

Remarks by

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“Further, Faster: Transforming Clinical Research”

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This text is the basis of Dr. Rathmell’s oral remarks. Use with the understanding that some material may have been added or omitted during final presentation.

Good morning! I’m thrilled to share the stage with Dr. Hudis, Dr. Schuchter, Dr. Carlson, and Dr. Verghese, for this opening session. Thank you for your excellent remarks.

What a great time of year! I always look forward to the ASCO annual meeting.

I’ve been attending ASCO for many years. I have grown up as an oncologist and a cancer researcher in ASCO, including as a graduate of the ASCO Leadership Development Program. And now I’m standing here as the 17th director of the National Cancer Institute...

(For the young people in the audience - pro tip, the ASCO leadership development program rocks!)

Quick show of hands: How many of you are oncologists, clinicians, or clinical staff? Scientists or researchers? In government or industry? Trainees? Patients or advocates? Did I miss anyone?

Great! I am hoping my message today resonates with all of you.

The NCI is an agency of the U.S. government, with a singular mission – to use scientific approaches to alleviate the burden of cancer. Our responsibility is to the public.

But it’s clear that we cannot do this alone; we’re all in it together, and that is what is great about coming together at ASCO.

Whatever your role or career stage, we’re all working toward the same vision: a future where cancer is a manageable disease, where we have effective treatments for every cancer, available to everyone, where most cancers can be prevented or detected early and readily treated, where all people know their personal risk for cancer, where high quality care is accessible everywhere, and ultimately, more people live longer, healthier lives.

When that describes everyone's experience of cancer, we will have ended cancer as we know it. We're not there yet. We're getting closer, but we're not as close as we'd like to be.

Of course, we've made significant progress in the past three decades, thanks to many of YOU here today. During this time, cancer mortality decreased by one-third, and we've seen breakthroughs like tumor-infiltrating lymphocytes for solid tumors and new targeted therapies, and countless more.

But I am impatient for faster progress. I'm sure we all are.

To make faster progress will require nothing short of a transformed clinical research enterprise. That's what I'll focus on today: the major problem we face in cancer clinical research, what it will take to solve it, and what the impact of our efforts will be.

First, the challenges. Think back to the last time you had to face a patient with cancer so advanced that the standard treatment would do more harm than good. Or when you knew a promising therapy was in the works, but your patient wasn't eligible for the trial. Or when you have wished you had better news for that family whose child had a rare tumor for which there isn't even a clinical trial. Or there is a trial but it's too far away.

Encounters like these push us to face hard questions: Are we fighting the most effective fight against cancer? Are we making progress for our patients as fast as we can? If we're being honest, as a field, we know we're not doing everything we can to move the needle further, faster. Let's be impatient for our patients.

Fortunately, the problem isn't a lack of ideas. The science is moving fast, and at NCI, we receive so many great research proposals that we can't fund all of them. There was a time where the clinical studies blew past the science, but in today's era, the pace of discovery science is incredibly fast, and getting faster, and we need a clinical research model that can keep up. Because we cannot be patient, when we have good science to move into the clinic.

So, we have a bottleneck. That is the problem. The solution is to transform the way we approach clinical studies. We have to make them more accessible, nimble, inclusive, and ensure that they're designed to answer the most pressing questions, rapidly, in the populations that need them. The good news is that our actions today determine the speed of progress toward the future. Every change today has compound effects tomorrow, turning small steps into giant leaps.

Think about a relay race and what it will take to shave down each leg a few tenths of a second, or even one or two seconds. Each person has to train a little harder, push a little further. When taken together, the whole team's effort will create significant change. If you look even closer, tight races are won or lost in the handoffs, from one leg to the next. In our work, that means looking at ways to accelerate translation, working together to master those handoffs.

I'll share an example. At NCI, we have a unit dedicated to pressure-testing novel approaches to clinical research to get ideas through the pipeline more quickly while ideas are fresh. Through this Clinical Trials Innovation Unit (CTIU), we launched a pragmatic lung cancer trial that is easy to open, easy to enroll, and easy to interpret. The innovation was testing the limits for speed. Accrual has been rapid, and uptake is brisk - a promising sign that we're on the right track.

And we're not doing this alone. The CTIU is a unique collaborative between NCI, the National Clinical Trials Network (NCTN), and the FDA, who is a KEY partner, as well as many others across the cancer clinical research community. That's what it will take to move our field forward, faster - joining forces and leveraging each other's contributions.

To deliver the future we want for our patients, we need to reimagine clinical research for the modern age. We can think about this in three major areas.

Capacity building today, to build our desired future, means ensuring that everyone working in cancer care is trained and empowered to deliver optimal care at the leading edge. It means that our workforce includes the best and brightest people who thrive on collaboration. We can capitalize on that spirit to build capacity where we need it most.

For example, NCI is pilot testing a Virtual Clinical Trials Office, to address staff shortages exacerbated by the pandemic. The office is a centralized team of remote support staff, including research nurses, clinical research associates, and data specialists. We're aiming to speed accrual to trials by boosting support to teams in community and remote settings.

In the modern era, equity and inclusion means clinical research staff are diverse in all respects and reflect the communities they serve. It means research participants mirror the true patient population. And anyone, anywhere can access high quality cancer care and clinical studies.

At the NCI, we've assembled a group of experts from across the country, charged with crafting new approaches to bring more leading-edge clinical research to community settings. The group includes partners across government, the private sector, as well as state, local, tribal, and not-for-profit organizations, including ASCO.

Finally, in data optimization, the opportunities are immense. We must work toward a future where data, and tools like AI, are leveraged to their fullest potential...where clinical research data are integrated with medical records, fully digitized, standardized, privacy protected, and accessible to patients.

Toward this end, we've joined our colleagues at the Advanced Research Projects Agency for Health (or ARPA-H) to develop an advanced toolbox, called the Data Fabric, that will accelerate data sharing & use, for patients, clinicians, and researchers.

We're also working with the Department of Energy to have the supercomputing power we need to maximize data utility, develop effective models, and capitalize on predictive analytics and digital simulation approaches.

I've mentioned many of our collaborators across all three principles.

We can't forget that people with cancer, their loved ones, and advocates must be true partners in clinical research.

As you can see, the principles I just laid out are aligned with the National Cancer Plan, a framework to guide change and accelerate progress. They're applicable to cancer research and care writ large.

Importantly, our efforts will set us up to deliver on the President and First Lady's Cancer Moonshot goals. We will be able to reduce cancer mortality by 50% by 2047 and improve the lives of those

living with cancer. We can make cancer a manageable disease. We can help people celebrate more graduations, holidays, and birthdays. We can reduce the fear associated with cancer. But it will take each of us doing our part.

We have a lot of good ideas, but we need your ideas. I urge you, individually, and within your institutions, to reflect on the three principles in your own work.

Scan the QR code here, and engage with us on social media, to share your ideas on what change you can make today, tomorrow, next week, next month... to move the needle for our patients further, faster. I look forward to your contributions.

To close, I want to share a story.

In the early 2000s, my patients with metastatic kidney cancer could only expect to live for a few more months. But when we tested the first targeted therapies (VEGF receptor tyrosine kinase inhibitors), we saw patients go on treatment and live an extra nine or ten months. And if we were lucky, in that time, the next drug would come along, buying them another several months. I felt a mix of hope, relief, and anticipation, like an exhale after holding your breath for too long... but knowing you'll have to hold it again.

I'm sure you know the feeling.

As I rode the waves with my patients, we'd hope for another wave to catch us, another therapy to try. And there was another, then another...And then, ultimately, no more waves. I was heartbroken... every time.

Many of them were in their midlife. If we'd had more treatments to offer, many of them would be alive today. Sitting here with us, at ASCO, celebrating advances.

We don't have time to wait. We have to be impatient for our patients. And that's why we come to ASCO. It's where we find hope. Now, we're not only buying time, riding waves from one option to the next. Now, we're working on opportunities for lasting cures.

The future is incredibly exciting, and it's our job at NCI to foster that enthusiasm to drive progress, through research, investigation, and creating the structures for everyone to be a part of the discovery process.

That ends cancer as we know it.

Thank you.