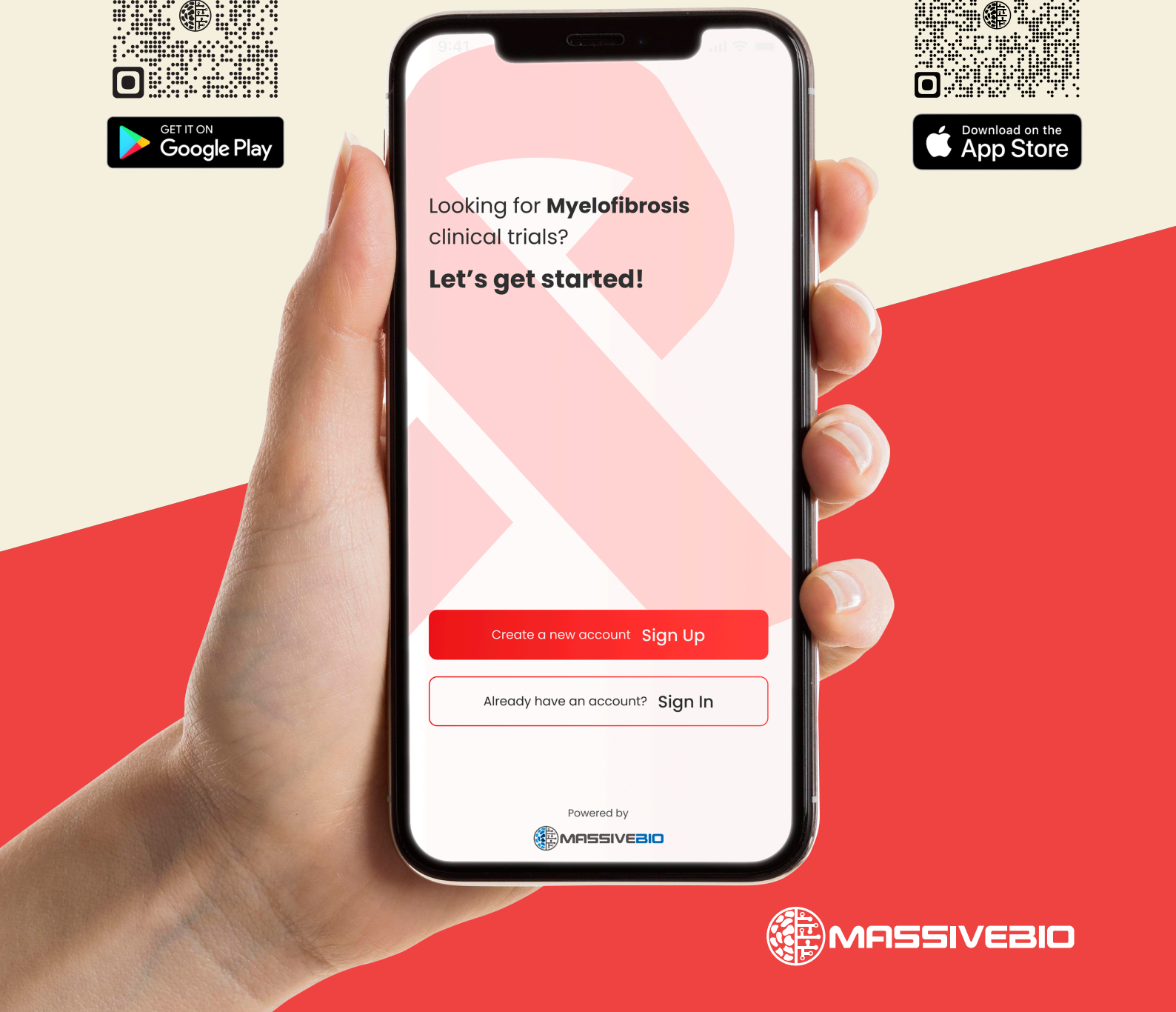

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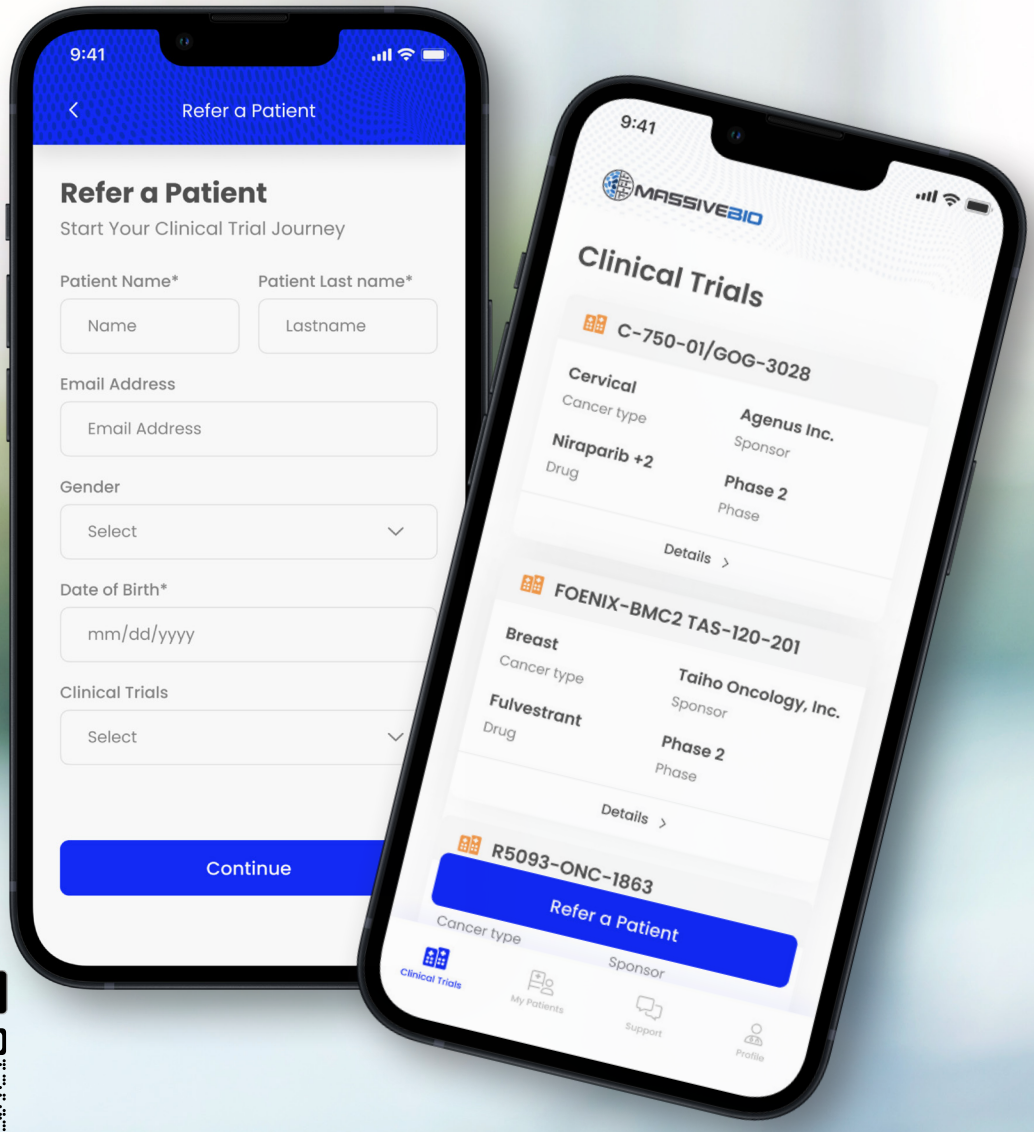
AI finds the right trials for you.

SYNERGY-AI offers a personalized, hassle-free, evidence-based clinical trial matching service to cancer patients. No one should fight cancer alone.



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SYNERGY-AI Cancer Clinical Trial Finder is a mobile app that uses your cancer type, stage, biomarker status, and other data points to identify clinical trials of cutting-edge treatments, at research sites near you. Contact us about enrolling in a clinical trial and let Massive Bio do the rest.