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Expanding The Reach Of Transformative Cancer Research Through Collaboration And Innovation

by

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Discovering and developing effective and durable treatments for cancer has long been one of the most challenging areas of medical research. Cancer is a confounding, aggressive and shape-shifting enemy that's not easy to defeat, and the challenge is compounded by many historical factors like limited access to and lack of diversity in clinical trials, and a lack of widespread and timely cancer treatment education.

Amgen Oncology is expanding the reach, impact and potential of innovative, life-changing medicines by pioneering meaningful advancements in core areas including hematologic malignancies, lung, prostate and gastrointestinal cancers. Additionally, as pioneers in the development and commercialization of multi-specific T-cell engagers, including the first ever approved molecule in the Bispecific T-cell Engager (BiTE[®]) class, Amgen is pursuing first-in-class research to transform what's possible in cancer care.

But innovative, transformative medicines are only impactful if they reach those who need it, regardless of their race, socio-economic status or geographic location. To that end, Amgen has initiated many novel collaborations to increase the diversity of clinical trial participants, educate patients and healthcare providers on the latest developments in transformative cancer treatments, and expand access to those treatments to patients around the world.

Bringing Clinical Trials To The Community Through ACORC

Participation in clinical trials allows patients access to the most advanced treatment options available. Traditionally, most clinical trials operated exclusively in academic medical centers.

But only about 15% of cancer patients receive their care in these institutions while the other 85% of patients rely on community cancer centers.¹

Until recently, this precluded the vast majority of cancer patients from clinical trial participation, with only 3% to 5% of eligible patients enrolled in oncology trials that are mostly located in urban areas.^{2,3} The costs of travel, time off work and the associated potential for job insecurity all pose significant barriers. Although clinical trials are open to every cancer patient who meets the trial enrollment criteria: geographic barriers prevent the most underserved patients from access; people of color, those at socioeconomic disadvantage, and those living in rural areas.

In May 2019, the company launched Amgen Community Oncology Research Collaborators (ACORC) to help community oncologists extend clinical trial opportunities to their patients. Since then, the company has joined forces with U.S. Oncology Research (USOR), Translational Research in Oncology-U.S. (TRIO-US), Sarah Cannon Research Institute (SCRI) and Sanford Research. To date, those four organizations have enrolled nearly 1,500 patients across 16 Amgen trials.

“Our ACORC collaborations allow us to bring clinical trials closer to patients, which became critically important during the COVID pandemic,” said Sharon Jameson, executive director, External Medical Engagement at Amgen. “Patients are our North Star, and we aim to connect as many patients as possible with clinical trials by making them aware of new, investigational drugs being studied that they otherwise may not know exist. We want to give patients the option to consider investigational drugs in clinical trials, and that’s 100% our mission through ACORC.”

Through community network engagement, ACORC collaborators contributed approximately 50% of enrolled U.S. patients to the CodeBreak 200 study in patients with *KRAS* G12C-mutant NSCLC. In addition to clinical studies, ACORC generates data through real-world evidence on currently available oncology treatments.

“It’s much more organized and efficient to work with a central organization that encompasses multiple sites,” added Jameson. “We recognize the organizations’ strengths and capabilities, so we can customize our work with each group based on their individual capabilities and needs.”

Increasing Representation In Clinical Trials With The Lazarex Cancer Foundation

But it’s not just about geography as racial, ethnic and generational diversity among clinical trial participants are critical to understand if potential treatments are safe and work well for people from these different groups. Yet, for decades, clinical trials have lacked proportional representation of historically underserved populations. Amgen’s oncology pipeline focuses on many disease areas that disproportionately affect racial and ethnic minorities, including cancers like colorectal, prostate, lung and multiple myeloma, and the company has made a top priority of ensuring these populations have equitable representation in clinical trials.

A 2017 FDA report on global participation in clinical trials found that only 2.74% of oncology trial participants were Black,⁴ despite the fact that Black Americans bear a disproportionate share of the cancer burden.⁵ To that end, Amgen has set the ambitious goal to exceed the current industry benchmark for representative enrollment in the U.S. in select therapeutic areas, including oncology, by 2026. To do so, the team contributes to initiatives to guide the industry towards an improved ecosystem, including work with PhRMA and others.

In 2018, Amgen joined the Lazarex Cancer Foundation's Improving Patient Access to Cancer Clinical Trials (IMPACT) program, which strives to improve patient enrollment, retention, minority participation and equitable access in oncology trials. What began as a pilot program with Massachusetts General Hospital (Boston, MA) has expanded to include 20 leading cancer centers and public health programs nationwide, coordinating efforts among all stakeholders to make clinical trials more representative of the real-world patient population.

IMPACT has already delivered concrete results: preliminary data shows 58% minority participation with 49% of participants coming from households earning \$25,000 per year or less. Clinical trials should be accessible to patients irrespective of ethnicity and socioeconomic factors, and Lazarex is a valuable and effective forum to offer support to patients who seek access to oncology clinical trials.

Driving Biomarker Testing Education Through Collaborations

To take advantage of the most advanced treatment options, patients and healthcare providers need to understand the latest advancements in biomarker research and testing recommendations. But rapid, recent and significant advances have left some patients and healthcare providers behind. We know most patients with metastatic NSCLC receive at least one biomarker test before first-line therapy, but less than half receive comprehensive testing of all the guideline-recommended biomarkers.⁶ Although most oncologists agree that comprehensive biomarker testing should be the standard of care for all patients with NSCLC, it's not always happening.

In 2019, Amgen began a collaboration with a number of different cancer community networks and organizations to accelerate the education and adoption of comprehensive biomarker testing. One example is Amgen sponsorship of biomarker educational programs by the Association of Community Cancer Centers (ACCC). ACCC has a community of over 28,000 multidisciplinary practitioners and 2,100 cancer programs nationwide, and ACCC estimates 65% of cancer patients nationwide are treated by one of their members.

"ACCC and other community organizations have a large network in terms of their membership, which augments the number of practitioners that we can reach to advance biomarker testing," said Byeong Yoon, Ph.D., executive director of Oncology Global Medical Affairs at Amgen. "These networks are the experts in helping their members navigate both the operational

challenges of biomarker testing along with the educational opportunities around the need for it, and we couldn't do it without them."

It's not just about educating healthcare providers. Barriers to biomarker testing are multifactorial and require many stakeholders working together to overcome them. Physicians, patients, laboratories, allied health professionals, and even payors have a vested interest in the latest advances and recommendations in biomarker testing and education, and no single organization can reach them all.

"We also work with other members of the healthcare community including patient groups, professional societies like Association for Molecular Pathology (AMP) and commercial reference labs to help address some of the key barriers to testing," said Dr. Yoon. "At the end of the day, addressing the current barriers to biomarker testing is not something that can be done by one or two groups. With so many stakeholders, it's critical that we collaborate with many different organizations to advance biomarker testing to help patients access appropriate treatments for their specific cancer types."

Accelerating Cancer Care Globally With Project Orbis

Amgen also works to ensure patients around the globe have access to the most advanced treatments as quickly as possible. Through the U.S. Food and Drug Administration Oncology Center of Excellence's Project Orbis, the company helps to facilitate and expedite product regulatory submissions in other countries, which may allow patients with cancer in countries outside of the United States to receive earlier access to approved therapies.

Together, these initiatives help Amgen Oncology deliver on its commitment to transform what's possible for patients impacted by cancer. Through cooperation with valued collaborators, the team continues to advance the science for more effective therapies and to improve access to clinical trials and improved treatments for as many patients as possible, no matter who they are or where they live.

Learn more about how Amgen is working to advance all angles of care for patients at [Amgen.com](https://www.amgen.com).

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