Jeff Allen – CEO, Friends of Cancer Research

We are about to enter a new era of cancer treatment, made possible by technologies that will modernise clinical research in ways that we have not seen before

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Jeff Allen is the President & CEO of Friends of Cancer Research, a research policy and advocacy organisation based in Washington, DC. His organisation works to accelerate the development of cancer therapies through evidence-based policy and collaborative research partnerships. Allen highlights the importance of diagnostics and biomarker testing to help inform patient care and support clinical research, explains how clinical trials can be accelerated, patient access to trials expanded, and how the US can maintain scientific leadership amid global competition and funding challenges. He also addresses the emerging role of artificial intelligence (AI) in healthcare, as well as the essential partnerships that make progress possible.

Can you provide a brief introduction to Friends of Cancer Research, including your mission and key priorities?

Our mission is to accelerate the pace at which new treatments are developed for people with cancer, Our work is predominantly focused on advancing regulatory policy. We run research consortia and bring stakeholders together to generate new evidence that answers key scientific questions in the field and designed to inform future policy opportunities.

While many of our projects are oriented around drug development, recently we have expanded work into diagnostics, given the critical importance of those tools to identify patients that could benefit from new treatments. We are also focusing on cell and gene therapy, with immunotherapy

becoming an integral part of cancer research and care.

What are your organisation’s contributions in the diagnostic space, and what challenges exist in aligning development with diagnostics?

Several years ago, the ability to identify patients based on molecular factors or genetic alterations and match them to an appropriate treatment began to shift the paradigm of cancer drug development. Now, if you look across pipelines, it’s estimated that over half of all drug development programmes have biomarker selection criteria associated with new medicines. These tools are essential in ensuring that patients get the right treatments at the right times.

An area of focus in diagnostics has been understanding the performance of different tests available. Often, a drug is developed with a companion diagnostic, but as it moves into additional areas of research or clinical practice, any number of tests may be available to evaluate a specific biomarker. We wanted to understand how frequently different tests with similar uses produced consistent results.

Through a series of scientific research consortia, we evaluated the consistency of outputs for numerous tests measuring tumour mutational burden and homologous recombination deficiency, both complicated biomarkers that have potential for variability if there is not an effort to ensure that test results are consistent across platforms. This is especially important for the clinicians and patients who rely on these results to determine the best treatment course. Transparency around test performance is critical because it should not matter what type of test a patient receives or where it is conducted. These types of partnerships can help inform efficient approaches for test characterization and inform potential policies as diagnostic tests are developed and introduced into clinical practice.

What options does your organisation see to help accelerate cancer research?

For many types of cancers, clinical trials test the next generation of drugs will take longer and longer to complete. This is because new therapeutic options have been successful, particularly when combined with earlier agents. This increases the time it takes to determine whether a new drug is safe and effective, the resources required to conduct a trial, and the burden on patients who may participate.

It is important to leverage emerging technologies that can measure drug activity earlier, and one area that we have examined is the potential role of circulating tumour DNA (ctDNA) as an early indicator of treatment response. We worked with many partners to aggregate and evaluate data from over two dozen trials provided by about 12 pharmaceutical companies.

For several different types of drugs and cancers, there are strong associations between a reduction in ctDNA within the first couple of months of treatment and improved overall survival. Having an endpoint able to indicate whether a drug is working earlier than currently available measures helps to prioritise promising compounds and expedite their clinical development.

These early measures could eventually be used to support Accelerated Approval, a tool the FDA uses to make new therapies available based on early endpoints, is something that has provided early access to treatments for serious illnesses. This pathway has been utilized by about one-third of all oncology drugs. With technology emerging so rapidly, there are emerging opportunities to measure disease processes and evaluate tumour responsiveness to new therapies earlier.

What barriers exist to patient access to clinical trials in the US and globally, and how can we create more opportunities to improve access?

Drug development and clinical trials have become both increasingly complicated and global. Sometimes, specific molecular alterations that may be the target of a drug can result in very small populations which can require a worldwide reach to identify eligible patients.

One complexity that can come from multi-regional trials is the need to manage differences in standards of care across global regions. If clinical trials are conducted in areas with a different standard of care for a particular cancer, the results might not be generalisable to the US population. Therefore, it can become complicated to identify an appropriate patient population to demonstrate efficacy and to ensure it is relevant to the populations that will eventually use the medicine.

Broadening trial parameters, such as expanding eligibility criteria, is one way to make clinical trials more accessible. Understandably, trials are conducted in a relatively homogenous population to limit variables that could affect outcomes. However, this also narrows the potential trial population. We have partnered with the American Society for Clinical Oncology (ASCO) and worked with experts across government, academic/clinical research, industry, and patient advocacy to identify specific areas where eligibility criteria for any given trial could be expanded.

Enabling more sites to participate and offer clinical trials presented another opportunity to improve patient access. There is a high level of specialised clinical trial expertise at our nation’s academic centres, but not all patients are treated at them. Approximately 80% of patients are treat in non—academic sites. So, a question is how to support more practices in offering clinical studies as an option for patient care. That comes down to infrastructure support, resourcing, and simplifying trials where appropriate so they can fit different practice situations and reach more patients.

What are some challenges that you see around the advancement of cell and gene therapies, and what are the solutions that your organisation has worked toward?

In recent years, cell therapies have demonstrated the potential to transform previously untreatable diseases. This level of technology to help patients in new ways is exciting, but we are likely only at the start of this frontier. For example, the FDA has approved about seven different CAR-T therapies for cancer, but there are likely to be many more potential targets and uses in different cancer types. As experience with these advanced therapies continues to grow, there will be a need to adjust along the way and consider policies that can be conducive to the next generation of therapies.

For the most part, these therapies are available in advanced academic centres that have developed the necessary clinical and manufacturing processes to offer these therapies. However, many eligible patients have trouble obtaining access. They may not be near a treatment centre or may encounter other logistical challenges. This may change as manufacturing capabilities are modified and technologies continue to advance.

A key focus area for us is optimising regulatory processes for evaluating safety and efficacy, particularly around subsequent generations of cell therapies. For example, as modifications are made toward new targets or manufacturing updates, there may be opportunities to demonstrate the impact of a minor change without having to restart development each time. We have worked closely with the FDA to create guidance documents that hopefully can compress that overall process.

In order for the US to remain a scientific leader, what aspects of the infrastructure will need support?

Through National Cancer Institute (NCI)-designated cancer centres and affiliate hospitals, there is an amazing network to implement clinical trials that would be difficult to replicate. That must be supported, and we have seen recently that other countries have been making substantial investments into their own research infrastructure. At the same time, some American policymakers have proposed pulling back on this support. It takes quite some time to recover progress when funding lapses, and it may have a long-term impact on our government's health and research agencies, as well as on the private sector that relies on this type of research. Priority number one is supporting that infrastructure predictably and consistently. Notably, Congress did step in recently to protect National Institutes of Health (NIH) funding. However, other parts of government, many of which play a critical role in cancer research and healthcare, are facing challenging times.

Aside from infrastructure, there are differences between the abilities of countries to support research as part of clinical care. The complicated healthcare system in the US can make it difficult to integrate the common systems that could optimize large scale data collection in a uniform way that could better enable health information to be used as a tool for research. As research becomes more global and complex, that will continue to be a challenge.

A third area is how to adapt to new technologies. Global clinical and regulatory practices vary, especially in how new technologies are incorporated into research. It is important to consider how our country can stay at the cutting edge of technological adoption and have appropriate regulatory oversight while accelerating the process.

What impact is AI having in the treatment development and diagnostic space?

The role of AI is an area of intense interest, particularly in healthcare. We must ensure that AI-enabled technologies are yielding accurate information, but the question is how to do that efficiently. There is a great deal of promise for things like utilising AI in pattern recognition to evaluate cancer biopsies and assist expert pathologists in identifying or characterizing various molecular characteristics. We are at the cusp of the potential of AI to catalyse new therapies by recognising targets that may not have been identified by past technologies. Ensuring the consistency of AI tools for this type of use will be vital.

An advantage of these technologies is that their performance can be demonstrated quickly and efficiently without adding too many delays into the drug development they may be supporting. Another potential opportunity is the use of AI-enabled imaging. Imaging tools have been a cornerstone of tumor measurement for many years, and while imaging tools have become more

sophisticated, they still use similar criteria for evaluating tumour response to therapy. Today, through AI-enabled imaging, therapeutic response may be able to be measured more efficiently, accurately, comprehensively, and perhaps even earlier than is currently possible.

What are your key priorities over the next few years?

Emerging technologies have the potential to transform cancer research. We are about to enter a new era of cancer treatment, and it is going to be made possible by these advanced technologies that will modernise clinical research in ways that we have not seen before. Our focus will remain on identifying opportunities to advance regulatory policy and expedite the development of new treatments. This includes multi-stakeholder efforts to advance endpoint development, validation of new technologies for improved tumour assessment via imaging and at a molecular level and identifying policies that can modernize and accelerate clinical trials.

To get there, I believe we'll need to collectively address fundamental problems, and that's only going to be done through strong partnerships. This includes identifying joint priorities and a willingness to do business differently at times – for example, sharing data or modifying processes. By implementing some of these new technologies and techniques, we can make remarkable advancements. Together, we'll be able to get further, faster.

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