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## Equity by Design in Clinical Research: EbD METRICS FRAMEWORK

**Webinar and Public Launch**  
Thursday  
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1:00-2:00pm EST

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**MRCT** MULTI-REGIONAL  
CLINICAL TRIALS  
THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD

**EQUITY BY DESIGN**

## Introduction

### Dr. Bierer

We'll just wait one more minute for people to come on to the Equity by Design (EbD) in Clinical Research.

You'll note that this is being recorded, and we plan to post this recording and the slides in about a week or two on our website

So, as people are joining, let me introduce this discussion today, and I'm really thrilled to have you all here.

### Slide 1

I want to welcome you to Equity by Design (EbD) in Clinical Research: The EbD Metrics Framework. My name is Barbara Bierer, and I am the Faculty Director of the Multi-Regional Clinical Trial (MRCT) Center, and I'm really thrilled to be launching this. It's been a 'tour de force' and an act of love for the last year or more. And we're going to launch the Metrics Framework and have some discussion afterwards.

### Slide 2

I want to mention on the disclaimer, which is that we are all expressing our own opinions, and we are serving in our individual capacity and not representing the U.S. FDA, NIH, and affiliated organizations or entities. Harvard and Brigham and Women's hospital is supportive of our work but does not endorse the views that we're reflecting today. We are supported by voluntary organization contributions and grants, and you can see that on our website, and we're committed to autonomy in our research, and we make our work fully available under a common CC license which you can read.

### Slide 3

I do want to say that we will be having a discussion- but first I'll be giving an introduction. I just introduced myself then Willyanne DeCormier Plosky, the Program Manager at the Multi Regional Clinical Trial Center, will be giving an introduction to the EbD Metrics Framework. She spent much of the last year working on this with collaborators whom you will hear from, and she will introduce it.

I want to give thanks to the team at the MRCT Center and the roundtable- and specifically Laura Meloney, Sarah White, and others. We're then going to have a panel discussion featuring Yasmeen Long: Director of Faster Cures, a division of the Milken Institute. She has served with us over the last year, but longer in spirit on the EbD Metrics Framework Roundtable, and then Dr. Rodrigo Garcia, who is the Vice President of Patient Solutions at PPD, part of Thermo Fisher Scientific, but really a Global CRO, and responsible for many of the diversity efforts there. We'll introduce them in a minute.

I do want to say that this is being recorded, and we will post the recording and the slides. Please put any questions as they occur to you in the Q&A or the chat. It's easier for us if you put them in the Q&A to follow along. It is also being closed captioned, and you can turn that on with your enablement buttons below.

#### Slide 4

I just want to give a mention to the MRCT Center and the current work in diversity and equity and inclusion.

#### Slide 5

We have worked on this for a significant amount of time, but the MRCT Center is really a research and policy center at Harvard and the Brigham and Women's Hospital that's dedicated to the integrity, safety, and rigor of international, multi-site, multi-regional clinical trials.

And we do this work by identifying emerging issues or unsettled issues and unresolved issues in clinical research, and then pulling together really diverse stakeholders in the industry, academia, nonprofits, patients, patient advocates, regulatory representatives, government officials, journal editors - whoever is involved in the question at hand to really define the issue and see what would be helpful. We do not just stop at a "here's what the problem is", but really try to find practical, actionable, and ethical solutions to the work, and then make those available to everyone. And we appreciate that. You know our first efforts are not our last efforts. We're going to continue to iterate and improve on the resources that we develop with our army of volunteers and enthusiasts. But nevertheless, we have to start somewhere and if we don't start doing, we can't get better.

#### Slide 6

With that, we've been working on diversity, inclusion, and equity since 2016 and we started that work when we had very good data cementing the fact that we were doing such a poor job in various aspects of diverse representation and clinical trials, such as race, ethnicity, sex, gender, disability, or accessibility of those trials, age at either end of the age-spectrum, multi-organ dysfunction, and rural/urban representation - and we really wanted to see what we could do to address this.

We had a work group of about 80 people working for about 3 years, and then the summer of the George Floyd murder we presented the first iteration of the work, and that was also accompanied by a number of tools. We have since made a website available with the information and a toolkit, and you'll see that the Equity by Design Metrics Framework is now a part of that website.

We didn't stop at that point but went on to really try to unpack all the different aspects of addressing diversity, inclusion, and equity and clinical trials- starting with participant and community engagement and education, and thinking about workforce development, so that we really empowered a diverse

workforce and provided opportunity for growth. Then thinking about the specifics of study design, and the eligibility, site, selection, and feasibility concerns that really impact whether or not at trial is going to be available for everyone. And then study conduct, which, of course, is incredibly important. Data standards and analytics, roles and responsibilities, and also genetics and real-world data. We took a pause and then started again with further issues in diversity and inclusion, specifically things like translation, the world of the IRB, and disability. All of which is on our website for your review.

We also have done a 6-part training session, which will be available shortly. It was done live, but the training session is available now, and we have the tools and resources for the IRB and investigators and have worked on disability and really worked on health literacy and clinical research and have resources for that.

But all of this depends on us being able to come through with a way of evaluating whether we're making progress or not. We can give, and we can all believe in this, but unless we move from talk to action and if we understand whether we're making an impact all of this is sort of good to have, but it needs to be implemented.

#### Slide 7

With that, we really started to think about who's responsible for making change, and the more we thought about it the more we realized that everybody involved in the clinical research enterprise from sponsors and regulatory agencies, CRO's, research institutions, principal investigators and their study teams, healthcare professionals, providers, community-based organizations, the participants, and ethics committees - everyone has a role, and everyone can make this better and can really commit to doing things differently tomorrow than we did yesterday. That learning from each other, listening to each other, really thinking about how to make this real in the work you do every day, requires transparency.

What works? What doesn't work? What should we know? What haven't we thought of? How do we approach this?

And it takes us working together, talking together, and learning from each other. But we also realize that it takes a real rigor of measurement, tracking and reporting. So that we can know not whether we *think* we're doing better but whether we *are* doing better, and that involves a really holistic approach to the evaluation of diversity, inclusion, and then, importantly, of equity and justice. And what you'll hear today is the efforts that we've had to create a framework which is intentionally broad. It's intentionally available to all organizations not just a clinical trialist or the clinical research; but all organizations dedicated to clinical research.

And changing this to think about: What are we working on today? What can we measure? How can we understand what is important for making change, track it, improve it and move forward? With that let me turn it over to Willyanne DeCormier Plosky and she'll introduce the Framework for you.

#### Slide 8

Thank you, Barbara, and thank you to everyone who's taking the time to be here this afternoon. It's wonderful to be here with you. My name is Willyanne DeCormier Plosky, I am a Program Manager at the MRCT Center. I am presenting this work on behalf of the team at the MRCT Center which includes Laura Meloney, Hayat Ahmed, Sarah White, and Barbara Bierer.

### Slide 9

I wanted to give you a little bit of the background into the Equity by Design Metrics Framework.

As Barbara mentioned, the impetus was the inequitable participation in clinical research and inequitable health outcomes which were well known but became much more clearly prominent during the Covid-19 epidemic. She did show the Diversity, Equity, and Inclusion Guidance Document which was published in 2020. It includes also an extensive toolkit. For those of you that have not seen it, it's about 400 pages and can be downloaded from the website here, or purchase from Amazon.

And then just as Barbara was saying- we had all of this momentum and lots of great discussion around diversity, equity, and inclusion, but we were really trying to think through: How do we move forward in terms of actionable approaches?

### Slide 10

Following the publication of the Guidance document, in late 2020, the MRCT Center convened representatives of professional, academic and patient advocacy organizations to form the Diversity, Equity and Inclusion Roundtable, which we'll just refer to as the Roundtable henceforth. The Roundtable expressed a need for better planning, goal setting, and understanding of processes for accountability and transparency around diversity, equity and inclusion, and expressed that there really aren't available metrics at the moment that can provide guideposts for measurement and comparison of progress for diversity, equity and inclusion.

### Slide 11

I just want to give recognition to the Roundtable. You can see here listed the organizations that were participating in the Roundtable, and to note as just said in the disclaimer from before, that this participation was in their individual capacities and not representative of an endorsement from their organizations. Many thanks to these organizations. We also had several external organizations that helped to review the Metrics Framework as well.

### Slide 12

So, how did we begin this process?

One of the ways is that we went back to thinking about really, what do we mean by diversity, equity, and inclusion? And I love this slide, because I'm a visual person, and I find it very easy to see where you kind of have the little guy and the blue jumper, and the guy and the red jumper and you can see how one is getting the apple, one is not. And so, we have these measures to move towards equity, where you see putting up the ladders and the different size of ladders, so that both the guy in the blue jumper and the one in the red jumper can actually reach. However, one can reach more apples, and one less, and thus we want to think about how we're trying to move not just toward equity but also towards justice. You can see in the last picture where this tree gets righted, and both had equal access to the apples on the tree. I just think it's a great representation, and it's something always to keep in mind- that we're trying to think through not just short-term goals, but also our long-term goals.

### Slide 13

As we worked together with the Roundtable, we brainstormed lots of different metrics, and I would say looking back to the analogy of the past slide some of those metrics were really “forests”- like very large encompassing measures.

Some were trees and some were leaves- very, you know, specific measures. We did recognize that we needed both quantitative outcome measures and then qualitative measures to show- okay, you have this outcome - but how do you get there?

We really need to identify the steps of that process. We brainstormed this all. We put it into this beautiful Excel spreadsheet, shared it with the Roundtable, and they diplomatically said, “oh my goodness, too much”- like this is just a morass of measures. So, we said, “Okay, great. Thank you for the advice. This is incredibly helpful. Back to the drawing board...”

#### Slide 14

We took a step back and reoriented, thinking about key themes within the diversity, equity, and inclusion process. So, we developed the 7 key themes that you can see on the slide. They start with commitment, leadership, and resources. We call these the foundations- institutional and study metrics for diversity, equity and inclusion and clinical research. 360-degree partnerships and communication- really if you don't have that community engagement, it's very difficult to get this process moving. And onto education and career opportunities, which we call workforce development. Strategies for inclusion of diverse participant populations which is around things like developing your study protocol and eligibility criteria and all of those kinds of processes, and then really bringing it around full circle- to reviewing what you've done, what your measures are, assessing if you've had any kind of negative externalities, and developing lessons learned. And then, how are you going to disseminate this out and advocate for progress in the future?

#### Slide 15

You can see that one of our biggest challenges during this process was to try to “frame” the framework. We have a number of these measures- as you'll see once you open the framework that it's extensive. How do we communicate this and develop it in a way that is digestible to different audiences? We basically put the Metrics Framework into layers. So, what you can see first on the screen is the topmost strategic layer where we have these 7 key themes. Underneath that we have an additional layer which is going to get into what we call tactical level measures, which are really breaking out the bigger strategic level measures, and then we get into more details in the operational level measures. We also really needed to develop a graphic representation of what this meant, so that people can share it and say, “oh, we're really interested in diversity, equity, and inclusion and here's a snapshot,” so it's not super overwhelming.

We developed, as you can see, this this Equity by Design wheel. This is the branding for what we're going to be doing. We really thought about developing a clinical research community. You can see the house and how each part really starts to shape the construction of that community for diversity, equity, inclusion. We have the strong foundations, the clearing paths and assessing and re-engineering. Finally, we also developed a user guide that is on the website, which is launched today- to help people navigate through the metrics framework.

We tried to make it as intuitive as possible, but probably it does need a little bit of guidance as you walk through.

### Slide 16

So, as you get into the metrics framework you will see that there's one theme per page. We did that, so that you could see kind of everything for that theme at one look for people who like a snapshot view. We developed quantitative measures that are below the theme. Currently only 4 of the themes have quantitative measures, but we are working to see if maybe we can develop them for all the themes.

Just to note: quantitative measures that are listed in the Metrics Framework are not a one-to-one relationship with the qualitative measures. Basically, if you have a quantitative measure, for example in Theme E, which is around inclusion strategies, that says number of participants screened, and you have another one that's around number of participants retained in the in the trial, really, those measures are an outcome of many different processes that are going to be the qualitative measure. So, you can't have a specific one-to-one relationship. We also give it examples of potential ways to kind of break down the quantitative variables. You can see for example, if you're looking at people screened, you could disaggregate by age, race, sex, gender identity for example.

We also put the variables into categories of regularly collected variables and additional variables, just so it wasn't overwhelming. And then we have qualitative metrics at 3 different levels that are increasingly more specific. These measures are intentionally broad, so all stakeholders can use this metrics framework. And they are not set in stone. I just want to say that from the outset these measures are not meant to be something where you take this Metrics Framework and say, "I must do exactly what's written here." They're really guideposts to kind of guide thinking and prompt thinking around what measures you could potentially use.

### Slide 17

This is a little bit of a snapshot of what you would see on a page. This is Theme E. You see that the theme name is listed at the top. Then we have a description of the theme which I have abbreviated for this slide. But basically, the description says what is in that theme and what's in other themes. Because a lot of the feedback that we got was that people would say "great, I'm looking at this theme, but why isn't X, Y, and Z in there?" And so, it gives a preface that some things are in other themes. And then below the description, you see some of the quantitative measures, and some examples of how those could be disaggregated. Below that, we have the strategic level of the qualitative. You see the main level there for E1: The study protocol drafted to be as close as inclusive as possible.

Then they're broken out- each strategic level measure usually has 2 to 3 technical level measures to really break it down. And then we get into what we call the operational level, which is getting into more of the details for people who are in the operational side of this, who really want to go into the details of how you get to these qualitative measures and quantitative outcomes. So, in the metrics framework we have one example per theme of how you could do one of these operational level kinds of breakouts.

### Slide 18

How we ended up doing this is we created standardized prompts that kind of drill down in a logic model format from the quantitative measures and the tactical level qualitative measures associated with those so really trying to generate thinking about who in your organization is responsible for that process? Who

are they engaging with? (Which is incredibly important, particularly when you're working in community engagement space). What micro-level budget are you using (so not the whole institutional level, but which specific resources do you need to get involved at the project or department level)? What actions are you doing to support the development of that product or process? What is the metric is focused on, and then where will the intended audience engage with the “what”?

### Slide 19

You can see here is an example of how this is broken out. On the left, you have the quantitative outcomes. Then drilling down into the qualitative outcomes and measures. And you can see here we have eligibility criteria we're focusing on and really thinking through all the way back into what we're talking about. Where are you engaged with eligibility criteria? What kind of activities? And then, who would be involved?

### Slide 20

The metrics framework has been posted today to the MRCT website. It's brand new. You can go to the website, and you can find the metrics framework, the user guide, and then there is a blank, editable PDF of the operational approach.

We would absolutely love everyone to test the metrics framework, to develop their own operational approach examples, and to give us feedback about how this is working for you.

Lastly, just to note that we're going to be working to create an interactive web version of the metrics framework where you could go into that circle that you see on the website, be able to click on the different themes, and then drill down from there. We also have resources for example, to support some of the information that's in there. For example, how other organizations have done specific parts of the metrics framework.

Thank-you, I'm going to turn it back to Barbara.

### Slide 21

Thank-you so much. So now we're going to move to a panel discussion. Just to remind you: please put your questions or comments in the Q&A or in the chat and we'll try to get to them. But let me start by asking Yasmeen, the Director at Faster Cures at the Milken Institute, to introduce yourself, to describe your role, and to comment on what the Faster Cures has done to promote diversity, equity and inclusion. I also really want to thank you for all of the work you did with us on developing this Metrics Framework as the rest of the Roundtable that we so appreciate.

### Ms. Long

Thank-you Barbara and good afternoon, everyone. I'm Yasmeen Long, the Director at Faster Cares, which is the center of the Milken Institute, and the Milken Institute is a nonpartisan nonprofit think tank. At Faster Cures, I lead our portfolio of work focused on achieving health equity across the biomedical research ecosystem using a multi-stakeholder approach, including how we approach diversity in clinical trials, how we invest in research, community engagement, health research workforce in that pipeline, and then engagement with policymakers. About a year ago we convened an advisory group of experts across stakeholder groups and developed an action plan for researchers, including academic researchers, patient advocacy organizations, funders, disease specific organizations,

biopharma, and federal agencies. And our focus now is to think about how we will implement that action plan, and recommendations that we developed in late 2021, and how that can be implemented into practice and processes for maintaining these efforts for the long term to achieve diversity and clinical research and trials.

So, I am very proud to have served on MRCT's Roundtable Planning Committee, which was a fantastic experience, and really a great resource for this work. So, I think this framework is really an innovative approach for standardizing this process, and I think the framework provides a mechanism for not only just measuring equity, but how this can support how researchers can demonstrate the impact of diversity, equity, and inclusion and research, and serve to measure accountability to maintain these efforts for future research and protocol design.

So, I'll pause there.

#### **Dr. Bierer**

Thank you, that was perfect.

And, Rodrigo Garcia, let me introduce you. And just so the audience knows, Rodrigo is one of the people (and the team he leads) who really put the put the framework to the test and tried to apply it. And he is here to say that he survived, and to tell the story. But let me first ask you if you could introduce yourself, and what work PPD is doing in this in this domain.

#### **Dr. Garcia**

Sure. Thanks Barbara and thank-you to you Willyanne and the MRCT team for giving me the opportunity to test the model and to contribute to something that we are all passionate about.

My name is Rodrigo Garcia, and I am the Vice President of the Patient Solutions Group within PPD, part of Thermo Fisher Scientific. One of my functions with my team is to bring diversity of patients in clinical trials. I am extremely proud that my team is completely diverse and has come from the sponsor side, like myself, before joining PPD. We also have people who are coming from the site perspective- they've been there and done the work. In some cases, some members are registered or licensed social workers. For us, that's extremely important- we need all different perspectives. What we do is we want to work very closely with all the key stakeholders. Obviously internally within PPD, but also externally with the sponsors. We decide, with the academia, and with the experts, like MRCT. Because, we may have great ideas, but we learn substantially when we actively listen, and we learn from the same matter expert from the organizations that are driving this.

In the case of the framework obviously I'm a big fan of the logic model from MRCT. I used it before for putting together the strategies related to diversity, and I like how it takes you, virtually hand-in-hand, and it walks you through the process. And when I was approached by MRCT to say, "would you be open to go again through the journey now, with this new toolkit?" I said absolutely, and I'll share my experience. But I would say it resonated very well with me. I need to confirm that everything that we're doing at PPD- you know how we're doing it makes sense- but you have to look it from different perspective.

You have to look at it thinking about who is going to do this? When? How? How are you going to measure success? And so, we're constantly challenging our ourselves (PPD) when we're working with our individuals or stakeholders but having the opportunity to use these this framework has been a fantastic experience. So, I survived, but I love it. So, thank-you again, Barbara.

#### Dr. Bierer

Thank-you. So maybe you could unpack it a little bit and we'll start with you Rodrigo. Where did you go? You know? How did you take it? And how did you really apply it? What did you find useful? And then, maybe more generally, although we could come back to this- What metrics have you used in the organization to see how you're doing?

#### Dr. Garcia

Sure. As Willyanne mentioned, there are the different themes. And then I was drawn immediately to 2 themes so probably I'm totally biased towards those 2 themes. One was all about the metrics, and the other one was about being strategic right, which is Theme E- it's strategy. How are you going to do this? So how I applied it is as we saw in introduction. Right? It has the quantitative self-explanatory. Then the qualitative. And then for the qualitative ones, we have the strategic, tactical, operational, and you know, it really tested me to think strategically. For example, for the Theme E for the strategies- study protocol design. How are going to do this to make sure we're being inclusive? So, that sounds logical. But then, the model gets tactical here, "this is how we recommend it". And then, as Willyanne was saying, not everything is set in stone, but it takes you to say, well, from protocol design let's start from the beginning, and then let's go to the details with an end in mind.

And once you do that, you say "okay, tactical is great but let's take it to another level". Now operational. What do we truly mean if we're going to say that the study design is going to be patient center-ed? The document tells you to say that's important of course, but how are you going to do it? And more importantly, who are you going to bring? Because yeah, in my case I'm sure everyone understands I cannot accomplish anything on my own. I need to work with my team. And something that I like very much about the framework is it is a little vague because not every company has the same titles, so we're trying not to put any titles per se. But we're trying to say at least, you should consider which organizations should be involved to enable you to have a successful inclusive protocol design.

But then, not only that it says, if you're going to include these different stakeholders (broadly) what are you going to be asking from them to help you to do this? And then again, you can go very nitty gritty. It helps you not just to say we're going to have a great protocol design which is going to be very patient centric and inclusive. How are you going to do that? This is how we're going to do it. And who is going to help you to do that? And then finally how are you going to measure that? So, if you're able to follow all those steps from my perspective at least, it's going to be easier internally, and externally as well, to structure the process to implement and to learn constantly. That's how I started to apply the very interesting Theme E, which is from my perspective, one of the most important ones. Let me stop there.

#### Dr. Bierer

Thank you, that's terrific. And Yasmeen, let me ask the same: What metrics do you use in Faster Cures? Or would you recommend? And have you established organizational metrics? Or how are you approaching progress?

### Ms. Long

I looked at it more from a sort of holistic and general approach. As an organization who conducts trials, how may we approach this? So, going through the framework, one of the main themes that I focused on was the strategies for inclusion of diverse participant populations in clinical research. And that theme was specific to the study process. So, I'll speak from experience and testing that out, using a holistic and general approach. But I focus on the following metric- study protocol drafted to be inclusive as possible- because this focuses more on the development of the strategies for implementation of diversity, equity, and inclusion and design of study plan. So, it really gets you to think strategically on how to make this work, for lack of a better word.

I took it a general diagnostic approach because we don't conduct clinical trials at Faster Cures. However, we do convene thought leaders and experts to advise our health equity and clinical trials portfolio, and this includes, how we eliminate the barriers to clinical trial diversity. How can we support those organizations who are trying to achieve that? And really to dismantle those barriers that prevent equity from being embedded in a research study design by thinking critically. The framework breaks it all down, so to speak, and we can really drill down those parts.

I will say that my favorite part of the framework, and one that I think will be the most helpful in thinking this through is determining the 'whom', and the 'what', and the 'when' and the 'how'. And we go over that in the framework, but I think, at least in my experiences, really thinking critically and strategically on who that is, who those partners are, who's going to execute it, and how you're going to do it right. Thinking of that altogether, at least in my experience, is sometimes that is thought of after the research, or after the protocol is designed. So really thinking that in the beginning process. And then within the framework, the corresponding quantitative measures, such as the number of participants, and most importantly, I think, the inclusion of additional demographic variables such as language, disability status, education level, income, and whether the participant has health insurance or not. Those are variables that typically aren't captured, and I think that they're very important in the analysis, and disaggregation of data. So, these variables, again, are not always captured, but the framework allows for the research designers to really think outside the box, so to speak, when addressing diversity, equity, and inclusion and the research process.

### Dr. Bierer

Thank-you. That's really incredibly helpful.

There is a question a comment in the Q and A box- Angie Chen says that she just checked out the toolkit and "it's amazing, with lots of practical tools to use. I can see already many of them that I can use directly in my daily work. Thank-you."

One of the things that I wanted to ask is when we worked at the Roundtable, I for one had a natural inclination to be as specific as possible and to say, "Okay, let's adopt this common set of metrics, and everyone sign on to this." And that now we will march forward and learn if you're more successful than me in this domain- what have you done that's better or that's different and what can I learn? And as we work through this, we realize that every organization is different. This, you said, Rodrigo. Everybody is taking different aspects as the first piece that they want to work on. You know some feel critically that you can't make progress until you've really attended to diversifying the workforce. Some feel that they can't make progress until they have the commitment of leadership resources to do the work.

Some of these other things, we stepped back and said, ‘Okay, let's present something that is comprehensive but really flexible, and allows adaptation to all of the different audiences, organizations, entities, and individuals.’ But that leaves open the question of whether we think that there could be a common set of metrics. Should there be a common set of metrics? How do we help each other? We did not at the MRCT Center and the Roundtable feel that it was our position to decide on those, and say, “Okay, this is what we're going to say nationally- every pharma company, every academic, every community health center should sign on to this,” because that's not where we are as a society. But, on the other hand, how do we now begin to learn what works? Is that always going to be an internal process?

#### Dr. Garcia

Yeah, Yasmeen do you want to go first?

#### Ms. Long

The answer is, yes.

That's the short answer. And I'll just say this quickly, so you can jump in Rodrigo. But, when I mentioned in framework, when we talk about the who, the how, the what. I think one thing I really drilled down- I think that for the ‘by whom’ and ‘with whom’- organizations can be rather successful on that as well as the ‘where’. I think the ‘how’ and the ‘what’ is really the challenging part. So, thinking of- and again we talked about community engagement and these are internal and external conversations- but internally thinking of not just reaching out to communities, but establishing those relationships, establishing that rapport, and establishing that trust, so that it's a collaborative process and they bring their significant expertise that should be valued. So, obtaining their feedback on the design of the research, you know? As well as the eligibility criteria.

And again, initiating that community engagement piece earlier in the process, and then also thinking on the accountability side is having research grant award review committees hold researchers accountable for ensuring that community engagement is required in the study design and not community engagement where there's just bobble-heads at the table. Going in and developing relationships with these leaders and building that over time- I think that's part of the ‘how’ that that could be challenging, but really has to be thought out. And then the ‘what’ includes listening to lived experiences right. What do you need to be able to participate in research? What would be most helpful for you and how would you disseminate that to the community? And listen to those barriers.

And then, depending on where an institution is, let's say an academic institution, the investigators may have direct contact with community leaders, and can already establish that rapport and trust at the beginning of the research development- not once the protocol has been completed, and it's like “oh we didn't we didn't think about that”. No, when they're thinking of writing the grant that's when you want to think about that. And being intentional with targeted and engagement-focused empathy and understanding of lived experience of community members to be a part of that research and establish that trust. The ‘how’ and the ‘what’ I think are really important aspects of the framework that can help organizations and researchers drill down what that process should be so that it's authentic and genuine.

#### Dr. Bierer

That's a great perspective. Thank-you so much, and Rodrigo do you want to answer?

#### Dr. Garcia

Sure. It's a great question, it's very difficult. As you said Barbara. I think our role, I would say, is to ask the questions that maybe a lot of people don't want to ask within their organization because it's a difficult question. To say for example, you mentioned the metrics and the question of are we the ones that are mining different variables and which going to be asked to patients or be gathered from patients about age, race, and ethnicity. But from the CRO perspective, I see how different sponsors are taking it. If you will more aggressively say "no, those are the standard ones, but we're going to be more aggressive and we're also going to start collecting data disabilities, veteran status, etc.", because it's part of that whole social ecosystem that we live in- those social determinants of health.

I think there's still a lot of variability, but at least the momentum is that people are starting to ask those questions internally. In the framework- one of the themes talks about data, and it talks about metrics. And one of the first questions is, "Do you know the metrics within your organization?". And I think that's the first question if you're part of a sponsor, or if you're part of a CRO, or you're for a biotech- it doesn't matter- wherever you sit in this ecosystem, you need to know how good or bad are our clinical trials right now from the diversity perspective. That will be the first key question, because sometimes in organizations you will realize the systems were not put together for answering that question in a simple manner. Then you must start saying, "Okay, we have to make sure we're collecting this consistently". We start measuring this in order to determine where we are, and then we can determine where we want to go. So, I think the framework helps to start asking those questions, and then to determine how good, or in which step we are, if you will, from 1 to 10. And then you can start getting more targeted about- "okay, we're going to start collecting this, we're going to start standardizing our analysis, so we will know how good or bad we are, etc". From a CRO perspective, it's not my role to determine, but it is my role to advise sponsors in saying: "This is what I recommend. Do you know this? Do you know where you stand?" And now, I see more and more sponsors at least saying that we're ready to have that conversation. We know we're good or we know we're not there yet, but we know we're going to get there. So that's really exciting to see that finally coming.

#### Dr. Bierer

I want to annotate two points that you made that are embedded. One is that some of this data that we're collecting and recommending that we collect is not to power trials to compare differences. It's in order to make sure that everyone has access. It's a social responsibility. It's not necessarily a scientific question to say, "are these different". So, I think that's really important because a lot of people will say, "look, we're never going to have enough people with 'X' disability plus all of these intersectional identities to do a scientific study on that." But nevertheless, we'll be able to say people had access, and over time. Of course, if we're able to find common data metrics, we could have interoperable data and follow-on real-world data. So that's one point. The second point I want to make that you made so clearly is at the end of the day, if a trial has appropriate representation, or doesn't, it's not one organization's success or failure. It's everybody working together. And therefore, it's not a company that succeeds or doesn't or an academic center that succeeds or doesn't or a community that has enough power or doesn't. It's all of us bearing in to change this. So, I really appreciate your perspective.

There's an interesting question here in the Q&A.

“To be inclusive of all stakeholders, or to include all stakeholders, how are quantitative measures best obtained? Tracked by fiscal year or calendar year? And let me just answer the way I would answer this. I think, as with many things it depends on what you're measuring, and how you're going to use it. And actually, in a clinical trial you might be measuring at each annual review- not necessarily either fiscal or calendar. If you're looking in organizational performance, and each member of your group has metrics that they are to perform to- they have goals. Maybe it's at their annual review. So, it's very much thinking about “What am I measuring? How am I going to use the measure? What am I going to do with what I learned from it? And how do I go forward from there?” So, I think that's a great question to sort of illuminate why this is flexible in the way that it's flexible and thank you for that question.

One more question: Where do we need to go forward with this framework? What are the next steps? How should we deepen it?

We've got some examples of logic models, but I wonder if maybe I could ask Willyanne to say what's on your plate as you think about it. And then we'll go to Rodrigo and Yasmeen.

#### Dr. DeCormier Plosky

Thanks Barbara. I think one thing going forward that would be incredibly helpful is, as I mentioned before, that all stakeholders look at the framework and start to digest it, and to send back their feedback and let us know- Are the appropriate measures in there? Are they comprehensive? Would you use them? Also, as you test out operational approaches and start to fill in the logic models, that process- and Rodrigo I'm sure could speak to that- is incredibly instructive. To understand, particularly, for people are coming from all different kinds of perspectives, really what they're looking at, and how they're utilizing the framework is incredibly helpful. And if people would be willing to share their thoughts, particularly the 'how', as Yasmeen said, and the operational approaches, that would be terrific. As we work to develop a web framework, we can append those (and anonymize them if need be), and say, “here's examples of how different organizations have been using this and thinking about it.” And we've been thinking about developing a library of all different kinds of things you could kind of slot into your operational approach. Different 'how's' that people have used before, different 'who's', you know, that would be helpful to filling those out. So, those are some of things on our plate- thinking about how to operationalize this. And I think the issue around standardizing is an ongoing one. To be able to compare potentially across organizations. But it's going to be a little bit further down the road.

#### Dr. Bierer

Yeah. Do either of you want to think about or address that?

#### Ms. Long

Yeah, just piggy backing off of what Willyanne said and thinking about number one: I think the framework will be helpful, you know, for us to use at Faster Cures as we continue to focus on implementation, policy engagement and dissemination of impactful recommendations towards achieving health equity and diversity and inclusion in clinical research. And using that framework to, as Willyanne said, collect feedback from the research stakeholders in the ecosystem. I think that could help to standardize the process. But also, to go back to community engagement, we think about participants - who were part of the research, and were enrolled in the research- but also us as stakeholders, engaging with each other and what methods work best? How can the framework be used to improve those methods?

And again, I think the beauty of this is that it really gets you thinking in ways that you normally wouldn't think of before. And that goes back to the 'how'. Because people want to know: "How do you do this? How do you do that?" But then, I also think it's our social responsibility as well to engage with each other and determine if the framework works for this type of organization. A small cohort of pilots, so to speak, that really help to not only show how usable it is, but also determining that impact. And then I'll just say lastly that right now, there aren't strong metrics to measure diversity, equity, and inclusion in research and that can be used as a mechanism to increase funding or for return on investment. I think that's where some of it can help align some of the incentives for researchers and organizations to do that as well. And sometimes I think that's a priority for certain organizations. There are many great ways to use it, but I think that each organization, whatever their priority is, they're going to use it differently. But, as long as there's an approach to be able to capture that information and analyze it for improvement, I think it is a helpful resource.

#### Dr. Bierer

Thank you. Really good point. Rodrigo?

#### Dr. Garcia

I completely agree. I think, from my perspective, they should just put it to the test. Use it and give it a try. Some of the things might not be a 100% applicable but I would say I would be surprised if you can apply 75% of the material, and it will guide you. And again, some things might not be totally applicable- it's okay. If you cannot do the 7 themes right away, it's okay. At the end of the day, this is a journey. So, I would recommend people review it. Consider number one: senior commitment. Okay, we already have that- perfect! Don't disregard it, because the document says that's great that senior leaders said they have a public commitment, but internal staff at organizations- are they aware of that commitment? If the answer is yes, fantastic! There are going to be ambassadors to this work. If they don't, then you have to educate them about the commitment coming from senior leaders. And this is why we have to invest extra time and effort when we're doing site visibility, because it aligns to our commitment. So just give it a try, put it to the test, and I'm sure you will find it extremely useful throughout the journey of bringing diversity of patients and health equity in clinical trials.

#### Dr. Bierer

Well, what a wonderful way to end this it's like such a great endorsement! Thank-you. And I have to say that one of the things that I'm looking forward to is really all of us committing to long term sustained change. We're going to need to figure out how to standardize the data, and really respect it, and educate the civil society on why it's important. It's not to use this against you, it's to use it to empower you. And working with one another to address the barriers that are beyond our control- things that insurance status. If we don't as a society address some of these questions, we'll never have access equitably. And if we don't have that, then we can't possibly ever be in a position of saying that we have achieved justice or equity in an appropriate way.

And only by having that data together and sharing it in a constructive way (not a critical way- this isn't the kind of 'we've got you'- it's how can we help you). And taking that perspective forward. It took us 400 years to get here. I trust it's not going to take 400 years to be better. But I don't think this is something we're going to see as a quarter result. I really appreciate the depth of thinking that went into this want to thank you, Willyanne, and the Roundtable. I also really appreciate the work of Faster Cures

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in keeping this top-of-mind as a policy and practical challenge that we're going to address together and being among the leaders in making sure that we have a crisp message and continue to push on that. And organizations such as PPD that have really made the commitment to sustain change.

So, thank-you. We look forward to hearing from you. Do check out the website and the toolkit. And Willyanne is looking forward to your emails. Thank-you.