ENABLING COMMUNITY-BASED RESEARCH THROUGH POLICY AND PRACTICE CHANGE

Announcer 00:00

Thank you for joining us. Please welcome the panel to the stage.

Kavita Patel 00:36

All right. We've got—we have quite the agenda for 60 minutes—59 minutes and 21 seconds—but no pressure. So, I'm—we're going to try to make sure that we can kind of both combine introductions that are somewhat more creative than the standard introduction, with also taking a little bit of—tack on what we're actually here to talk about because we learned that in doing our panel prep that community means different things to different people, so we're going to actually try to start in the spirit of having each of us tell us a little bit about ourselves. I'll kick off to try to appropriately model, but then talk about kind of—through the lens that we approach our professional lives, as well as potentially our personal lives, because usually the two blend—kind of when we think about community and we're thinking about clinical trials, research, expansion, what does that actually mean, and how can we expand that through this conversation over the next hour. So, I'll start and try to model this. Kavita Patel, I'm an internist. I'm a professor at Stanford—have a long history in kind of the policy space, where I worked on a number of efforts, both legislatively and in the White House, on actually trying to bring everything that we could think about better health-care access, clinical trials, breakthrough innovations—to the community. And my approach was, because I'm a doctor, that the community was where care is delivered—that didn't often take place just in a hospital or a clinic—in fact, most of it took care outside of those places. And wouldn't it be amazing if we could harness trusted people and places in a community to then do a lot of this work? And I had the fortune of working with Democrats, Republicans, Independents—it was one of the few topics that was nonpartisan. You might call it bipartisan, but everyone agreed, and yet I would say 2025 we're still trying to figure out how to do it. All right. Paul, no pressures, but go ahead.

Paul Burton 02:33

Thank you, Kavita. So great to be here. Thank you for having me. So my name is Paul Burton. I'm chief medical officer over at Amgen. Despite my strong Northeast accent, I am British. That's my one joke. [inaudible]

Kavita Patel 02:46

Or your Southern California accent.

Paul Burton 02:47

Yeah, my Southern Californian accent, yep. I'm a surgeon by training. I've been in industry about 25 years, and most of that time, I've been trying to find the elusive community-based clinical trial. And so, for me, I think community is a seamlessly integrated group of people all working together for a common goal, which is to do great clinical research, answer a meaningful medical question, and do that in a cost effective and time effective way. That's community.

Kavita Patel 03:18

That's a good—I like that. Is everybody hearing that, like drilling? Okay, so that's like, not in my head, my dentist's—PTSD nightmare. All right, that's fine. All right. I just—sometimes it's a voice in my head, sometimes it's real. All right, we're gonna get—Debra.

Debra Fraser-Howze 03:33

I'm Debra Fraser-Howze. Hello everybody. Where do I start? I'm the founder of Choose Healthy Life, which is a program I founded during COVID with Black churches across the country. We started with 50 Black churches and grew to 120 Black churches in 13 states, where we actually gave out care and testing through the Black church. We hired people in the Black church to give out care and testing. We now have those churches doing a wellness program with Quest Diagnostics. Prior to that, I was the founder of the National Black Leadership Commission on AIDS, where I actually advised two presidents of the United States, both Bush and Clinton, on advisory panels on HIV and AIDS. Before that, I worked in industry at OraSure Technologies, where I worked on the development of the over-the-counter HIV tests, Ebola tests, Hepatitis C tests, and brought them all to fruition. So I have a mix of both not-for-profit and for-profit work, and recently just graduated from seminary. So I'm really mixed up. I'm probably one of the most mixed up people on the panel. Next.

Kavita Patel 05:02

Wait, what is—wait hold on, Debra. I feel like Debra is community, but I don't want to make this, like bad assumption. So how would you think about talking about what community means to you?

Debra Fraser-Howze 05:11

All right, this is hard to follow.

Martin Landray 05:11

I don't need to define the community. It's just been done. And we had that discussion. I think—it's very often in health care and in clinical research, in clinical trials, we think of community very much as geography. We think of it as a particular place. Occasionally, we think of it, as you've just said, Deborah, as a particular skin color, or something similar. But actually, community is something that is shared. I grew up in a community. My father was the community doctor, and when the community—members of the community were ill, they came to the house, they knocked on the front door, and if they bled on the carpet in the front in the front hall, my mother got crossed. That's community care. So—but I think when we think—I should introduce myself, I'm Martin Landry. I'm a professor of medicine and epidemiology at Oxford University. Fundamentally, I'm a clinician. I went into medicine because I saw what medicine could do to—for the community. But, over the last 25 years, I've been focusing on clinical trials. I've been focusing on, how do we know that those treatments that we use, those treatments we don't use, or the new treatments we could use, how do we know that they're any good? And that starts, in part, by focusing on the community. What is the community with—that we intend these medicines to be used for? And how do we take our research to those people, so that they are at the beginning of the question and that they're at the end of the answer? And that, I think, is what community-based research really looks like.

Debra Fraser-Howze 05:11

Oh. Community, to me, you know, I said this when we were on the phone. Someone once told—I was struggling with identifying what community is, and he told me—one of the ministers told me—community is not who you, who you ride the bus with every day and who you go to school with every day. Community is actually whom with you have an intertwined destiny. So, whomever that is. It's not the person next door, but it's who that person is. And I think that today, and I don't want to get political, but I am by nature. When I look at Mamdani, and see what he's done, the people who came around him, those young people that are under 30, that he got so excited—so many of them voted for him, because they see themselves in him, because it's that intertwined destiny that they see. It's not that he was this or that, but he galvanized them because they know that, somewhere in there, they saw them. And that's what community—it's not Black people, White people, Jewish people. It's not that. And if we can get deeper into that and understand what that trust brings, that's the community that you need to find. And that is going to bring you what it is you need.

Martin Landray 08:14

I love it. Vicky.

Vicky Leamy 08:15

Vicky Leamy, vice president of therapeutic science and strategy at IQVIA. We're a contract research organization. That's the side that I sit on of our organization. My background is global health. I've been in global health for 30 years. My particular specialty has been Middle East and Africa, specifically. I focused on infectious diseases and vaccines for the majority of my career, but have been recently broadening into other areas that are either adjacent or just of interest. I oversee a lot of our pandemic preparedness work at IQVIA and oversee our partnerships that are focused on pandemic preparedness. So, I come at this from a clinical trialist lens, and also from someone who thinks about things under duress. And Deborah has the mic drop moment—when she talks about what a what a community is, no one's going to top her in terms of this shared destiny concept. But, when I think about community from a clinical trialist perspective, it just—it's all the people we're not serving. We serve so few in bringing clinical trials as clinical care. We have this entire blue ocean of individuals that serve our shared destiny that are not participating because we are not getting it to them, our clinical trials. So, the lens that I'm coming at is, how do we make it more equitable? How do we make it more accessible? And selfishly, we run a business. I want to make our businesses better too. Because, all of the problems that we talk about, how difficult it is to recruit trials, it's that 95 percent that's not served. So, it is the solution for the community and for ourselves.

Kavita Patel 09:49

Wonderful—Kent.

Kent Thoelke 09:50

So, I'm Kent Thoelke, the CEO and founder of a company called Paradigm Health. I don't know if I'm schizophrenic or I can just hold all of those definitions in my head at the same time, but I really think about community for us in a literal sense, in that—when I founded the company, I had been in clinical research for 30 years. We are no better at serving people that live in community or rural areas today, for trials, than we were 30 years ago. And the frustration for me is that it literally, in cancer care, is the difference between living and dying for these patients, simply by geography, by socioeconomic status, by the color of their skin, by where they grew up, and that just seemed fundamentally unfair to me. From a community perspective, my father was diagnosed with glioblastoma. I know everything about glioblastoma, I have been in this community for 30 years, and even I had a challenge navigating his care. More disturbing to me is that the neuro-oncologist had a challenge just, you know, helping us figure out how to care for him. And the reality is, most physicians, in rural and community-based care, want to do the best for their patients. It is physically impossible for physicians in academic medical centers, let alone community, rural-based settings, to keep up with all of the literature on how to ensure a patient gets the best care. Simultaneously, if you think any physician out there is spending more than 10 or 15 minutes with your chart to understand

longevity in the course of your disease, and then how to best treat you with all of those millions of articles on best care out there, that just isn't happening. And so, about two or three years ago, when I launched the company, large language models were just coming into practice. And our ability today with technology, to read a patient's chart in its entirety, to contextualize it, to help physicians in community- and rural-based care understand what options are really out there, and connect those patients to best possible care, can be done with technology in a way today that it never could be. Ultimately, I think that patients that are in rural settings, that are 50 or 100 miles away from the best care, that don't have access to an academic medical center that aren't white, middle class, or have access to insurance deserve to be served by technology like this to make that access more equitable. That infrastructure needs to be nationalized. This can't be done one hospital at a time. It is a very expensive proposition. We are talking a multi-billion dollar investment. And we just happen to be very fortunate that we found a group of venture capitalists and foundations that also believe in that mission—that everybody deserves access to that care. And so, that's what we do.

Kavita Patel 12:33

So Kent did a good job of getting into our next topic, kind of solutions, but we're also going to kind of pair that with some of the barriers to those solutions. Maybe Ken, I'll just let you tag on to this. You offered us like an example, very concretely, of a solution that Paradigm is centrally located in. But, how can you describe, maybe some solutions that might be reaching, or are there none? How can we get to populations, as you just mentioned, whether it's rural or others, but I'm trying to see if each panelist can talk through a solution that they can see, like light at the end of a tunnel, trying to get to that 95 percent that Vicky was talking about. Anything come to mind?

Kent Thoelke 13:13

I mean, labor arbitrage is key, right? Post-COVID, the amount of labor available in community and rural settings for care, let alone research, is almost...

Kavita Patel 13:23

Is it the nurses?

Kent Thoelke 13:24

It is nurses, study coordinators, physicians—it is the entire ecosystem. And I think that technologies, even today, the fact that we require humans to read an electronic chart and reenter electronic data into another electronic system, is crazy to me. And so, technology can do all of that, but again, we provide our implementations at no cost to community- and rural-based health-care systems because we're well-

funded. But the reality is, all of these things, we need everybody on the stage to be able to provide those different pieces of the puzzle. We just do the tech piece.

Kavita Patel 13:57

It's not a small thing. But yeah. Vicky, how would you think about solutions, whether they're in IQVIA or outside, just things you're seeing, and it doesn't have to be rural, per se, but something that's closing that 95 percent gap, to your point.

Kavita Patel 14:10

Like a national, I mean Saudi Arabia and sickle cell, for example—

Vicky Leamy 14:10

Yeah. Yeah, exactly.

Kavita Patel 14:10

—that literally took, like the country—this is a big problem.

Vicky Leamy 14:10

It is a big problem.

Vicky Leamy 14:10

I'm going to lead with the problem and then back into the solution a little bit. You know, I think that there's a couple different things about the way in which we consume health care in America that drive the patterns—and we need to be thinking about how we bring clinical trials to the community. Just a couple statistics—50 percent of all of the visits in America are done at the primary care level—only 20 percent of visits are done with a specialist. The rest are surgical, which is something to consider separately. But, when you think about how health care is consumed, and then you think about what we demand of our clinical trialists in terms of the tests that they're going to do, the amount of time that they're going to administer, scale, it's mismatched, and that mismatch makes it very difficult to do what Kent is saying we need to do, which is to create an ecosystem that can do this in a more automated fashion. So, I think one of the key challenges that we have, and we need to do, is we have to match the way in which we design our clinical

trials to meet clinical care where it is. And I draw inspiration from the work that I do in Africa. I think because Africa has come a little later to the clinical trial space than others, they've had the benefit of seeing how we've done well and how we could do a lot better. And they're engineering things in a way that is just a little bit more seamless in terms of integrating community. Africa CDC has put forth the notion of a hub and spoke model, which I think is very important when you're trying to push into areas that don't have the resources available. So, I advocate heavily for the hub and spoke model—cell and gene therapy has managed to do this in Saudi Arabia and Brazil as well. There's other elements outside of just in infectious disease. I think that really—

Kavita Patel 15:24

We're going to go solve it.

Vicky Leamy 16:05

We have to solve it. And, I think that, you know, you talked about, how do we have other resources available? Deborah, I think you've got good examples of how we've got other resources available that are not necessarily clinicians. And part of this is going to take a policy play, in the way in which our requirements for GCP—there's still this paper-based kind of rigor that just doesn't make sense in a digital world.

Kavita Patel 16:30

Save the exciting paper-based for the next question—fax, paper—we're going to talk about all of it. Yeah. Martin, any solutions that come to mind?

Martin Landray 16:40

Well, the first is, I think, is actually to go back to community. I think there are two different elements of community there—and particularly when one thinks about health research, there are people who have disease who'd rather they didn't, or at least they'd rather you made suffering with that disease more tolerable, and there are people who don't have disease who would like to keep it that way. And those are two very different communities and two very different mindsets. So that's the first thing. In the disease, make the disease go away. That's a relatively easy concept. In the prevention space, actually, success is that nothing happens. And that's a hard concept to think through and think about how you're going to prove and how you're going to convince people that's indeed what you're achieving. The second thing I'd say would be around design. Anybody can design a trial that nobody can do and nobody can take part in, and frequently, that's exactly what people in this room do.

Kavita Patel 17:36

Not any of you, but yes.

Martin Landray 17:40

Well, actually all of us. That's exactly what we do so often, over and over again. And when we did the recovery trialing in COVID—so 50,000 people, every single hospital in the country took part, first first protocol drafting into first patient in nine days, first answers in 100 days, first change of practice in four hours after announcing the result, globally in the following four weeks. When you do that, the key to that is be really clear on the question, and then cut out everything else, so that you make sure that it's operationally viable. That includes, for the community, the community of frontline health-care workers, and the community of patients who come and come and need their care. The third element, I will just touch on the technology, given Kent —talked about the technology. Why are we asking humans to spend large amounts of time sifting through paper notes, or worse still, to sift through one lot of computer notes and put it into another set of computer notes? I would also ask the question, why are we asking humans to read and remember the protocol and the standard operating procedure? Actually, why aren't those just workflows? Can't they just be automated? That's what we've done at Protas, the company I've set up since, over the last few years, is to say, well actually the protocol is the operating system. That is actually how the trial is to be run. And if I want to buy a pair of shoes from Amazon, and other retailers online are available, but, if I want to buy a pair of shoes from Amazon, I don't know how their supply chain works. I don't worry about the security of their finance system. What I want is the choice. I want it in real time. I want it now. And I want the right shoes and the left shoes to arrive at my doorstep at the right time. And if it doesn't, I want to be able to send them back. But, I can be pretty confident that Amazon does not spend 40 percent of its budget with individual people going round checking bits of paper, and that the delivery man really did turn up with a right shoe and a left shoe at my address. And yet, that's what industry does all the time. So there are huge opportunities for good design, working with the community, and the technology, to actually take the complexity out of this. Remember, commerce, finance, personal banking—they're all highly regulated, highly sensitive issues, with very sensitive data, detailed processes, and an awful lot of money riding on them. And yet, medical research seems to be stuck, as if we're in the 1980s, except, instead of getting people to write on pieces of paper, we get them to write on pieces of glass. And, instead of getting the cheap people, the clerical people, to write on the pieces of paper in the 1980s, we now get the expensive people, the investigators and the doctors, to write on the pieces of glass. That's insanity. So I think there are ways in which one can say—actually, what's the question? What's the community? How does one make it easy? Get the design right, and then use the technology to drive that through, so that actually, what the experience can be, is between the member of the community, the participant, the patient, the member of the public, and the clinician at the front line—and the clinician doesn't need to be a doctor—and how does one spend the time on that one-to-one interface, rather than all this other stuff. Which, let's face it, it's for us. It's not for them. Actually, the reason we're doing this research, it's for them. It's for the people, it's for the community, who have the who have the problem, or ideally, in prevention, don't have the problem, want to keep it that way, and how do we get results that are then—we can cycle back to those same people and can make improvements.

Kavita Patel 21:30

Yeah, Deborah, how would you think about solutions that you've seen?

Debra Fraser-Howze 21:34

I can only speak to what I know. And one of the things that always surprised me when I was in industry is how much money you all spend on clinical trials. It just used to blow my mind. So, why are they doing this? Why are they going through all of these changes. When you talk about—when I talked about intertwined destiny, the one thing I know that you need, and you need, and you need, and I need, to go into a clinical trial is—we need to trust. You got to have trust. I have to trust what you're giving me. I have to trust you—that you've given me something that you're not going to kill me with. And for me, a Black woman, I really got to trust you, because your history has not been too good with me and my people. So I have got to sincerely trust you. And from what I've seen, a lot of money has been spent on all of these different agencies that you give money to to bring people in, like—and then sometimes the trials work. Sometimes they don't. People drop out of the trials. You give money to the people that stay in. Sometimes they do something. It's just a hodgepodge of things I that I've noticed. But, one thing that I have noticed, that during COVID, our community wouldn't get tested. They didn't trust anybody. They said that they're going to take my DNA, and I don't want them to have my DNA. Heard of Henrietta Lacks? They took her DNA and made all kinds of things and never even compensated her family for the stuff that they took from her, for the DNA that they took from her. The community didn't forget that. So they didn't want to give up their DNA. And they left it alone. They wouldn't get tested. When we started going through the church, not only did they come in and get tested, but when I brought Quest into the churches, they rolled up their sleeves and started letting the phlebotomist take their blood so that they could be a part of this blueprint for wellness. Now how do you go from not wanting to get tested to giving your blood in the church? That was a major leap. That was trust. They trusted us. When Reverend Sharpton got up and said, I want you all to get tested. I want you all to take the blueprint for wellness, we actually treated and tested and serviced 24 million people around the country. The majority of them Black. When we put something in the bulletin, the church bulletin, that said, we've got this clinical trial being opened—because one of the doctors came in and said, we got this clinical trial—can we just put it in the church bulletin? And we got people lined up in the church that, you know, my son got something, something's wrong with him, and this sounds like something that he needs to be involved in. He's losing his hair. He's doing this—can I come in and find out more about this? Something that simple, got two or three people—so it was two or three people, but it was two or three people they didn't have, to get, to ask, and then somebody else ask somebody else. Those are the kinds of things that were so easy. It didn't cost no money and got people involved because trust was involved. Now, if you scale that, with 120 churches, or 50,000 religious organizations around—where the pastor gets up, where the bulletin is written, where people are saying to other people, Miss Nancy's across the street. Miss Nancy. We found something out about somebody in the church—that there's a possibility that your son might have a cure. Because we found out about something that he could possibly get involved in. That kind of word of mouth can't be compared to anything else. Because that trust is essential. And if you just take the time to listen to the community, it's not stupid. They don't have it all wrong. And the fact that you could have that kind of possibility of diversity in your trials, of people who can be trusted in it, and if you've got the navigators of people on the ground that are helping to support that, with whatever that is needed to support those people that stay in the trial, that kind of trust is golden. So I'm looking at what I know. I'm not telling you some pie in the sky, and I'm not telling you it's easy, and I'm not

telling you going to scale it to a million overnight. But I'm telling you that you should try it. It might be something that would open your eyes and be something that makes sense.

Kavita Patel 26:20

It really stinks you have to follow that Paul. I know, I know. You've got a solution or two up your sleeve.

Paul Burton 26:28

Yeah, don't follow—

Kavita Patel 26:34

Reorganize the panel. Don't follow Deborah. Yes, but—

Paul Burton 26:37

There's a few statistics I find interesting. There are three. The first one is this, and actually it comes from the Milken Institute. It says that, in the USA today, only 12 percent, so one in eight people, actually have sufficient health literacy to be able to navigate the health-care system today. So, only one in eight of us, right, can navigate the system. The second piece is some work from the Mayo Clinic. People who go to the Mayo Clinic for a second opinion—89 percent of them leave it with a new or different diagnosis. Imagine that. So, most people can't navigate the system. When they finally get into it, they get a slightly wrong diagnosis. And what we kind of taught in medical school—what's your purpose as a doctor, make a diagnosis and come up with a treatment plan, right. So, I think that underpins a lot of the issue. And then, add a layer on that, the fact that 70 percent of people live more than two hours from a standard clinical trial site. So, you know, if you've got a 7- and a 10-year-old, and you've got to get them on a bus, and you got an 8am appointment. It's not going to work. So, I think—making clinical research easier—we've all said it. I mean, I think it is the fundamental answer. Kent and I, when we were both in different lives about five years ago, did a study called CHIEF-HF, which kicked off in May of 2020, and it randomized people with heart failure to a diabetes medicine, a pill, or placebo. And we kicked it off right at the start of the pandemic, and we enrolled 450 people—completely decentralized. We shipped study meds to their home. They did all of their study visits on an app, got consented over the phone—thing went gangbusters. We made it easy for people. So I think, you know, solutions are there. I think it is easy to do, but we've got to let go of something. And I think the reason, as Martin said, that we make everything so complicated, is we're nervous that 'what if.'

Kavita Patel 28:44

Right. With CHIEF, I remember when that, that was pretty—what seemed groundbreaking—to be able to enroll people easily, and then have everything, from trial enrollment, to even just information along the way, to the clinician, the enrollee. But I was always a little surprised that that didn't seem to spread into some of the other trials. Maybe aspects of it had, but it seemed like an incredible model. And I had always wondered, like, then why stop there? What happened? Yeah, are you able to speak to—

Paul Burton 29:16

It was Kent's fault.

Kavita Patel 29:17

It was Kent's fault.

Kent Thoelke 29:18

It was my fault.

Kavita Patel 29:18

I think it's always better, but he's further away from me, so I will blame you, but—

Paul Burton 29:22

I think the pandemic happened.

Kavita Patel 29:23

The pandemic happened. But, one could argue that could even potentiate, or see the light for why this was important. So it would be—

Kent Thoelke 29:30

Yeah, but I think—I mean, it did—I mean, Paul was part of that. I mean, it took vision, leadership, and courage, in a pharma company, to say, we're going to do something different. It took regulators to say

okay. If—had COVID not happened, I don't know if that would have—I don't know if we would have had that reception to say, sure, you can do a clinical trial without ever having a visit, in a drug that's going to get a label extension. That would not have happened. And so, it was a combination of things. I think that, post-COVID regulators went backwards a little.

Kent Thoelke 29:54

That's what I was going to ask you. I mean, that same world, we remember that. So, what changed? It's just—

Martin Landray 30:07

But, it is the case that there is huge risk in not getting the answer to whatever this question was. I mean, if the question was a dumb question, you shouldn't even be doing the trial, and there's plenty that fail that test. But, if the question is a good question, then the biggest risk is you don't answer it. And if you don't recruit, and if you don't follow people up, and you don't look after the participants, you won't answer the question. That means that some treatment that's currently being used, continues to be used, even though it's either duff, useless, or, as I've found some in the past, just plain unsafe. One of my claims to fame is to have a—to do a big cardiovascular outcome trial and get a drug withdrawn that had been in market for 50 years, because it had been being used as a second line therapy for lipid lowering over a period of about 50 years. And it turned out, when you do a big trial, that it doesn't prevent heart attacks and it does increase the risk of going to hospital with pneumonia or serious bleeding. We didn't do the trial. We didn't know the answer. Actually, the risk was not doing that trial, and not getting that answer. So, I completely agree. The perception of risk is all wrong. And I think the opportunities to do things so, so differently, is absolutely there. In the same way that we have seen complete transformation, from, say, personal banking, as we first moved on to personal banking onto our mobile phones—when all you could do was actually basically read your bank statement—it's not actually a bank statement, it's a view of your database, by the way—but when that was all you could do, everybody said, my high street bank is going to close. What am I going to do? How am I ever going to cash a check? And all the rest of it. Now, if I have to go into a bank, I curse the bank, for why do I actually have to go there? And I can walk—I can get on a plane in London, I can arrive at Dulles, I can go up to a guy and wave my mobile phone in Starbucks, he gives me a cup of coffee, my credits gone down, his has got his has gone up, international exchange rates have been calculated, and all sorts of other stuff has happened. And all I've done is wave a phone at a machine. We have to think of things very, very differently.

Kent Thoelke 30:07

Well, yeah, and—I don't know. I think pharma is, historically and simultaneously risk averse and super cutting-edge, which is bizarre to me. But—and I'm sure that Vicky hear the same thing. Every time I talk to a pharma client, I say, we should go out into the community with this trial. I don't know. I don't know. I'm like, okay, your model sucks, right, because 90 percent of your patients are at academic medical centers. Your recruitment rates—70 percent of your trials never reach those. So, your model is broken. So, why is

this model good? And they have all sorts of reasons. Well, community-based patients, we don't know how compliant they'll be, we don't know if the data is transferable—I'm like, it's all garbage. It's all made up. And so, sorry pharma, but pharma is the problem, right? So, and the reality is, if we could recruit into the community- and rural-based system at 4x, 5x, trials would get done in half the time, drugs would get to market—and to Deborah's point, instead of 60 million for a Phase III, maybe it's 20 million, which allows pharma to invest in their pipeline and bring more drugs to market, which saves more lives. Everything about this model is better, and yet, with the tips of their fingers, they are holding on to a legacy-based, paper-based, old model. And I—it's mind boggling to me, and I'm hoping at some point, you know, if you think about your reference to Mamdani, and to Vicky, how people get care—younger patients will not accept this model. They will not.

Kavita Patel 31:29

We're not—we're going to see—we already are seeing a drop off of trials, especially in, it's not even about age, it's just, there's a compression of—I'm just not going to put up with that. We're not going to do that. Martin, you had something you wanted to add.

Martin Landray 31:40

No, the system—I completely agree. The system is completely broken, completely unsustainable, and completely unimaginative. And this concept of risk is a blindness to the risk that is going on every day. And the question is, who is who is going to shift? And I don't blame the regulator. I don't blame pharma. I don't blame CROs. I don't blame academia. I blame all of them, because they have been in so many rooms where everybody just points the finger around the table. It's in a different order, depending which way you're seated, but that's what happens.

Kavita Patel 32:17

Right.

Kavita Patel 34:39

So that's inherently tied to incentives, which we're going to try to touch on. I'll let Deborah—then people can think of their answer. We're going to talk through, so, some of this is not just financial, but, a lot of it can get motivated by—whether they're economic incentives, behavioral incentives, policy incentives, or some combination of all three, or more. And so, keep in mind, after Deborah makes her comment, we'll go through the line to kind of think of—all right, now we—what if we had, each of us, the power to implement or initiate certain incentives that could change this dynamic, what would they be? So—but first.

Debra Fraser-Howze 35:13

So, this what I would—this is—the seminarian in me has been worked up now. This is the seminarian talking. COVID was a bad thing. But, and—the health-care system as we now it has been demolished. Somebody took a chainsaw to it, if you didn't notice. And other people just blew it up. So now, we have virtually nothing—NIH, CDC, everything just virtually gone. But, what an opportunity. What an opportunity to start all over and make it what we want it to be. Maybe this meeting is the opportunity for all you brilliant minds to be in one place. You got venture capitalists. You got funders. You got doctors. You even got somebody that walks around with a Bible on a regular basis. You got everything here. Maybe this is the place that you say, let's, on a regular basis, come together and figure out—how do we build back better? How do we create our own Project 2025, 2028, 2029, whatever it is? And build our health-care system back, or our clinical trial system, or a system that looks like it's going to work. Look at these examples that they said. They make sense. All the sense in the world. Let's create a bunch of examples like that. This, the churches, the community, and put all of that together and say, this is what we're going to do. It's not impossible. Other people have changed America with a plan. So why can't we just come together with a plan and just present the plan to whoever it needs to be presented to. That's what my seminarian sense is telling me. That this is possible, and I think that you are the ones to do it. Don't look for somebody else to save you. Save yourselves.

Kavita Patel 37:18

Alright, Deborah. You just wrote the introduction to the solution book. I'm going to ask Paul, what would be regulatory, some incentive—it could be FDA must do *dot dot dot*, clinicians should do *dot dot dot*—what would that look like?

Paul Burton 37:39

We're talking here to get more people into trials, to streamline—

Kavita Patel 37:41

—to basically, I think nobody came into this room, not with not some sophistication around the awareness of the problem. I think that a lot of us have worked on these solutions in different ways, but probably, like each of us, been frustrated when you come up against—well, this is we have to have this in paper, here's what this is required. There's also, I think, some falsehoods around—I will say, having worked with the FDA, and some of you in the room have done this—there's some falsehoods about what they think that regulators want or expect. And unfortunately, those get codified into serial like, this is just how we do things, and this is why we do these things. But the truth is, nobody actually thought that. So, I'm curious if there's something where you feel there's an opportunity—maybe we take a cue from Deborah, like if we're writing the solutions playbook, we have some of these solutions—but what needs to be paired with it? Do we need to pay for it? Obviously, if we paid for more examples like this, maybe people would come up

with them. But, what would a solution—sorry, actual tangible kind of policy, or—what would that incentive need to look like?

Paul Burton 38:49

First of all, I agree with you completely. I actually think the policy stuff is there.

Kavita Patel 38:55

I do too.

Paul Burton 38:55

Right? I mean, between 2020 and today, the FDA have just banged out guidance.

Kavita Patel 39:00

Even recently, with just how you can do n-of-1 trials. And—I agree.

Paul Burton 39:06

You know, it's all there. And either we don't bother to go and read it, we can't find it, you know, or we're just too busy making PowerPoint decks, or something else, to actually go and [inaudible]. So, I think the policy is there.

Kavita Patel 39:21

I do too.

Paul Burton 39:23

I'd say, honestly, look—Martin has spent his life, many of us have spent our lives, doing clinical trials. What really is it for? You need an important question, and then you need reliable data. The problem is—well, I think the opportunity is that the data are all out there in our electronic health records. Now, maybe in the UK National Health Service, you actually could do this. But here in the US, everything is so fragmented,

right? I mean, we talk to patients. We all have friends, even with grievous diseases. If you're seen in one system, you just can't communicate, right? You can't get your piece of data out. You can't get your CT scan and go and take it somewhere else. So, for me, the incentive, or the big change, would be to somehow harmonize data, make it usable and accessible, which I don't think it is today. That would open up a world of possibility.

Kavita Patel 40:18

Does that need to be done from a federal, right—we already have some interop—we have information blocking, and some of the other things already in place. So, it is actually with a pretty significant monetary penalty for any organization to, kind of, block information from being accessed. But, I think you're alluding to—it doesn't matter if you have portals upon portals, if it still makes it time consuming and complex. It just creates more friction. So, is it something that needs to have, like a regulatory oversight, because the pieces are there.

Paul Burton 40:52

The pieces are there. Cooperation. And you can go into Blue Button, right?

Kavita Patel 40:57

Right. You can—right. And that was the intention behind it.

Paul Burton 41:00

But you try and get a large electronic health-care organization in this country to talk to another one, to go and talk to a large health-care system, and one on the East Coast. It's not happening. Try and go and get the CT scans out of one other thing and share them. So I think it's organizational collaboration.

Kavita Patel 41:21

—that sort of collaboration. And I got a reminder—I'm a very bad moderator—that you can submit your questions, and I see a bunch of them now in this iPad. I'm going to tell you that because I'm so technically savvy, I already knew they were there. But, while we start talking about incentives—so Deborah, just, to build on that.

Debra Fraser-Howze 41:41

I'm going to let these guys take my spots.

Kavita Patel 41:47

Okay, I love that. All right. I'm going to go out of order and ask Vicky to go next, and then Kent and Martin.

Vicky Leamy 41:54

I think the incentives exist already in terms of the amount of money that we spend in the clinical trial space. It's more about rearranging it to some degree.

Kavita Patel 42:02

So it's kind of alignment of the incentive, and maybe a little bit of pain, like, if you don't actually make it easier, then it's kind of painful, a little bit.

Vicky Leamy 42:11

Yeah, and I think a lot of what Paul and Kent were talking about around risk really comes down to the industry's risk aversion to trying something that hasn't already gone through a pathway that has been proven as successful. And this is particularly important to the point that I was making earlier, that we need to match clinical care and primary care in terms of the endpoints that we're collecting. We often collect things that are not part of the standards. They require extra effort. They require extra skilled individuals, above and beyond what your average practitioner has, and so how do you strip that back down and still have confidence that you're going to be able to generate the evidence that you need? And there's this crossover interplay, where you go, I get intense evidence in a small cohort, but it's very costly to generate it. Or, do I get lesser, in terms of the endpoints, but they're more—they're the endpoints that are actually used in clinical practice. And maybe there's a trade-off of the number of people that I have to bring in to the trials to be able to feel confident that I'm actually having an effect. And I think these are the things that we really have to start considering as an industry is taking that risk, that we don't want to expand the number of people that we're bringing into trials. But, if you're going to go into community, you may have to, because you've got a much more heterogeneous population that you're measuring. And so it's we're an outbred strain as humans. We've got to just take that risk on. I think the the incentive really is going to have to get people to be brave to do that scaling, because I do believe that it will—the cost per patient will come down over time, and the evidence generation will be more in line with what we actually need to make some decisions for clinical care.

Kavita Patel 43:49

Right. One question Vicky, that came from the audience—what country in Africa were you referencing when you were describing the hub and spoke model that you worked on?

Vicky Leamy 43:57

So, if you go to the Africa CDC website, they'll talk through several hub and spoke models, some within each individual country, and then some that are region—they have regional coordinating centers. I would start looking at the regional coordinating centers out of Africa CDC, but each individual state within Africa is working on how they're going to implement that hub and spoke model. We're helping with some of that work through our partnership.

Kavita Patel 44:18

Okay, great. Kent, your thoughts on incentives—you can be brave and bold and say.

Kent Thoelke 44:25

I mean, on a public policy perspective, I think that, in the same way that we adopted EHRs with meaningful use, we need something from the federal government to incentivize community- and rural-based systems to participate in research. If there's not a financial incentive for a physician to take billable hour time and participate in research, it's hard to make it happen. We are lucky enough; we have some very large systems that have created research units, RVUs, for their physicians to participate. So, there is that piece, I think, from a policy perspective. I think the other thing is, you know, money always wins. As much as I'd like to think that people have good motivations that—when Deborah was talking about HIV research, I think that, if you look at Truvada and pre-exposure prophylaxis for HIV patients, if you think about public policy and where we're spending our dollars, the amount of money it costs to prevent people from getting HIV versus the amount of money we are spending to treat people that become HIV positive, it's not even close. And so from a policy perspective, it's the same thing with cancer. Cancer in this country is now a chronic illness that we pay billions of dollars to treat, because we diagnose it very, very late. And those patients get access to, Martin's point, potentially the wrong therapy, suboptimal therapy that causes downstream costs. I mean, there's all these financial implications—so from a public policy perspective, and all the actuaries out there, we need to figure out how to spend better to treat patients with optimal care at the right point in their journey, as opposed to catching them at the end and playing catch up.

Kavita Patel 45:59

That brings—someone asked a question about community-based research around models of care. We've been kind of focusing on, let's call it, therapeutics, diagnostics, devices, but the actual model of care, which we all agree is broken, hasn't necessarily also had its time to have a community-based research kind of focus. So, if any of you have thoughts about that, it would be interesting. Truvada is a good experience

where, a lot of the funding for HIV prep and many HIV clinics has been eliminated recently, and it's actually forcing many of the advocates—some of us remember practicing when it was GRID, and then AIDS, AIDS wards, and then when I saw the first antiretrovirals clinically, I thought, this is nothing short of a miracle. And to think that we are potentially bringing back the very thing that we could prevent is troubling, and that's not because we don't have a therapeutic or a potential line of sight to even a vaccine, but we've decimated the funding for some of the models of care. So, I would just answer—someone in the audience asked that, but it would be interesting to think about, how can we focus on a community-based research model of care to even provide some of this, you know, in some way.

Kent Thoelke 47:11

There are systems. Sanford is a really good example. Sanford, you know, is based in South Dakota. They cover seven or eight states. They have a research-based model. They have jets that they take physicians out to community and rural settings to bring research in. It doesn't matter if you are in western South Dakota or in Wyoming, they will bring those patients into their hub and spoke model. Not to say South Dakota is like Africa, but, you know, from a model perspective, there's lots of things that we can learn, even in community and rural settings.

Kavita Patel 47:41

And we need both.

Kent Thoelke 47:42

You need both. You need both.

Kavita Patel 47:43

Martin, any thoughts around incentives? And then I'll throw in a question, since I want to try to—I've been told use iPad in big blaring font here. So, go ahead and answer that. But I would like—because Martin, I just like the accent, so I'm just going to have you talk. Can you talk about what—if everything is broken, you talked about recovery and kind of the trial and this model, so if we could actually do the rebuilding, what would you potentially prioritize? So, incentives, what would you prioritize?

Martin Landray 48:07

So, I think on policy, people have said it. I think most of the policy is there, but people overinterpret it. And they interpret it as rules, and they then overinterpret those rules. And people get—become professionals

at overinterpreting the overinterpretation of the rules, and then training other people to overinterpret the rules.

Kavita Patel 48:30

Right. I just like you saying rules over and over—yeah, keep going.

Martin Landray 48:33

So, there we go. So the first thing is about princ—we have to go back to principles. And when you want to innovate, you have to go on principles because there aren't—there isn't any historical precedents. So you have to understand the principles. Most people are trained in GCP, which tells you a bunch of set of rules, none of which have anything to actually to do with design, or none of which actually have anything to do with community. But they're about documenting. They don't teach you how to do a trial. They don't help you to think. They're simply about documenting. That's a big mistake. Second piece about incentives is money. People are paid to do stuff. They're not paid to achieve stuff. So the more you do, the more money you make. Nobody is going to say, stop doing that, because they lose money. Third thing about incentives is there is risk aversion, and there is, what you might like called—like to think of as the lemming effect. Nobody wants to be the first one, but once one jumps, everybody wants to follow. And you see that as a consistent pattern across the sector, and I'm not looking at any particular part of that sector, but that is true. To rebuild the system, if the system is blown apart, and one were to rebuild the system, then I think you do have to think about, where are the patients, where is the community? Your example of young people thinking about the world very differently—I think that that is absolutely the case. You know, it's a sort of, you know, not in my name type situation, whether that's communities that you were talking about earlier, about—Kent, with communities with HIV, whether it's about Black communities, whether it's about people with cancer, whatever it might be—this system is not serving us. And I think that that is a sort of fundamental starting point, because that then drives all the other economic drivers, and then the financials.

Kavita Patel 50:33

So take that a step further. So the first priority would be to get the community, kind of—raise the profile of what's not working, and show at least a bit of a burning platform to offer, and then maybe have that brave—I kind of call it the cold start problem, right—that brave first person entity, otherwise, that's willing to kind of come try something.

Martin Landray 50:54

So I think one of the things that happened in—when we did the recovery trial at very beginning of COVID, then—number one, nobody knew how to treat the disease. So there wasn't any—nobody could—people

could be definite. They could be definite and be right or wrong, and nobody knew. Number two, there was a huge burning platform in terms of one in four people who went into hospital were dying, and there were very large numbers of people going into hospital. And that was exactly the right time when innovation was possible, because there was a huge community. I don't just mean patient. I mean the whole community was saying, how do we solve this? The agenda had one item on it. How do we solve this problem? That is also true in so many other diseases, whether they're rare diseases or common diseases, that are causing so much disability, premature death, and burden on families and the economy. So I think you have to start there. But the other part of not in my name is things like a consent form. I have not yet met a patient or a participant in a trial who's asked for the consent form to be longer. I haven't actually met many who've ever actually read it, because, and people have done studies of this, it takes 35 to 40 minutes just to read from the beginning to the end. It's 8000 words—no pictures, just words. Yeah, that's not consent. That's not consenting me. That's not explaining it in my terms. That's not allowing me to make a sound judgment. So these are, I think, elements of, if you like, not in my name, but they have to be matched on the sort of, if you like, the industry side. And those are doing trials—model trials are done by industry, of course. By some sense of, actually, there are things that we can't solve, there are questions we can't answer, there are markets we can't access with our current system. So I'll give you a little example of a sort of thought experiment. Take Alzheimer's disease, terrible disease, huge breakthroughs recently, but they are not population solutions to the problem. They're very expensive. You need a lot of imaging. They're only going to be used in a very—in a minority of cases. There's going to be a chunk of issues. So people are turning their attention to prevention. Some people in the past have even talked about, is there a vaccine for—to prevent the onset of initial cognitive decline and so on. Can you imagine doing that trial? That trial is going to require tens of thousands of people over 5 to 10 years. It's actually going to require a much larger number of people to identify the sort of people who have the right genetics that are going to make them a high risk. And you've not only got to find those people, in all their shapes, sizes and colors, and locations, you've got to find those people, measure their cognitive function over a long period of time, and then you've got to find out what happens. But that is such a fundamental problem. If we could prevent the onset of dementia even by three years, let alone five years? Boy, would that be worthwhile. But that's a problem industry can't quite solve at the moment. They can find, and people are finding, if you like the biotech solution, here's the target, here's the drug or the vaccine or whatever, but the last mile, it's actually quite a long mile, is the piece that they can't do. And so I think those will create the examples where actually that—the option is go there and do it differently, or don't go there at all. And in those circumstances, then I think industry is prepared to innovate. Then I think regulators are prepared to accept something different. Then the community, the patients, the public, are going to be clamoring for something different. So finding those examples of the things that we can't currently do, but we—what we—boy, would it make a difference if we could do, will be the driver, I think, if you're like the sort of economic type, mindset type driver that we're needing.

Kavita Patel 54:44

Right. Paul?

Paul Burton 54:45

Well, I was just going to add—I mean, I agree with everything. And Deborah said at the start, around trust—I think the energy of activation is high. We have an inclusive global health organization at Amgen, and in there, we've invested in two programs called Reach and Rooted, where we go into the community. And then there's a Clinical Trials Access Collaborative, and the Milken has a group called ENRICH-CT, and we participate in those things. It's difficult to scale it, and actually, the effort you have to put in, it's worth it, but, it's a high bar to set.

Paul Burton 55:33

Yeah, I think so. And Kent said it, you know, the—so we've got to get into the communities, that's clear. And then we've got to try and take some of the workload out. We can't have—what is it Martin? Eighty-page consents and 400-page, you know, protocols. And we've got to try and incentivize.

Kavita Patel 55:35

It's just that inertia?

Kavita Patel 55:53

All right, so I'm going to try to get through a lightning round. So, even though I like hearing all the voices and accents, let's keep the answers short. So I'm going to try to combine and collapse a couple of themes here. So non-medical drivers, some might call it social determinants, but there's so many things that kind of live around that create barriers, but could also be solutions. Is there anybody that's seen anything that could be paired, for example, with clinical trial recruitment, around transportation, food, housing—is there anything like that that anybody in the panel can come to mind? Okay, go. Kent, yes.

Kent Thoelke 56:26

I mean, you know, we partner with the American Cancer Society. And everybody has a vested interest in solving all of those problems, right? So they have lots of solutions. It's not one solution. Every community has different needs. Patients have different needs. You almost have to tailor it, which is not scalable, but for an organization like ACS, much more tailorable, because that's what they do, right? I don't have to solve that as a tech company. I need to find partners who can.

Kavita Patel 56:49

So this gets to something that someone has asked around, how can we actually, kind of, create sustainability to fund—the question was around community-based organizations, I could extend that to

yours, Deborah, to kind of the ACS—how is there a mechanism to allow for a community-based organization to do this work for the trusted networks to develop?

Debra Fraser-Howze 57:10

You have to fund community-based organizations that have access to other organizations. The community-based organization itself has to be trusted. And it has to have its tentacles in other organizations that can provide the social determinants of health. No one organization can do it all.

Kavita Patel 57:15

Can you help partner with their organization?

Debra Fraser-Howze 57:24

They have to partner with other organizations.

Kavita Patel 57:32

—to be able, though, to help. I've worked with community-based organizations, and when you come in, there's always this power dynamic. You're an academic medical center, and you can't have that.

Debra Fraser-Howze 57:43

You can't have it. You cannot have it. So they've got to be able—you've got to be able to see and they've got to be able to prove that they can partner with the neighborhood food bank, they can partner with—then the churches are a good example. They partner with everybody. People bring them clothes, people bring them food, because that's the center in the community where all of that has to happen and they have to give all of that out. So that's been a good place for us, but we have seen community-based organizations that try to hold on to power and won't let anybody else in. That's not where you got to go. So you got to make sure that you're going somewhere that can give access to your organizations to help. If not, it won't work.

Kavita Patel 58:26

Vicky, how can we, someone is asking, how can we better leverage data and technology to connect to, like those primary care settings, or something that we can do to describe how better we can get this into a primary care setting by using existing data, existing technology into primary care.

Vicky Leamy 58:46

I mean, I think Paul and Kent actually gave good examples of how they're actively doing that now, and the barriers that we have in the United States, in particular—we've got disparate systems where that data is housed, and getting that data to talk to each other is part of how we have some struggles. I think your organization has found ways to work around that and getting structured and unstructured data to be readable in a way that can be consumed for a clinical trial. But there's this passiveness to having a near virtual patients. Someone has to do it, and I know of systems where we're piloting it and and it's working. And again, that's in the African context, and to think that we can get past that hurdle, in Africa—we still need to pilot it here. And it comes down to the thing that we've all discussed, and it's bravery. Somebody needs to be brave.

Kavita Patel 59:41

All right, let's be brave. Okay. Deborah, you get to close this out because, no—we all want to hear more from you.

Debra Fraser-Howze 59:46

We have one minute remaining.

Kavita Patel 59:47

Yeah, I know. Please. You get to wrap this up. You can say whatever you want. Yeah, just talk.

Debra Fraser-Howze 59:53

Faith and fear. The two things can't exist in the same place. You can't have fear and faith in the same house—can't happen. So what we're saying to you is have the faith that you can do it, because you can make it happen. You can turn this whole thing around, if you want to. All you have to do is demand it and do it. You're going to be okay. Trust.

Kavita Patel 1:00:18

Amen. I want you to run for president next. I will put the first check in. You heard it here. Thank you.

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