

# PRESIDENT'S CONVERSATION

October 21, 2020 | Transcript



**Tamsyn Theo** [00:00:24]

Welcome to today's event. Our presenters will be joining us shortly. Before we start, we have a few tips for using this video conferencing platform. You will have the opportunity to ask questions in the second half of the event. Please use the Q&A tab on the upper right-hand side of your screen to add your questions. We will answer as many as we can. If your Internet bandwidth isn't strong enough to stream the video, you can use low bandwidth mode. Note that you will still hear the audio, but you won't have video. To turn on closed captioning, click the settings button in the lower right corner of the web browser screen and toggle the closed captioning slider. If you're having technical difficulties, our support staff can help troubleshoot. Please email [events@fredhutch.org](mailto:events@fredhutch.org) or call 206-667-1119. Also, please know that this event is being recorded. We will share the link after the event. And with that, please enjoy today's program.

**Dr. Tom Lynch** [00:01:33]

Good afternoon and welcome, everyone. We have a terrific group today. We have 200 people on the call. Many local and national, longtime supporters and friends of the Fred Hutch. And for some of you, maybe the first time you're connecting with us, we have found these forums particularly during the pandemic to be wonderful opportunities to share some of the incredible science that's happening at the Fred Hutch and how we're responding to the COVID crisis at this point. And I really do look forward to spending the next hour together and sharing some of the very best that's happening here.

I'd like to start by sharing Fred Hutch's Land, Labor, and Justice acknowledgment, which recognizes the ingrained injustice that has shaped and can use to shape our culture and institutions. We acknowledge that we work and live in the traditional lands of the Duwamish, Tulalip, Muckleshoot, and Suquamish tribal nations. We thank the original caretakers of this land who are still here. We support the ongoing struggle for justice against racist, religious, sexist, xenophobic, ableist, trans-antagonistic and all oppressive violence. We recognize with gratitude those who sacrifice, struggle and labor to make our freedoms possible and challenge us to learn, work, and live justly.

And we read the land and justice acknowledgment before all group meetings and large group meetings at the Fred Hutch. And it's one of the reasons the pandemic has spotlighted all of us. How communities of color are disproportionately affected by disease. And this is not just COVID. It's also cancer. We know, and Nancy Davidson will be joining us today from breast cancer standpoint. We know that black women have almost a 40 percent higher risk of dying from breast cancer than white women. We know that in prostate cancer, it's similar for black men with far worse statistics in terms of prostate cancer survival. And here in Washington state, American Indians and Alaskan natives at the highest incidence of lung and colorectal, cancer, are most likely to die from these diseases. And I think our understanding of COVID-19 in conjunction with where we are in the Black Lives Matter movement and the social justice moment, it's pushed us harder to recognize these differences, not just in COVID, but also in cancer. We're very grateful that our supporters, partners, and patients, who benefit from our research understand, how important this is to achieve our mission.

Today's conversation is going to really be terrific and one that I think you're going to enjoy and going to really enjoy asking questions. Our topic today is navigating cancer and advancing cancer research during COVID. What impact as COVID had on cancer? That's what we're going to focus on today. I think the one thing we have learned very clearly is how important science is, how important generating ideas are at the Fred Hutch. True whether you're talking about COVID and the work of our VID staff or whether you're talking about cancer and everything that happens in our clinical research division, population sciences, human biology and basic sciences. Ideas become cures and cures start here. Really important part of what happens at the Fred Hutch. As many of you know, Fred Hutch researchers step forward as soon as COVID-19 arrived in the US, there have been major, major contributors in the effort to stop the pandemic. Trevor Bedford and his team at the Seattle Flu Study, as you know, the Seattle Flu Study is a great example of collaboration within Seattle, between the Brotman Baty Institute, University of Washington, Seattle Children's and the Fred Hutch all working together. And we know that the Seattle flu study has transitioned to the COVID study, and it's allowed Trevor and other molecular genomic epidemiologists to be able to characterize and understand the nature of our epidemic.

Also, earlier this month, month we launched the COVID-19 Clinical Research Center, which is one of the first facilities in the nation designed specifically to test novel interventions to treat and prevent COVID-19. And I think a really good example of why that resonated so much with me when Larry Corey first talked about it, I think about the work of Nancy Davidson, who we're going to hear about soon. Nancy's work that demonstrated, you know, being her2 breast cancer and advanced disease can have some benefit, significant benefit for women. But when you treat people with breast cancer, with her2 treatment early, you increase the cure rate. And the same concept might apply in viral diseases. We know, for example, that with Tamiflu, if you use Tamiflu early in the course of influenza, you get your greatest benefit. Maybe that's true with remdesivir as well, maybe that's true with the monoclonal antibodies as well. And yet, you can't study early disease in a hospital. It requires a special outpatient clinical research center to be able to do that. We're talk the people who were leading that effort and talk about how important that's become here at at the Hutch. So, as you know, ending cancer is our core mission. That's why people come to the Hutch as scientists and it's why we come to work every day. Fearless science that doesn't hesitate to ask important questions doesn't has to push us forward in this mission. And I think COVID has changed the way we work, it hasn't changed what our focus is as we move forward. And I think one of the things that makes me most happy with the opening of the Steam Plant, the example of that work, it just opened, I think we have a Steam Plant video to share with you today.

You know, when you look at that video and you see that building, you think about the people who actually built that building more than 100 years ago, what it was designed for was to produce steam that would drive the industrial engine of Seattle. And now it's become a very different facility, incredibly collaborative, a kind of place where team science is going to be able to really thrive. And what we've chosen is to have some of our most important science there. Science that focuses on the immune system. Science that focus on the creation of cellular therapies are in that in the Steam Plant. We're delighted that the facility is now up and running.

So today we're going to have three of my colleagues who are going to join us and talk about a subject. We're going to look at the effect that COVID-19 has had on cancer patients. We're going to look at how we've adapted care at the Seattle Cancer Alliance and here at the Fred Hutch, and we're going to talk about the impact of research, clinical trials and our mission to develop new treatments. So I'd like to begin our discussion by introducing Dr. Nancy Davidson. Nancy holds

leadership positions at the Fred Hutch, the Seattle Cancer Care Alliance and the University of Washington. As everyone knows, she's the President Executive Director of the Seattle Cancer Care Alliance, and she runs our clinical research division here at the Fred Hutch. Nancy's also extremely well known as a world renowned breast cancer researcher and has accomplished remarkable things in her career, being one of only two women to be the president of the American Association for Cancer Research and the American Society of Clinical Oncology. And Nancy, I think we want to talk a little bit today about what's happening at the Seattle Cancer Care Alliance in terms of clinical care and how COVID has impacted this. I want to just start off by commenting how remarkable it seems that your team has done in terms of patient safety. So before we talk about the actual disease, tell us a little bit about what you're doing to make the Seattle cancer Care Alliance safe during this time and make our patients feel comfortable with care at that point.

**Dr. Nancy Davidson** [00:10:34]

Tom, from the very beginning, we knew that cancer wasn't going to stop. And so we had to continue our cancer care and our cancer research in a time of COVID. So we've taken all the steps that all of us are taking, physical distancing, handwashing, masks, all the things that we should do in our everyday life. We absolutely do in the context of the Seattle Cancer Care Alliance. We worked very hard at the very beginning to think about when patients need to come in and to minimize the time that they have to come in. We worked pretty hard to think about how we can use telehealth, where appropriate, to make sure that individuals can get some of their care at home so they don't even have to come in to see us. So and then, of course, we've all had the access to rapid testing, which we do as a matter of routine. If somebody has to have a procedure, for example, and of course, we're very careful to test people at that even have the least hint of symptoms so that we can make sure that we're able to optimize their health, protect them and their family, and protect our staff.

**Dr. Tom Lynch** [00:11:31]

And I think the question I would say is, how do you think COVID-19 has impacted the lives of cancer patients? We already know that cancer itself is an extraordinary event in the life of any person. How is it, what has it been like for patients during this time?

**Dr. Nancy Davidson** [00:11:48]

It's hard to imagine a worse combination than getting a cancer diagnosis, taking cancer therapy, and then doing this in a time of COVID. But people are so resilient. Tom. And I've been so impressed by how many patients have just rolled with it. In a weird way sometimes for patients, you know, you don't have much of a social life. You don't go out very much anyway right now. And so it's an easier time if you're really involved with your cancer care. You have to stay at home and to do your regular activities in a home setting. But I wouldn't underestimate how difficult it's been. I do think, though, that cancer patients and cancer providers are always very focused on safety measures anyway. And what's good for us is that everybody's focusing on it now. And so we're all helping to keep our cancer patients safer.

**Dr. Tom Lynch** [00:12:35]

And Nancy, you know, our colleague Ned Sharpless, who runs the National Cancer Institute, Ned authored an article, which talked about how some of the impact of COVID on outcome from cancer patients is that we may see more cancer death as a result of mis-screenings. And you're an expert in breast cancer and have commented frequently on how early detection is made a difference in the outcomes that we see from breast cancer. Are you worried about women missing

mammograms? Remind everyone this is Breast Cancer Awareness Month. Does that factor into your thinking about where we stand and early detection?

**Dr. Nancy Davidson** [00:13:12]

I couldn't agree with you more. I think that Dr. Sharpless pointed out to us that modeling in our experience so far suggests that up to 10000 more people will die from breast and colon cancer over the next decade, because of our lapse in screening or less screening during this COVID time. You know, we took a little break from screening right at the very beginning of the COVID pandemic, because we didn't know everything that we know now. And also, we want to be in a position where we could retain our protective equipment, which was in short supply at that point. But, you know, screening is open. We encourage people to come in for their regular screening. Very, very safe in our facilities. And so I think people shouldn't miss a beat about making sure that they do all of the age appropriate screening for cancer that they would be eligible for. We are open for business.

**Dr. Tom Lynch** [00:14:02]

Perfect. And, Nancy, I know that when you come to the campus of the Hutch, and not see that remarkable construction project, which is ongoing right next to the SCCA building, can you tell us a little about that, because I know you're incredibly proud of that.

**Dr. Nancy Davidson** [00:14:17]

Yeah, actually we're proud of two things that happened despite the pandemic, Tom. First within the existing building of the Seattle Cancer Care Alliance, we completed a renovation of our seventh floor into a new care model where basically patients go to their patient care room and everything comes to them. The blood drawer comes to you, the scheduler comes to you, your infusion comes to you, your doctor comes to you, your nurse comes to you all in one space so that you don't have to walk around our building. Everybody comes to you. Yeah, we organize that, Tom because, of course, we thought at the time that would be more patient centric. But it turns out we were maybe a little visionary. And it turns out to be very good mylo care at a time of a pandemic, because it allows patients to be a little bit more of a protective bubble while they're in our facility. So that went live in June. This is where our gastroenterology medical oncologists centralized their practice right now as we try out this new model. And you're right, we had a virtual groundbreaking in the summertime for the expansion for the Seattle Cancer Care Alliance. It's going to be right next door to our existing building. I look at it a couple times a week. I go up and look at how they're moving the earth around. And we're incredibly excited that this new expansion will be online and the early part of 2023. For those who come into the campus for any reason, I hope you'll look at our construction site. And for those who are staying away, I hope you'll be with us in a year or two when we have more to show.

**Dr. Tom Lynch** [00:15:40]

And Nancy, it's it really is remarkable what they've done just in a few months. They're making great progress there. So it's really terrific. So thank you so much. Look forward to hearing from you in a little bit. Next, I'd like to introduce John Lee. John's a clinician researcher studying prostate and bladder cancers. He's an assistant professor in the human biology division at the Fred Hutch and he sees his patients at the Seattle Cancer Care Alliance. We know that the diseases that John treats are are tough diseases. They require a great understanding of the biology of both the prostate and bladder tumors themselves. And John is using pioneering big data approaches to find surface proteins on the surface of prostate and bladder cancer cells that could be targeted with immunotherapy. And part of the Hutch efforts, one of things we're really working on is trying to

make immune therapies work better in patients with solid cancers. Immune therapies have been remarkably effective for patients, who have patients with leukemia lymphoma and some great successes in melanoma, real cell, and some lung cancer and some in bladder cancer, So I guess it start off with with John, your bladder and prostate or very different diseases. When you think about them and their ability to be treated with immune therapies, what excites you and makes you think that there's opportunities there for four novel approaches?

**Dr. John Lee** [00:17:10]

And I think that there's a lot to be excited about in the treatment of prostate and bladder cancer. Tell you a little anecdote that when I was a medical student, a senior physician once told me that specializing in this area as a physician scientist would be career suicide. So I can tell you now that things have changed quite a bit in the last 15 to 20 years, and that's related to efforts really led by investigators here at the Hutch. But it was advanced and established new standards of care for treatment of patients with advanced prostate bladder cancer. I'll give you two examples. For instance, my colleague recently led a study looking at maintenance immunotherapy in patients who responded their first line treatment for advanced bladder cancer. This has recently become standard of care and is really a good option that extends life. Quality of life patients, who have otherwise sort of waited around until their statue of progression of their action go on. We'll give you a second example, which is the work of Keith Nelson and others in the Prostate Cancer Research Program, who've been involved in multi-institutional efforts to characterize alteration DNA that define different subsets of advanced prostate cancer and a really important work driven by this group identified DNA repair defects, prostate cancer that due to the recent approval of new drugs for men with prostate cancer that happens. I'm also excited about many areas of science that are advancing for both of these diseases related to next generation imaging. And certainly, as you mentioned, the development of new immunotherapies, which my lab focuses on, is really unleash the cancer central of the human system.

**Dr. Tom Lynch** [00:18:55]

And John, as COVID impacted your lab, I'll give you a sense of how your lab is functioning during COVID. And what do you think, have you missed a beat or not? Where do things stand with your lab effort is as impacted by the pandemic?

**Dr. John Lee** [00:19:11]

So I started my lab here at the Hutch in early 2018. It just really started to hit our stride when labs ramp down due to the COVID pandemic in March of this year. And as you can imagine, as a early career investigator, this was especially daunting. I will have to say that, you know, that leadership at the Hutch was extremely supportive and really focused on putting the safety of the staff first and then the subsequent safety precautions and phased approach to really getting us back into the labs was very thoughtful and very suited. In all, I'd say the ramp down delayed many of our projects by somewhere between three to six months. But I can say that we're now back to Prepandemic levels of productivity and the Hutch in funding organizations have been especially mindful of this impact and the impact it's had on cancer research overall. They've really provided a lot of leeway for investigators like us. You know, the future is still uncertain. There is a lot of anxiety associated with a potential third wave of COVID. And many charitable foundations are not as financially sound as they were prior to all of this happening. So you know, we do fear that there may be long-term effects on cancer research funding.

**Dr. Tom Lynch** [00:20:22]

Yeah. And I guess one other question for you in prostate cancer. We talked at the very beginning of this presentation about the different outcome between African-American men and Caucasian men in prostate cancer. Where do we stand in understanding that disparity in prostate cancer? Prostate cancer screening and treatment, and has COVID impacted any of that or any other things that make you worried that there could be a disproportionate impact in cancer outcomes in that setting?

**Dr. John Lee** [00:20:53]

Absolutely. You know, I want to acknowledge that as you have, that black Americans are disproportionately affected by the pandemic, and many have held a long round of skepticism, negative attitude about the medical establishment. And I think this is certainly well grounded because of sort of historic, well-documented missteps. You know, this is in the setting a recent work that really indicates that men have access to state of the art standard of care prostate cancer will actually do as well, if not better than their white counterparts. So I do have a fear that this pandemic will reduce the fire of black Americans with prostate cancer this year and that they may be at the greatest risk of delay cancer diagnoses as well as treatment in this area.

**Dr. Tom Lynch** [00:21:46]

So, John, thank you very much. We're going to bring you back in just a few minutes to answer some more questions. Really appreciate it. Now we'd like to introduce Kristi Stiffer. Kristi is an associate vice president for clinical research support at the Fred Hutch, who also coordinates clinical trials at the SCCA. She's someone who is, as you could imagine, indispensable across our institutions. Also provides operational support for the Hutch as COVID-19 Clinical Research Center, which we talked about earlier. And she's also very important in making sure that our clinical trials meet the requirements of national cancer institute and all the other regulatory agencies that look at us. So, Kristi, welcome. It's really fantastic to have you with us today. So the first question I'm going to ask you is, how was COVID-19 impacted our ability to do clinical trials at the Hutch and the SCCA? What did we do? I know you and Fred had an incredibly important role in making decisions about what trials we could safely do. Tell us a little bit about what happened in the in the spring and where we are today.

**Kristi Stiffer** [00:22:57]

Yeah, thanks. Thanks, Tom. It's been an interesting journey, just to say the least. Just to give folks an understanding of some of the volumes that we're talking about when we're looking at our oncology clinical trials in of themselves. In a year, we have about 500 active treatment trials that are open to accrual. And we grew about twelve hundred patients on those trials. And so as the pandemic became clearer, the situation we were dealing with, we had to make really quick, tough decisions about how we would manage our clinical trials and our patients that were either on clinical trials or a lot of times their only treatment options are to enroll in a clinical trial and thinking about the risk versus benefits in a very different environment. And so what we first really looked at the phase of trials and so early phase trials by design are really looking at safety and they're looking at dosing, for example, not even looking at efficacy. And some of our later phase trials are the randomized trials where we're providing an investigational product and some patients are randomized to receive standard of care. So in those cases, we said if there's not a demonstrable clinical benefit to patients, then those are not the trials that we should be enrolling to right now. If there's a there's a treatment option that we can provide patient that's what we should be doing. So that was really the big picture approach when we first started looking at and assessing trials and enrollments. And then we really had to take a look at some of the individual trials to say whether some of the interventions were likely to lead to inpatient visits for four

patients that otherwise may not go inpatient or ICU visits, because we were working with our hospital partners, who had very stressed system from the PPE supplies to just staffing levels in the hospital. And so we couldn't continue to stress those if we had alternatives to offer patients in that case. And then we also had to think about a lot of our patients are immunocompromised. A lot of them travel all over the country and from other parts of the world. And to consider that on a case by case basis of whether that increased risk of bringing someone here to enroll in one of these trials was worth the potential clinical benefit of some of these interventional treatments. So that's really where we started are our assessment. And we had an amazing team of our faculty leaders and representatives from SCCA and from our hospital. We had an infectious disease faculty who are providing us daily input on where we stood with our census in the hospital. What infection rates were looking like, and what our capacity was to really bring additional participants that potentially need additional care when they're going on these trials. Then what really was the responsible decision to make across trials and within individual patient scenarios?

**Dr. Tom Lynch** [00:26:08]

And patients obviously come to the Fred Hutch for clinical trials. If a patient came now, would they have the full range of clinical trials available to them?

**Kristi Stiffler** [00:26:18]

Yes. So we did ramp down to about 50 percent of our clinical trial accruals and end trials that were enrolling participants, and I'm happy to say that we are back to pre COVID numbers, both in accruals and number of trials available to participants. We actually started ramping back up in early May, which I think is just a testament to the passion and the dedication of all parts of our our environment and our institutions and in keeping people safe and also prioritizing, providing treatments, and doing our research. So, yeah, we are we're back to full capacity.

**Dr. Tom Lynch** [00:27:01]

And Kristie, one of the things I am most excited about is the new COVID Clinical Research Center. I had a chance to tour facility. It's really a beautiful building in that it's a great example of how you can repurpose something to make it work. So what we did that was a facility that was being used for punker research space and also some development office space for the Obliteride bike ride. And it was repurposed and several different clinical areas were built out, as well as areas to be able to protect staff and visitors, patients who are coming in, participants in trials. The great thing is you can drive right in. There's a parking lot right there at the facility and all staying in within the same facility, walk right in without having to go outside. So it's got very nice access for patients. I think one of the other key things is we really couldn't have COVID patients going to the SCCA to participate in clinical trials there, because of the concern of putting other patients at the SCCA at risk. It became a wonderful opportunity to do that. So tell us a little bit about the work of clinical trials, because we know, you know, whether you're a fan of President Trump or not a fan of President Trump. I don't think we should get into politics on a on a call today. But I do want to say that many of us are hopeful that one of the reasons he may have done well with COVID, it was the combination of Remdesivir, monoclonal antibodies and steroids. And the fact that he got those drugs and he got them fairly early in his course, certainly could be consistent with him having more effect on him early. Obviously doesn't prove anything, it's a case report. And so we need more data. And that's why this facility is so critical, is to find that out. So what drugs are we testing so far? And the facility has only been open for a couple of days. How it been going? How are the trials going so far?

**Kristi Stiffler** [00:28:56]

Yes, it's been really exciting to be involved with that. And also watch how a lot of our expertise that's allowed us to be successful in oncology and in our vaccine development and infectious disease work have been able to come together to really make this facility happen, to treat COVID infection early on in the infection, like you said, to bring people in before they're outpatient and try to get ahead of the infection. And so we do have trials activated and enrolling. One of the trials that we have open to enrollment is the Regeneron trial, which is one of the drugs, the monoclonal antibody cocktail that the president received. And so we are rolling on that trial. He also received Remdesivir, which has been primarily researched in the inpatient setting and is now moving into the outpatient trials, which will be enrolling for within the next week we expect. There currently isn't a trial that is combining those therapies. So I think it's important to note that he received those products as part of what's known as a compassionate use application with the FDA, which is something that has existed and we actually rely on for some of our patients at times. But currently the trials are investigating those agents independently.

**Dr. Tom Lynch** [00:30:19]

And there's a lot of there's a lot of paperwork and most compassionate use uses, isn't there?

**Kristi Stiffler** [00:30:24]

There is. You know about the way the FDA is set up, that mechanism is really trying to reduce the paperwork, and the turnaround time from it starts with, first, a physician who is willing and believes that there is an investigational product that is the best answer or prospect for a patient to receive. And they need evidence of that. And then the next step is to go to the actual sponsor or the manufacturer of that product to say, OK, I have this patient. And I think that they'd benefit from this product, may we have some supply of a product to get this patient off label. And then the next step is to go to the FDA. And in reality, we can get that turned around within days, actually, because a lot of times, you know, these are treating patients who are really ill and have no other treatment option. So there is a really short turnaround time for that process. Again it's a case by case basis. And it requires people dedicated to getting that patient, that treatment.

[00:31:27]

And I know it's something really important that we do offer to patients in these circumstances. I'm just going to guess that my suspicion is that the president didn't have a lot of trouble with the paperwork or getting the necessary approvals. But we'll let we'll let that be figured out by other people down the road. I'd like to invite back Nancy Davidson and John Lee. We've got a ton of great questions. And folks, the question line is open. Please feel free to ask questions. We both have questions have been submitted by some of you in advance. And we also some questions that are coming in as the as the call has gone on and we'll try to answer has made them as again, if we can't answer all the questions, your individual question, we'll get answered and you'll get answers to your questions. We have people who are posting some of the some links to some of the topics we've been talking about. So please open up the Q&A part of the of the call so that you can see the discussion that's going on there. So I guess the question I'll ask overall, what are some of the positive outcomes of what we've done and some of the changes? I read a fascinating article this morning by Tom Friedman in The New York Times and editorial where he talked about what life might be like post pandemic and how we might change both in terms of our educational systems and our work life. How do you think our work life will change post pandemic? And we'll start with that with Nancy. What do you think, Nancy? Where is it going to be like in in three years or two years?

**Dr. Nancy Davidson** [00:33:01]

All of our lives, Tom? Or just medical and research life...

**Dr. Tom Lynch** [00:33:07]

Nancy, go wherever you want with that because I bet the people called would like any of your help.

**Dr. Nancy Davidson** [00:33:13]

Yeah, I'm going to start with medical care and I'm going to say that I hope the key elements are going to be unchanged, which is, you know, being patient centered and trying to figure out what's best for the patient and what we can take from what we've learned to make that even better. I hope what we're going to see is real, real careful attention to when patients can be cared for in their home, and whether there are other ways that we can do that. And when they actually have to be having into our facilities for us tonight colleges, so much of what we do is interventional, right? We do tests. We do imaging. We give treatments. And so a lot of that probably will require that you be in the office, per say. But there might be other things that we can do for our patients, for example, routine follow up. I hope we're going to see a lot of that. I hope we get to see telehealth really be crystalize as a regular part of medical care for everything, including cancer care. For me as a researcher, I hope that people like John, are going to continue to be enabled in the lab. I think that's still going to be an issue in lab kind of experiences I'm sure he'll talk about. I do wonder for us as a society how much will travel? You know, Tom, I, and you, I suspected John spent a lot of time on the road going to various scientific and medical meetings. And I haven't gone out of town for a medical meeting since February 20 something. I've been here the whole time. I sure miss my colleagues. I miss informal interactions that we have, I miss some of the really deep interactions. We've been able to accomplish a lot of our work remotely. And so I hope we're going to figure out how to right-size that as well. When do you really need to get on a plane and go somewhere and do it face to face? And when can we actually do things in this virtual world? And can we learn how to use it the most effectively?

**Dr. Tom Lynch** [00:35:02]

Very good point. And John, I'm going to ask you a similar question. I'm going to throw a little curveball because one of our participants, a gentleman named Casey King. I'm wondering if it's the case king that I know from from New Haven, Connecticut. But Casey King has asked and said that mixed reality applications like the Microsoft HoloLens, just a possible technologic solution for cancer research in the era of COVID. Tell us a little sense of how technology might be involved and whether something like the whole application might have some benefit. John, what do you think?

**Dr. John Lee** [00:35:40]

I completely agree with Nancy. I think that developing new technologies in which we can connect to virtually will be really key moving forward. I spent countless hours on planes and airports traveling for grant review panels, for scientific meetings, obviously enjoying the companionship of peers in the research field. But I think, you know, for safety's sake and for practicality, I think we can accomplish a lot just via virtual meetings. We do miss something that we don't get with in person meetings. Perhaps some of these virtual reality or HoloLens types of technologies to bring some of that back work. These are brands that we are in company and not physically distant says we are now with many of our colleagues.

**Dr. Tom Lynch** [00:36:30]

And, Kristi, you actually have thousands of people, maybe not thousands, certainly hundreds of people who are working in clinical research across the University of Washington, Seattle Cancer

Care Alliance, Seattle children's, Fred Hutch. How have you seen the ability coordinate all that work change during the pandemic? What lessons do you think you've learned to make us a better place in terms of regulatory and compliance and protocol adherence as we move forward?

**Kristi Stiffler** [00:37:02]

Yeah, that's an interesting question. You know, early on in the pandemic, we started having daily calls with research managers across four institutions we work across on a daily basis in our clinical research. And to have all of those representatives from our different research groups come together on a daily basis and hear what each other was dealing with some of the challenges because of COVID, but also just some of the other challenges that they'd be facing anyway. And to see how quickly we could resolve some of these issues by having those types of relationships and ongoing conversations. It was it was pretty remarkable. And so that's one thing that we've carried forward. You know, as things have become more stable and we've learned how to work in our new normal is having more frequent teleconferences across the organizations. Instead of folks feeling like they needed to trek across areas of Seattle or campus to get somewhere for people to be calling in is really increased from the communications and links between our teams, which I think has been really beneficial. We've also been able to work across teams and in ways to limit exposure of additional staff to the clinic as well. And so we've had teams coordinate. If we know that we have files across three of our groups that are requiring some research staff to go to the clinic on that day instead of sending three separate people from those teams. We can organize to have one person do whatever those tasks are in the clinic to reduce the exposure for everybody. And it's been one of the really, really great results of working in this way.

**Dr. Tom Lynch** [00:38:55]

That's great. And so, Nancy and John, with you on here, I think it'll be hard for us not to answer some of these questions that have come in, because given your expertise and given the impact of prostate and breast cancer have on so many patients and so many family members, and I suspect we probably have several survivors of breast cancer or prostate cancer on the line with us today. And so, Nancy, one of the questions we've gotten for you specifically is metastatic breast cancer, what are you most excited about right now? What's the one thing that's happening in metastatic breast cancer that you say, gosh, that's going to really have an impact?

**Dr. Nancy Davidson** [00:39:34]

I don't think you can ask me to pick among all my children. I think there are a couple of things I'd like to bring to everybody's attention. One is that the field of her2 metastatic breast cancer has continued to explode. You know, this is the place where her septum was the first treatment. We've now got a half dozen treatments that target her2 Gene in one way or another, in which we can now bring to bear in the setting of advanced breast cancer. And we're beginning to test them more and more in early stage breast cancer. In the field of triple negative breast cancer, that's the ones that don't have the estrogen receptor. They don't have the progesterone receptor. They don't have the her2 protein. So where our fallback has been to chemotherapy, we now have the opportunity to use the first at the checkpoint inhibitors. You know, those immune therapies are used for so many diseases down in which had not been very effective in breast cancer. It looks like they actually could be used to good effect with a certain chemotherapy for advanced triple negative breast cancers. We also have our first targeted agents or other agents for a triple negative breast cancer specifically. I'm really excited about that. In our research area, Tom, we're busy doing CAR-T cell trials for certain kinds of advanced breast cancer, trying to bring the technology and the thought process that have been developed here and blood cancers and figure out whether we can bring it to bear into a certain subset of breast cancers. And finally, in the

estrogen receptor, positive breast cancers, we shouldn't forget the big impact that the drug is called the CDK4/6 inhibitors have had in the last couple of years where we pair them with hormone treatments. So I think my point would be the breast cancer is actually a lot of different diseases and that we're making headway in each of these subsets of breast cancer in advanced breast cancer with new agents to combine with our old agents. And we're now able to think about how we can bring them in certain circumstances to try to treat earlier breast cancer, like you talked about earlier. You know, where you take something that works in the advanced setting, whether it's an infection or cancer. And then you think about applying it earlier in the disease spectrum in the hopes that you can head off more serious complications.

**Dr. Tom Lynch** [00:41:46]

Nancy, thank you, John. You and I are both vulnerable to having to take boards in oncology every certain number of years. And when Nancy just told us will be our board refresher course for the breast cancer section of the board. So we can stay on top of that. John, perhaps you can answer the same question in bladder cancer. excuse me prostate cancer, which we talked about it earlier. In prostate cancer, what's the one treatment for men with advanced prostate cancer that you're most excited about?

**Dr. John Lee** [00:42:17]

I would say right now, the one treatment that I'm most excited about is actually a radio lightening therapy. And so what that is, is it's essentially a little chemical molecule that's very specific for a protein that's expressed on the surface of prostate cancer cells, and that's linked to a radioactive molecule. And so we can actually introduce these into patients, who really owns to the prostate cancer directly and that radioactive molecule event and damage to prostate cancer cells and kill them. And so this sort of technology targeting a protein called. Yes M.A or prostate specific antigen, it's already been tested in Germany in hundreds of patients and patients with advanced prostate cancer it's been shown to reduce PSA levels are prostate specific antigen levels or a marker that we use to follow the activity of prostate cancer. There have also been responses where tumors can live longer and just because of the trial structure, that's different in the US versus Germany. I'm asked to go through multiple steps now, but this is in fact advancing in trials and states and we're hopeful that this is one of the standard of care treatments for advanced prostate cancer.

**Dr. Tom Lynch** [00:43:33]

Which is which is terrific. Kristi, I guess a question I would ask you is, as someone who's involved in thinking about clinical trials. Nancy and John and I get a lot of emails from patients and family and friends, who want to know about clinical trials that might be available given disease. What do you think the best suggestion you would have for friends or patients that contact you? How should people learn about clinical trials that could be available at the Fred Hutch or other cancer centers around the country?

**Kristi Stiffler** [00:44:05]

That's a great question that we have so much information available to us and sometimes that can be a little over what overwhelming. I would start, of course, with the Fred Hutch and SCCA websites to look at the trials that we offer, because I think we're obviously a world renowned cancer center, and if you're lucky enough to live in this area, that to me seems the natural place to start. If someone's looking across all types of trials and not necessarily focused on cancer or even in this region, you know, our government has put a lot of focus on developing COVIDtrails.gov, which is the national Website and database that has all of our all of our trials conducted across the

country and as well as result reporting for a lot of those trials. And there's just been a big push to have that transparency across all the different types of trials that are being conducted. And that would be another place I'd recommend people go to get that information, which is really important.

**Dr. Tom Lynch** [00:45:11]

So thank you. Thank you for that. Next, I have a question that has come in, I think would be good for Nancy. Perhaps John, you might have a perspective or Kristi as well on that question is, you know, we've had this focus on COVID, has it detracted from some of our cancer abilities? And specifically, the question is, what about rare cancer? Meaning and it sounds like the person who asked the question is concerned about sarcomas and research and sarcomas. So the question would be, has COVID made it harder to do cancer research and particularly rare diseases like COVID, I mean like sarcoma. How do we see any potential opportunities for sarcomas down the road? Nancy, you and John, if you have some thoughts on that.

**Dr. Nancy Davidson** [00:46:08]

We have a really terrific sarcoma program here at Fred Hutch UW. You know, as you point out, it is a rare group of diseases or a lot of different kinds of sarcomas, as we were talking about earlier. I think the clinical trial group has not missed a beat. All the things that Kristi said that were relevant to our entire clinical research portfolio, that kind of brief pause and now the ramp up, has continue to be true across all diseases, including our sarcoma team. And I would point out that our shared combat team actually just completed and reported a really nice early phase trial from our center that looked at individuals with a advanced sarcomas of all types and treated them with an old drug, doxorubicin, a chemotherapy drug, but combined with one at the new checkpoint and they just published this a couple of weeks ago. What they showed with this combination was safe and that it was effective in some patients and they were able to do the kind of correlatives science that we'd like to see, where they're trying to figure out who's who in this patient population. And I think they've come away with the sense that there might be certain subtypes of sarcoma or this combination might be able to be tested more appropriately in the future. So I would put that out as a snapshot, Tom, for health research is that it's not going away because cancer is not going away as fast as we would like. And our disease groups, whether they're studying a common disease or whether they're studying rare diseases, they really aren't missing an opportunity. They are thinking about how they're going to move their science and their research forward every single day. And we're making sure that we can keep it safe for our patients to be with us, learn to take advantage of that research if they're so inclined.

**Dr. Tom Lynch** [00:47:48]

That's that's fantastic. And John, along those same lines, there are rare subtypes of prostate cancer, for example. Do we have research in those rare subtypes and patients who may have, let's say, a neuroendocrine phenotype of their prostate cancer or another type of unusual genetics, their prostate cancer? What are the options for patients in that setting?

**Dr. John Lee** [00:48:10]

So many variants of prostate cancer are near and dear to my heart. That's something that I study for several years as a postdoctoral fellow and continue to study. Hutch is really about the way in defining these different rare variants of prostate cancer, It's really related to research studies in which patients have really contributed tissues for analysis. And so we've been able to do genetic analysis, proteomic analysis to really establish what are the differences between these different types of cancers. And we are, in fact, making headway in determining new types of target

treatments that may be effective and effective in one sector of the prostate cancer or another. We are trying to get trials up and running to really serve these populations that otherwise don't have any effective options.

**Dr. Tom Lynch** [00:49:03]

Right. And I think that's an important, important point to mention the importance of having clinical trials, even for rare diseases. And Kristi, you deal with an element of this, which is, you know, the National Cancer Institute looks at us and they don't like it when we have trials that are open that don't accrue, even if they're for rare disease. So if you take a rare cancer, some of the pediatric tumors, for example, which don't fortunately don't happen very frequently, or some of the rare subtypes that John was talking about and some of the other rare subtypes. How do you handle that as someone running the clinical research process? You know, there are some subtypes where you could open trials for patients we might only see one or two a year. For those one or two patients, it could be incredibly important. How do you handle that from your perspective?

**Kristi Stiffler** [00:49:53]

Yeah, it's challenging, and you always want to balance the efficiencies in resources and operations against the impact you can have with those one or two patients in a rare disease. And so ideally from my perspective, I'm looking at the resource say how are we best using these resources? And it said in rare diseases, it's not just about the numbers. And so those have to be considered with different criteria than are our trials that are for rare diseases so that we aren't we aren't overlooking those opportunities to make that impact. And so we actually have provisions in policies that are exceptions to some of those rare diseases and those trials that are targeting specific molecular subtypes of tumors and things like that. And so that we again, we're not excluding our ability to make impact in some of those trials where we know the enrollments will be lower. And so we have to balance that with some of the trials that that have larger enrollment numbers. But it's definitely a balance. And we ensure that we have resources and space for all of it. That's critical to our mission.

**Dr. Nancy Davidson** [00:51:14]

May I interrupt? Just to follow up on something Kristi said? Because, you know, I think lots of cancers are rare diseases right now. And one of my favorite examples is a kind of rare molecular change called the track fusions, which some cancers have. Turns out these things could take place in a lot of different kinds of cancers and in kid cancers and in adult cancers. And so one of my very favorite papers last year actually was a report of testing a particular drug for this called Laratrectnib for these track fusion cancers. So first they had to figure out who the patients were. We participated in it. And it turned out if you really identified those patients, that this inhibitor, this track fusion drug was very, very, very good. And so here, because of people like Kristi, who allowed us to open this very rare trial, we had the ability to have our pediatric oncologist, our adult oncologists and our pathologist be involved in this trial, which demonstrated the efficacy of this drug. The youngest patient was four months old, treated here in Seattle at our children's hospital up into adults with all cancer types. If they had this transfusion, they did extremely well with this drug. And this trial, which you allowed us to help open, here is the one that led to the approval of this drug by the FDA. So these are such important trials because they can make a difference in establishing a drug that's important for a rare, but important subset of patients.

**Dr. Tom Lynch** [00:52:42]

And that's incredible, I mean, it's a really remarkable example of that and a really good example to point out about how we can all work together in that respect when questions come in, which I'll

take and not that I have the answer to. But the question is, when will we have a COVID vaccine? So I'll give my stab at trying to come up with this.

As you know, we will have some data, which we expect by the end of this year on the first interim data should be available toward the end of this year, probably on the Moderna and Kaiser products, which are the mRNA vaccines. And I read yesterday that the Moderna product would have its first interim analysis once fifty-three events have happened. And now what we don't know is, are those events in the treatment arm or those events in the people who received the placebo? So is it the treatment arm or the placebo arm, that makes a big difference and how those adventures are or are seen in those two arms will make an enormous difference overall. Now, that early analysis might show something dramatic. So if there's fifty three events and forty nine of them happened and people who got placebo in three happened and people, who had the vaccine, I think that's a pretty good sign that you're going to see it pretty early emergency authorization or approval once some safety information is available. So it's not like the data will come out in late November and the drugs available for people to get at CVS in mid-December.

They've got to also make sure, there's two elements on vaccines. There's the efficacy and then there's the safety. And then they've got to look at the safety to make sure that's the case. So that's why my gut would say that, that even if the data is dramatic, we're probably talking the early part of next year for when it will be available for people. The reality is, is as John and Nancy and Kristi know very well, usually it's not forty-nine and three. Usually it's something that's slightly less clear than that. And it might be that they have to wait till the next analysis when there's more events to get a sense of the difference between the two groups. And so that's something will be very important. And there's statisticians who look at this really carefully and there's an FDA advisory committee that will also look at this. And we're delighted that one of the Hutch, his own is a member, that FDA advisory committee, Dr. Steve Pergam. And he'll be part of that committee that will look at this data and get a sense of what's happening in the vaccine world. In fact, the person, the FDA who is responsible for vaccines, Dr. Peter Marks, will be the guest speaker at our faculty retreat, which is happening next week. So our faculty members will have a chance to talk to Dr. Marks. I'm not sure he'll be able to say much about this. I suspect that will be considered highly confidential, but we'll certainly have the chance to ask him about this. So I would say that we'll get our you know, the publicly available information is we'll get some early looks we'll be in November, December-ish. We're probably talking about a vaccine becoming available, hopefully early to mid-part of twenty-one. Assuming that things go well.

What I just saw right before this call was that the state of Washington has come up with this initial plan for how, whenever that vaccine is will be distributed. And they've been very careful to say that they'll be making strong efforts to make sure that vulnerable populations, both in terms of people who might be at increased risk for getting the disease as well as complications of the disease will be prioritized and that they will work hard to make sure that the vaccine is distributed in an equitable fashion. And so, again, it depends what the what the vaccine is, what the characteristics of the vaccine are. Is there any way to know which populations might benefit more from the vaccine? That's another question we have to ask. What about children? What about what about patients with other comorbidities? Do they do better with one vaccine or another? So that's for thought on the vaccine. I don't think, I don't think it's possible to really be more precise than that at this point as we look at that. And so the last question which just came in, I will send to Nancy, which is kind of what you just talked about, but it's specific for for breast cancer. Astrid asks, What is your experience with genomics and precision medicine applications in breast cancer?

**Dr. Nancy Davidson** [00:57:29]

Well, we use an early version of precision medicine in early stage breast cancer pretty much every day. You know, there are multi gene tests that are out there commercially available, things like the archetype test for the mama print test, which we use in the early stage of breast cancer to help us select for or against the use of chemotherapy in addition to hormone therapy. Looking at these things in more metastatic breast cancer that's coming along right now. Right now, I think we're trying to figure out what the value is going to be at metastatic breast cancer for these panels. Help us select for precision therapies that the genes that are available to us right now that have particular targets are BRCA one and BRCA two mutation breast cancers, and also these breast cancers that have pixie three eight mutations. There's a particular agent that's available for them as well right now. So if it's breast cancer, a little bit more, a couple of genes at a time. But I think that we're very much in the exploration stage of how we can do a larger profiling and perhaps that will be useful to identify more specific treatments.

**Dr. Tom Lynch** [00:58:33]

Right. Nancy, thank you. John, thank you. Christy, thank you. I want to thank all the supporters and donors to the Fred Hutch who participated in today's call as well. I mentioned at the very beginning how incredibly important fearless science is ending both cancer and COVID-19, and that the world really does look to the Hutch for new ideas and for cures for these diseases. Fearless science needs your support now more than ever. You can imagine this has been a very challenging year from a philanthropy standpoint, because of all the difficulties people have had economically and and with the pandemic, you can go to [fredhutch.org/donatenow](https://fredhutch.org/donatenow) to directly support the science that's needed to end cancer in the pandemic. I hope you've had a chance to hear some of the most exciting elements of what we're doing at the Fred Hutch. Again, I appreciate everything people at the Hutch are doing to approach both cancer and COVID. Please save the date for our next president's conversation, which will be on Wednesday, November 18th. Thank you all. Wish you all a fantastic afternoon.