

Inviting Innovation in Cancer Clinical Trials

It's no longer acceptable for cancer clinical trials to take years to design, launch and complete.

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Thanks to advances in technology, data science and infrastructure, the pace of discovery and innovation in cancer research has accelerated, producing an impressive range of potential new treatments and other interventions that are being tested in [clinical studies](#). The extent of the innovative ideas that might help people live longer, improve our ability to detect cancer early, or otherwise transform care is staggering.

Our understanding of tumor biology is also evolving, and those gains in knowledge are being translated into the continued discovery of targets for potential [interventions](#) and the development of novel types of treatments. Some of these therapies are producing unprecedented clinical [responses](#) in studies, including in traditionally difficult-to-treat cancers.

These advances have contributed to a record number of Food and Drug Administration (FDA) approvals in recent years with, arguably, the most notable approvals being those for drugs that can be [used for any cancer, regardless of where it is in the body](#).

In some instances, the activity of new agents has been so profound that clinical investigators are having to rethink their criteria for implementation in patient care and their definitions of treatment response.

For example, although [HER2](#) has been a known therapeutic target in breast cancer for many decades, the new [antibody-drug conjugates](#) (ADCs) that target HER2 have proven to be vastly more effective than the original HER2-targeted therapies. This has forced researchers to rethink fundamental questions about how these ADCs are used in patient care: Can they be effective in people whose tumors [have lower expression of HER2 than we previously thought was needed](#)? And, if so, do we need to redefine how we classify HER2-positive cancer?

As more innovative therapies like ADCs hit the clinic at a far more rapid cadence than ever before, the research community is being inundated with such fundamentally important questions.

However, the remarkable progress we're experiencing with novel new therapies is tempered by a

critical bottleneck: the clinical research infrastructure can't be expected to keep pace in this new landscape.

Currently, many studies struggle to enroll enough participants. At the same time, there are patients who don't have ready access to studies from which they might benefit. Furthermore, ideas researchers have today for studies of innovative new interventions might not come to fruition for 2 or 3 years, or even longer—years that people with cancer don't have.

The key to overcoming this bottleneck is to invite innovation to help reshape our [clinical trials](#) infrastructure. And here's how we plan to accomplish that.

A transformation in cancer clinical research is already underway. That transformation has been led in part by the success of novel precision oncology approaches, such as those tested in the [NCI-MATCH trial](#).

This innovative study ushered in novel ways of recruiting participants and involving oncologists at centers big and small. And NCI-MATCH [has spawned several successor studies](#) that are incorporating and building on its innovations and achievements.

An innovation that emerged from the COVID pandemic was the increase of remote work, even in the clinical trials domain. Indeed, staffing shortages have caused participation in NCI-funded trials to decline. In response, NCI is piloting [a Virtual Clinical Trials Office](#) to offer remote support staff to participating study sites. This support staff includes research nurses, clinical research associates, and data specialists, all of whom will help NCI-Designated Cancer Centers and community practices engaged in clinical research activities.

Such technology-enabled services can allow us to reimagine how clinical trials are designed and run. This includes developing technologies and processes for remotely identifying clinical trial participants, shipping medications to participants at home, having [imaging](#) performed in the health care settings where our patients live, and empowering local physicians to participate in clinical trials.

We also need mechanisms to test and implement innovations in designing and conducting clinical studies.

The [Pragmatica-Lung Cancer Treatment Trial](#), an innovative phase 3 study launched by [NCI's National Clinical Trials Network \(NCTN\)](#), was designed to be easy to launch, enroll participants, and interpret its results.

NCI recently established [Clinical Trials Innovation Unit \(CTIU\)](#) to pressure test a variety of innovations. The CTIU, which includes leadership from FDA and NCTN, is already working on future innovations, including those that will streamline data collection and apply novel approaches to clinical studies, all with the goal of making them less burdensome to run and easier for patients to participate.

Data-Driven Solutions

The era of data-driven health care is here, providing still more opportunities to transform cancer clinical research.

The emergence of [artificial intelligence](#) (AI) solutions, large language models, and informatics brings real potential for wholesale changes in how we match patients to clinical studies, assess side effects, and monitor events like disease progression.

Recognizing this potential, NCI is offering funding opportunities and other resources that will fuel the development of AI tools for clinical research, allow us to carefully test their usefulness, and ultimately deploy them across the oncology community.

Creating Partnerships and Expanding Health Equity

To be sure, none of this will be, or can be, done by NCI alone. All these innovations require partnerships. We will increase our engagement with partners in the public- and private-sectors, including other government agencies and nonprofits.

That includes high-level engagement with the Office of the National Coordinator for Health Information Technology (ONC), with input from FDA, Centers for Medicare & Medicaid Services, and Centers for Disease Control and Prevention.

One example of such a partnership is the [USCDI+ Cancer program](#). Conducted under the auspices of the ONC, this program will further the aims of [the White House's reignited Cancer Moonshot](#) by encouraging the adoption and utilization of interoperable cancer health IT standards, providing resources to support cancer-specific use cases, and promoting alignment between federal partners.

And just as importantly, the new partnerships we create must include those with patients, advocates, and communities in ways we have never considered before.

A central feature of this community engagement must involve intentional efforts to expand health equity, to create study designs that are inclusive and culturally appropriate. Far too many marginalized communities and populations today are further harmed by studies that fail to provide findings that apply to their unique situations and needs.

Very importantly, the future will require educating our next generation of clinical investigators and empowering them with the tools that enable new ways of managing clinical studies. By supporting initiatives spearheaded by FDA and professional groups like the American Society of Clinical Oncology, NCI is making it easier for community oncologists to participate in clinical trials and helping clarify previously misunderstood regulatory requirements.

These efforts must also ensure that we have a clinical research workforce that is representative of the people it is intended to serve. Far too many structural barriers have prevented this from taking place in the past, and it's time for that to change.

Expanding our capacity doesn't mean doing more of the same, it means challenging ourselves to work differently. This will let us move forward to a new state, one in which clinical research is integrated in everyday practice. It is only with more strategic partnerships and increased inclusivity that we can open the doors to seeing clinical investigation in new ways, with new standards for success.

A Collaborative Effort

To make the kind of progress we all desire, we have to recognize that our clinical studies system needs to evolve.

There was a time when taking years to design, launch, and complete a clinical trial was acceptable. It isn't acceptable anymore. We are in an era where we have the tools and the research talent to make far more rapid progress than we have in the past.

And we can do that by engaging with many different communities and stakeholders in unique and dynamic ways—making them partners in our effort to end cancer as we know it.

Together, our task is to capitalize on this work so we can move faster and enable cutting-edge research that benefits as many people as possible.

We also know that there are more good ideas in this space, and part of this transformation includes grass roots efforts to drive systemic change. So, we encourage you to share your ideas on how we can transform clinical research. Because achieving this goal can't be done by any one group alone. We are all in this together.

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