

**Discussion session transcript**

Moderator: **DR. BARBARA BIERER**

Discussants: **MS. LASHELL ROBINSON** and **DR. RAVI THADHANI**

DR. BARBARA BIERER: Let me open this discussion. I want to encourage everybody to please put your questions into the Q&A. I'm going to be moderating this discussion. My name is Barbara Bierer. And I want to invite LaShell Robinson, who's the Director for Diversity and Inclusion in Clinical Trials at Takeda Pharmaceuticals, and who has really been a voice for change among the pharma industry. And Ravi Thadhani, the Chief Academic Officer of the Mass General Brigham and a Professor of Medicine and Academic Dean at Harvard Medical School, who's really leading much of this process at the Mass General Brigham, which is my employer, and my home. Welcome to you both. I wonder if you wanted to start with just a few comments, with respect to what you've just heard and how the organizations in which you are working have responded or taken on this challenge with the renewed energy that I think we all have seen over the last few years. Lashell?

MS. LASHELL ROBINSON: First and foremost, again, thank you for extending that invitation to join the webinar. And I hope we provide some insightful guidance. To your point earlier, if we looked at the landscape, even two years ago, I would say the commitments across various pharma companies were not very specific to diversity in clinical trials, and really talking about patient centricity, innovation and how to meet those needs. Around the time of the [start of] the pandemic, we really saw a rebirth of companies being forthright about what that health equity commitment meant. And for many it meant an actual commitment to diversifying their clinical trials. I know our company has a public statement that clearly talks about health equity and how that even starts with equitable access to clinical trials and boldly stating that the elements of diversity vary from company to company. But for the most part, I think we're almost safe to say that every company has some sort of commitment, some sort of statement, some sort of voice when it comes to how they will be addressing diversity and inclusion in clinical trials and even health equity for that matter.

DR. BARBARA BIERER: Thank you. And Ravi, I know Mass General Brigham has made a commitment to this area. Do you want to speak to that and to what that journey has been like?

DR. RAVI THADHANI: Sure, happy to, and thank you Barbara for the invitation. I’m certainly honored to share the stage with Ms. Robinson, who has a tremendous amount of experience in this space. As you said, Barbara and really articulated nicely in your slides, at Mass General Brigham our CEO has made a statement of a commitment, a multimillion-dollar commitment. We have a plan. There are finances allocated to this and we have metrics involved. We have looked at, for example, employee compensation for the employees that interact with our patients (research assistants, technicians, coordinators, research coordinators) and look at pay scales and salaries. And understanding that [trial participant] populations are incredibly diverse populations, we've had outreach efforts from our group to the community for clinical care, but also [outreach] for research to expand our biobank to our community centers, which we hoped we had done in the early part of the pandemic. But we looked at those community centers that were significantly affected. As you know, I think we've made inroads there. We have talked about research and again, how it dovetails with clinical work. When the testing for SARS-CoV-2 came out, we developed laboratory tests in-house and we deployed them into the community as a priority. Hiring practices, as you know Barbara, have changed. I think the word that Ms. Robinson used was “rebirth”. They [hiring practices] have changed in our organization as well, with a requirement for search committees, we now have the first underrepresented minority who's a chair or vice chairman of our IRB, which we never had before, sadly. Then thinking about remote access with a distribution of iPads and participation with clinical care as well as research. So, a number of these areas have undergone a rebirth. There's still a lot of work to be done, though.

DR. BARBARA BIERER: Great. So, let me let me ask- how do you figure out what to work on? You know, of all the things? How do you prioritize? How do you, organizationally, equip yourselves in very different settings, (an academic medical center and a pharmaceutical company) to understand what's going to be the highest and best or the most? And how we begin? LaShell?

MS. LASHELL ROBINSON: I think one of the exciting parts of this change is that a lot of organizations also dedicated resources. And with the investment in resources, it really provides that opportunity to pause, and take a look at that internal company data. Before any major decisions can be made, it's really important to take a look at how companies have been performing internally when it comes to diversity, and not immediately comparing it to US census data, etc. but also take a look at their portfolio. I think that one of the points that you made during the presentation was the uniqueness of companies. I always like to say clinical trials are unique just like our patients, but companies are unique as well. And their portfolios differ. With that differentiation of the types of disease and treatments that they are going to be making, that is going to create a difference in the types of patients that are enrolling. It is a good idea to take a step back and look at the workforce. We know that patients have spoken very candidly about not only research sites being diverse, but also about industry being diverse and HR efforts doing that. Again, looking at those gaps at a very disease specific area, looking at things like clinicaltrials.gov, and also FDA snapshots to identify how am I doing compared to industry? And how far do we need to go? And then really doing an assessment with our patient advocacy and partnerships that pharma companies hold. Are those diverse? I think a lot of us are really realizing that even some of our patient partnerships can stand for a little more diversity when we're looking at patients. And so how do we also network with other communities or other outlets or different avenues that we may not have considered as conduits for health literacy, health education. And then from there, you can start prioritizing: are those are operational aspects that we really need to focus on? Is institutional change thinking about something as simple as designing a protocol, or do we have some areas to really leverage our community partnerships? I do think it's important to look at the company landscape, look at the data, and then start making those prioritizations. And of course, the added resources can only help move that forward.

DR. BARBARA BIERER: Yes. And Ravi, do you want to take that as well?

DR. RAVI THADHANI: Sure. Happy to. It's a great question Barbara, because the question is: which direction do you start with? Sadly, I will say when we looked in every direction, whether it's the participation in our biobank with less than 15%, underrepresented minorities, hiring practices that don't have measures in place to mandate search committees, diversity of applicants, or salary scales for our most diverse workers, we felt that we needed to do some of those things. In fact, all of those things, regardless of whether or not they were going to make a big impact. Knowing that they were actually critical to do again and using that lovely word that Miss Robinson uses in terms of rebirth. Where we end up will actually depend on a number of these areas, some of which require economics and finances and some of which require search committees, for example. And we will find out with sort of a rear-view mirror to ask the question: where did we actually make an impact in terms of participation in clinical studies (among other metrics)? And then double down [on those actions that were successful] moving forward.

DR. BARBARA BIERER: Interesting. And one of the questions in the chat is: How do you organizationally recognize and reward work in [DEI]? Through appointments, promotions, and tenure, as well as incentives?

DR. RAVI THADHANI: Sure. It's another important question. And as you probably have heard Barbara, through our Dean, as well as a number of other individuals in the in the Council of Deans, we have felt that the inclusion of metrics related to DEI and measures and metrics that have actually been achieved in those areas should be, and will become, part of a standard promotion package- not as an exception, but actually as a rule. Do we have that in place today? We don't. But we're actually working on what does that mean now. For the very first time, including those metrics will be critical and mandatory.

DR. BARBARA BIERER: It used to be true that all professorial searches needed to be constituted by professors. And I can tell you that the diversity of professorships has been challenging to say the least at Harvard. Is that also changing?

DR. RAVI THADHANI: Yeah, it has. So, the first thing we did, as you know Barbara, is we said that the positions that we hire for leadership, chairs and chiefs, should be either professors or associate professors. When we put out a search that includes associate professors, for example, on the search committees, that allows us that window of opportunity. As you said, we have far too few full professors from underrepresented backgrounds, and we need to change that. But we certainly need to make sure that we are inclusive in terms of the people on the committees as well as the people applying for those positions.

DR. BARBARA BIERER: And have you made, for instance, your hiring practices in industry more thoughtful about this?

MS. LASHELL ROBINSON: I would say yes. One of the measures that definitely has been implemented is also looking at training around how to be more diverse and inclusive, and thinking about some hiring that we were doing around support roles. And it actually [hiring notices] went through an assessment to make sure that there weren't any words or phrases that would actually be exclusive rather than inclusive. So those are all of the different aspects that we are looking at. HR is expanding the panels of the people who are interviewing, which is similar to what we just heard. It's making sure that it's inclusive, not just from a race or ethnicity perspective, but also leadership-wise, because we know that certain elements of leadership have less diversity. And so again, to your point of expanding it to even associate professors- that same approach has to be taken here. And also for diversity of thought that also comes into play. And so, from all of those different elements we've seen the impact of that from a diversity perspective of race, ethnicity, age, etc., and even experience.

DR. BARBARA BIERER: Interesting. One of the things that always is challenging is finding the resources to do this kind of work, and then figuring out how to deploy those resources. Is it [resources] to an individual or to a committee or to a division? How have you dealt with those various tensions? What's the organizational structure? How do you embed DEI? How do you argue for the kinds of resources that are necessary?

MS. LASHELL ROBINSON: I think like a lot of people who have been doing this work over the years, many of us started out in a working group. It was a nice to have. It was something that we were doing in addition to our job, simply because of the passion and recognizing the need for it to have pull through in the organization. But over the years, I think there's a recognition that this takes a lot more work than just a work stream or something that's adjacent to your normal work. And so you have seen these particular positions. One of the things that I can certainly appreciate is that my position is very specific to diversity in clinical trials. As we have other diversity officers that are focusing on this really complex issue- it does allow for that hyper focus. A DEI HR officer that can really focus on removing those barriers related to hiring practice, and even learning and development- for example, looking at how we start doing some more cultural competency training. I reflect back on some of my earlier days at having my very first role in DEI in clinical trials, and somebody asked me, “can you help us with hiring practices?” I think now there's a recognition that, in order to have this big move, it really does need to be embedded into the way that the company works. Moving again, from that thought of it being a nice to have, and really towards the thought process of how can this be good for business? And how can it actually help the business and bottom line if we include a more diversified and creative [workforce]?

DR. BARBARA BIERER: That's great. And Ravi?

DR. RAVI THADHANI: How we allocate resources is always tricky in an academic setting. What we've decided to do is allocate it to a central committee. We certainly have an Office of Diversity, Equity and Inclusion. Together with that office, as well with a number of other leaders, it was decided that we were going to make multiple interventions- cross cutting in multiple areas- whether it is research, education, clinical care, outreach, or community efforts. There's no probably surprise to anyone, right, that there are other people who are screaming and yelling that they need resources. That said, you know, the money can only go so far. But those individuals that get the resources are held accountable and are held accountable on the metrics. It's accountability, and it's a multi-year investment from the institution Barbara, so that it is not just a one and done kind of effort. Because the metrics are over time, and the interventions will happen over time as well.

DR. BARBARA BIERER: When do you set this out? Do you establish metrics? You know, intentionally at the beginning, or do they evolve from it? And what kind? How do you do that part? Because obviously it's like days saved in the hospital. Everybody can claim credit for something that is very complex. So how do you do that? Metrics and Evaluation is revenue.

MS. LASHELL ROBINSON: From my end, I think it's multi-pronged. I always like to have multi-year metrics that everyone is very clear on that touch every single aspect of the organization. But even having those trial level metrics, site level metrics- all those points of accountability become critical. And to your point, wherever it allows you to hold that accountability, if we are not tracking site metrics, and it's simply just a trial metric, it becomes very difficult to have those conversations. For example, we know a site is perhaps in a more diverse neighborhood, but they're really not adding to our trial when it comes from a diversity perspective. And then for those individuals that may not be in charge of the day-to-day trial operations- that's where we have to look at goals, maybe across therapeutic areas, or across company goals. So those collective aspects are really important. You have that operational pull through and company buy-in. Everyone has a role. They may not be the same, but everyone has a role in how they can contribute. And having those individual goals clearly marked out with a metric is the way to kind of get to those year-long collective changes.

DR. BARBARA BIERER: Terrific, really helpful. And, Ravi, for the academic medical center, how do you think about that?

DR. RAVI THADHANI: We have metrics, Barbara, some of which are very concrete. For example, to improve the diversity of our boards. We have multiple boards, and we have a central board, and we made a specific definition of what percent of underrepresented individuals [should be on these boards]. Because while it's a stretch for us, it's a target for us. And so we have concrete measures in some of those areas. We certainly have softer measures. But once I’m held accountable for the hires that we do in my office, and all the other executives are asked “who have you who have you hired in the past year?” Did you have a search committee for those hires? Who can who participate in the search committee? And what was the granular look at the pool of applicants? And so they're softer [metrics], but nevertheless, they're critical to highlighting the points. And then we have ones that we create. For example, if our biobank has a diversity of 15%: can we get that to 18-20% in the next three years? We have created some ourselves as opposed to being handed some of those metrics.

DR. BARBARA BIERER: And are you currently tracking diversity in clinical trials? And if so, how are you approaching that? Because I know pharma companies are starting to track that with every trial every and not just by institution, but by therapeutic area, and then by division, and actually beyond therapeutic area to each disease. Because, you know, prostate cancer is different than glioblastoma. So how are you thinking about that?

DR. RAVI THADHANI: Right. So, you remember the NIH grants- we have to fill out those tables every year. And those tables are tables that say, “who have you enrolled?” And what is the ethnic and racial diversity of the individuals you've enrolled, including differences in gender and so forth? Those are required by the NIH. So, we have those metrics. On the one hand, when we get to the clinical trials, they're not standard, I think Barbara as your as you're highlighting, there are sponsors that come to us and ask to collect that information. But often, that's not the case. And so that's less consistent. Now the good news is that there are automated trial management systems that are now building in those kinds of metrics. So, we can begin to follow them. But we're just at the beginning of that process.

DR. BARBARA BIERER: Yeah. And am I correct, that industry is starting to track that or has been tracking that?

MS. LASHELL ROBINSON: I would say that it has been tracked in certain companies, but the consistency- that's also been a journey. I think what has been great about drug trial snapshots is providing some of that consistency. You can even look at the older data and tell that there have been some refinements and improvements since the earlier 2000s and 2010s. And even now that standardization has really helped. To your point. I also think that's why NIH grant-funded research has also been more diverse: because we're proactively asking for those numbers. It's very interesting, because very early on, that was a little bit something that teams would shy away from- asking sites they didn't want to offend because they thought it was a little off-putting. But we know from research that if there's no concrete metric that we're asking for tracking towards, it gives no one a baseline of where to aim for. And so the power of incorporating that metric has really proven to stimulate an uptick in diversity. And it has become one of those core best practices across industry to track it- not even at the site level, but to all the other measures that you just mentioned.

Dr. RAVI THADHANI: Can I just add to the point that Ms. Robinson made? And that is the other ancillary way we've tried to track this is looking at the languages that our consent forms come in, whether they be Spanish, Haitian, Creole, Chinese and so forth. We've talked about this before and you actually mentioned it in your talk as well. It’s (translation) expensive to do. They're not mandatory in many of our clinical trials. But we're beginning to track how many of our clinical studies actually have more than one language for a consent form- just as a rough metric in terms of how much effort people are putting in this.

DR. BARBARA BIERER: One of the things that the MRCT Center has done is done a lot of work on this (translation). And we'll have another conversation, Ravi, because I have some ideas. But you know, one of the things that I think has changed in industry is that: if you go back to industry (when they haven't translated an informed consent form), they're very willing to translate now. And I think we should make that standard practice. And then what if we do the translation [of study and patient-facing documents] at the site and we give back that translation to you to use for other sites? You know, so we're not re-creating the wheel. I think that we should be getting, at a minimum, full informed consent documents translated. I mean, it just doesn't make sense that we give an English-speaking person a 37-page consent form, and a one-paragraph consent form to someone who speaks Spanish. I mean, yes, it's a process. But why do we for one and not for the other? So that kind of thing I think we're all becoming more sensitive to

DR. RAVI THADHANI: I 100% agree. We're talking about mistrust and lack of transparency. And so, part of even translating that full informed consent, rather than having the short form, is a way to reduce that mistrust in the informed consent process. So between pairing that down, and obviously, getting it to a sizable and readable aspect- simply just translating is one of those ways. I've seen it in real time where you can almost tell that the sites haven't followed up on those translations. And we're literally seeing it in real time in the real patient population.

DR. BARBARA BIERER: Yeah, so interesting. I think that there's both a whole set of practical issues that we can tackling the sort of boots on the ground kind of thing, as well as this the culture change that makes everybody better. We're going to be talking about that in the next few sessions together. But I do think that the attention to this has been long and coming, but it's real. And I just hope that we don't lose that focus, until we really don't have a problem. And that is unlikely to be in my lifetime. Of course, I'm old. But what can I say?

DR. RAVI THADHANI: I think Ms. Robinson said this as well- it's the multi-year commitment. This is not a single year, and just lip service. It's multi-year, with accountability each year, and a multi-year investment. I don't think we've done that before. I don't think we've been held accountable to that before. I don't think people have looked at us to do that before. But I think it is required.

DR. BARBARA BIERER: On that score, one of the questions from the chat that I want to dig into a little bit is that we don't currently really collect data on health disparities for social determinants of health. In the work that we do, how would you approach that? And how are you approaching that to understand how social determinants (whichever we choose to think through) are being addressed and coming into our analysis as important factors?

MS. LASHELL ROBINSON: I know from our end, the incorporation into actual protocol design, that we're not there yet. I think certain elements we do a great job of looking at- like looking at comorbidities, which is a great example of something that we readily track as part of the clinical trial process. But other factors like socio-economics, and things around insurance accessibility- we don't do a great job of tracking that currently. But I do think it's leaning there, because what we are seeing are the outputs of that on the back end when our patients are needing those medications. So really having that full analysis, around who has and has not, is going to really help us start on better planning from an operational perspective around what to even include in the site budget. Do we need to have more money accounted for things like screening or things deemed the standard of care because this impacts patients a little bit more? So, I think we're still at the very infancy of doing that. To speak candidly, we do a great job with those aspects that are health related. But the other aspects that are almost more on the social end or socio-economics, and we can definitely do a better job of doing that.

DR. RAVI THADHANI: Yeah, I'll just echo what Ms. Robinson said. So, for the very first time, as part of this effort- a multi-year, multi-dollar commitment Barbara, we are actually now capturing social determinants of health in our community sites clinical sites. We’re just at the beginning stages to think about food security, and to think about safety in the household, and number of children, how many jobs people have. We've not collected those kinds of information in the past. We now have a financial commitment to collect that information and figure out how we actually can improve care in the communities after we collect that information and use it in the appropriate way.

DR. BARBARA BIERER: Are the variables the same that you're collecting in the community as in the clinic, and in the academic or the health centers as in industry? I've been doing this work, you know, in in, in an NIH grant called Rad-X for underrepresented populations, which is looking at testing and vaccines in underserved populations. And what's remarkable is that the NIH forms differ from what the what the federally qualified health centers (FQHCs)are required to collect. I ask, “are we kidding?” How are we ever going to put this data together? When it's so complicated and when you think about intersectionality. What work are we doing to sort of find a common set of metrics that we can all push forward?

MS. LASHELL ROBINSON: As far as the guidance- part of our work is aligning with either some sort of US census data when it comes to how we're describing race and ethnicity. I'm thinking of a conversation earlier, where we were speaking with France around their collection of data only to discover that they were using ethnicity almost synonymous to how we describe it in the US. So, I think some guidance around standardization of how we're going to categorize certain aspects is that first step. But to my earlier point, I don't think that industry has quite gotten around to that when it comes to social determinants of health. And that would be a first step, because it did make a large difference in how we're seeing recordings related to race and ethnicity and being able to zone in on those gaps. So that's that first step is getting that standardization. That's a common language.

DR. RAVI THADHANI: I do believe not in all of our areas, but in, for example, the cancer trial space, understanding of financial security and why people go into significant debt and claim bankruptcy is important. We're beginning to collect that information on a cursory level, but we're also seeing some sponsors, again, in the cancer space, being interested in it. Now, I don't think that we've harmonized the way we collect that information. But understanding why we don't have representation and what challenges trials in cancer pose- we're beginning to see an interest level of capturing some of that information. However, it isn't harmonized.

DR. BARBARA BIERER: Really interesting. So, how have you approached this question of uninsured populations? What do we do about that?

LASHELL ROBINSON: I think to your point, oncology is one of the largest health areas where we see that financial toxicity really start impacting patients- not only in a real-world setting, but even in a clinical trial setting. One of those exercises that we've actually done, even at sites, is ask “how does that impact their patients?” In particular, are there any differentiations that you see based on different diversity factors, whether that's race, whether that's ethnicity, whether that is local socio-economics? And is it just your patients that don't have insurance? Or what about those patients that have “not so great”? And how do those out-of-pocket expenses impact their trial? And really asking that tough question- does it cause bias in that informed consent process? Are they truly able to equitably offer the trial to every single person- or is insurance a barrier? And getting that anecdotal and turning it into quantitative information has really helped cement decision-making. Getting that that information from the site, in the absence of having a formal form, and tracking social determinants of health has probably been the best method.

DR. BARBARA BIERER: I think that collecting that data will also help our arguments with CMS, because it's problematic at its core that people are excluded because of insurance. I personally think we can take care of the expenses of travel and of getting to the place, and that's sort of a rounding error. It's the medicine and then the compensation for research related injury that's really problematic.

DR. RAVI THADHANI: What I'm beginning to see, again mostly in the cancer space, is a stipend program and assessing needs. And I know, although not uniformly been rolled out, that Dana-Farber is working on something like that. I know MGH has worked on that. How effective they have been, I obviously curious to know. And like you said, there are those rounding errors like parking and lunch and so forth. They're still very meaningful. Yeah. But the stipend program is my hope is they've gained traction.

DR. BARBARA BIERER: Let me ask one final question in the minute, which we'll start with Ravi, because you've been very solicitous up till now. If you could, what would you do if you could afford it?

DR. RAVI THADHANI: Well, I anticipated this question. And I'll be quick here. Polling my leaders at the organization, the consensus was that we could certainly have a wish list. But we have to ask the question more in the context of what our outcomes should be. In other words, where do we want to be a year or two years from now? Do we want to be where our patient-facing materials are diverse, and we are able to translate our consent forms? [Do we want to be where] our workforce, which are where trust begins, and communications are multi-lingual and multi-cultural? Can we think of those decentralized studies actually taking place? Can we make sure that we provide the sort of reimbursement and tuition for the young people as well as for the patients as we just talked about? So, it's multi-pronged? And are the outcomes based on assessments? And that's sort of a snapshot of a wish list.

MS. LASHELL ROBINSON: I read that question as well. And I guess, for me, I am personally selfish. I long for the days where I had time to actually attend some of the community conferences and where I had the time to actually connect with patients and really directly hear them. Some of my best and favorite moments are actually attending those events and listening to people about how clinical research was a positive benefit for them, and other patients listening to that. I think for me, it's not necessarily monetary- it would be time- the days longer, the weeks longer, so that we can really have those authentic connections. And I guess personally, for me, because I love doing the work.

DR. BARBARA BIERER: Oh, that's a wonderful place to end. And I want to say this is exactly how we wanted to start this series. To hear from the leaders in our organizations just how serious this commitment is, and how, how it has tenure- we are going to commit to it and stay on it. We're done talking- we're now doing, and we're going to continue until we've really changed the way we work. And I look forward to working with you all going forward. I know there have been many questions that have come in, we'll be answering them over time. And I want to thank you both for your participation and leadership and commitment to this effort. Thank-you.