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GSK plc - Special Call - GSK plc

Tuesday, June 6, 2023 10:00 AM

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Jimmy Muchechetere, Aude Scheuer, Unknown Analyst

Frannie DeFranco Executive

Hello, everyone. Thank you so much for joining our investor education event on clinical trial diversity. I'm Frannie DeFranco, a member of the Investor Relations team, and I'm honored today to introduce you to our guest speakers: Alberto Fernandez, SVP of Global Clinical Operations at GSK; and someone who many investors may already know, Dr. Kimberly Smith, SVP and Head of R&D ViiV Healthcare. Here is our agenda for today's call.

First, Alberto will provide an overview of the importance of clinical trial diversity to patients, regulators and investors, then we'll talk about the research GSK has published on this topic and how we see that supporting industry efforts in this space. Then Kim will join us to provide a case study on the benefits we saw from our applied approach in our studies for a long-acting prep with cabotegravir.

With that, let me hand it over to Alberto.

Alberto Fernandez Executive

Thank you very much, Frannie, and hello, everybody, and welcome to this session in which we are going to explore the importance of clinical trial diversity, on what GSK is doing in this emerging area of interest.

As you have already heard from our CEO, the ambition of the new GSK is both positively impact the health of more than 2.5 billion people which is 1/3 of the current worldwide population, and that obviously includes a lot of diversity. In a company that operates globally with such an ambition, diversity, equity and inclusion are core to our purpose of getting ahead of disease together. We have an obligation to plan and execute well on the DEI strategy, not only internally for our workforce, but also externally.

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In this competitive and evolving landscape, we must ensure that our science incorporates and represents such diversity in the population we are targeting, and it cannot be left to random planning. A scientifically appropriate representation of diverse patients in clinical research becomes critical for advancing our understanding of new medicines and vaccines to ensure the biggest positive impact on all possible patients. Bringing diverse patient population in our clinical trials, taking into account race, ethnicity, gender and other relevant factors of diversity will ensure that our data represents outcomes closer to the real world.

Let's go to the next slide. Let's take first a closer look at the regulations. What is already in place as a guidance for clinical trials first in the U.S. The Food and Drug Omnibus Reform Act was enacted after the pandemic in December 2022, and that has been the first guidance we have received in that respect. We assume that all the regulator agents -- regulatory agencies will come with more guidance later on.

The legislation in the U.S. requires that the FDA go through several steps before finalizing a formal policy in this area. And GSK will be engaged in the forthcoming period and participating in clinical trial diversity workshops to share our experience during the next phases of the FDA consultation.

Notably, it's important to remind everybody that while FDORA required guidance will formalize the regulatory requirements, the FDA is already calling for submission of diversity action plans in accordance with the existing guidance. It means that although there is no formal regulation, actually, the sponsors need to act on it and submit those plans proactively. And the FDA is also coming with comments on guidance on those plans. So we continue working with them. With this legislation in mind, let's look at the journey that GSK has been on to embed inclusive research into our clinical trial processes.

We go to the next slide. What we can see here is that over the last 15 years, we have been learning how to apply the science behind clinical trial diversity. Sometimes, it has been about the road. And definitely, over the last 4 years, it has been an inflection point, I would say.

Initially, without the process in place, something which was widespread across the sector, many studies enrolled just available participants and not always in the most appropriate proportions to represent the diversity. In our recent history, we know that 2 of our large brand name products, the vaccine Shingrix and the biologic Benlysta, transparently did not initially enroll enough minorities in their studies, and we were made very aware by the regulators about that part.

We realized after that feedback, that this was important. So we learn from that. And we learn what we could do better. We also learned a lot about why it was important for everybody, especially the patients that we do much better in this area. We saw that even as we are still learning, our intention to do better showed promise.

We instituted a dedicated clinical trial diversity team, and as you know, we have recently published results for our RSV vaccine that not only are very positive, but also we can show that this data can apply to many kinds of people.

Now we are qualifying those learnings into repeatable processes so that we can make clinical trial diversity business as usual, which is the way it should be. Some of the key moments in

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that journey is first in 2018 when we had the first dedicated clinical trial diversity lead. And from this point in time, that leader, which was a team of 1 started interacting internally with our own teams, externally with the community, with regulators and with investigators to ensure that a holistic understanding of what was required to -- and has this capability at GSK was necessary.

Then COVID pandemic started in quarter 1 2020. Although, as you all well know, these were very sad circumstances. COVID served an accelerator to finally develop the specific strategies to increase clinical trial diversity. We realize that we have to do more to ensure our programs would contain right diversity, especially in the U.S. but not limited to.

In 2021, we invested in increasing the global demographics and diversity team head count for greater impact. And we also invested significantly in technology to leverage the historical data and also the present clinical trial data to learn more about how we did in the past, how to learn from it in the future.

In 2022, the global demographics and diversity team started developing and implement steady level diversity plan requirements before subjects are enrolled in any large late-phase clinical trial. And also, they do and use epidemiology assessments for the feasibility in late phases studies.

Let's go to the next slide. This is obviously the journey, but it has not been free of challenges and learnings. GSK trials has shown marked improvements over the last 5 years with a specific focus on how to solve the challenge for patient eligibility. We are now refining, as I mentioned, our feasibility using real-world evidence in epidemiology data to ensure that our patient recruitment strategies are based on the epidemiology of the disease and not just on the raw availability of patients.

In order to access the right patients, we are working to enhance our access to clinical trials by having a more strategic site selection based on demographic and geographic analysis of relevant sites that could lead to underrepresented populations; opportunities offered to enroll in our clinical trial should they wish to, obviously.

We are also developing site cultural-based competence training to drive inclusive behaviors in the investigational side team. And also, we are putting together a focus on growing the number of investigators with diverse background. And that is more of a long-term strategy we have in place.

We have industry-leading coalition partnerships through peer review -- through that peer review study and the publication we have done. We have been approached by other companies and by different CROs to learn more how are we doing things and to make sure that they also start implementing those strategies. We are also addressing the inequity of access to trials and implementing processes to remove barriers of participations, and we believe that the utilization of decentralized clinical trials is one important tool, but not the only one. As I indicated, the geography and making sure that the awareness of the cultural differences are also brought into not only the community but also the investigators. Those are important components.

And above everything, we are also monitoring the progress with near real-time data tracking

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and to the monitoring of all those plans and how do we execute on them.

Let's go to the next slide, in which we are going to look quickly at our clinical trial, our study on clinical trial diversity. Our retrospective study on clinical trial diversity investigated the historical representation of U.S. based participants in GSK clinical trials. The study looked at all the clinical trial demographic data from 595 GSK and ViiV trials involving almost 110,000 participants from the U.S. in the period between 2002 and 2019.

The results published in the clinical trials, Journal of the Society of Clinical Trials, demonstrated that using the real-world epidemiology data rather than the traditionally used benchmark for the U.S. Census Bureau race and ethnicity data, would ensure clinical trial enrollment, reflects the populations better affected by the different diseases. This type of results will inform GSK and other clinical trial sponsors how to better design research to represent the diversity of the real-world patient populations, given that some diseases disproportionately impacts certain racial and ethnic groups.

Let's go to the next slide. We didn't stop by just setting the team, investing in technology, publishing our paper. We have also set targets for ourselves. In 2022, we established a new rating for our ESG targets, which is one of our corporate KPIs. And this measurement tracks our progress against key metrics aligned to each of our 6 focus areas, including diversity, equity and inclusion.

For DEI, we have aspirational targets for employment but also a clear goal that 75% of the Phase III studies initiated in 2022 would have a proactive plan in place designed to enroll appropriately diverse trial participants, consistent with the disease epidemiology. At the beginning of 2023, we already reported that we exceeded the target in 2022 with 100% of the Phase III trials, having those proactive demographic plans in place. And I'm very pleased to inform that in 2023, we are also on track to deliver.

If we go to the next slide, what we have learned during this journey is that we cannot do it alone. We need to collaborate, and we need to make sure that we got together with other companies and with other parties to make sure that we implement that at scale, not only for GSK, but for the whole industry.

So to make a meaningful progress on diverse participation in clinical trials, we really need that meaningful collaboration with regulators, with patients, with academia, with other biopharma companies and with a wider health care ecosystem so that together, we can achieve a share goal of better health outcomes for everybody. We are definitely committed to this approach. And to that end, we are working with a number of professional organizations, universities and contract research organizations, including those that you can see on the deck.

We're obviously welcome to open up even more collaborations beyond this. But now it's important that we illustrate how to make it real, how that works in realizing a real case. And I'm pleased to be joined today by Dr. Kimberly Smith, Senior Vice President, Head of R&D ViiV Healthcare, to talk through a case study to show how clinical trial diversity is brought to life to create a positive impact for patients.

Kim, before we get into that, can you let the audience now how working with others help to improve health equity? Over to you.

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Kimberly Smith Attendee

Thank you, Alberto. It is clinically important that we focus on partnering with the organizations and the communities that are impacted by the diseases that we seek to treat. And so I think that when we think about clinical trial diversity and health equity, it is important that everyone recognize that it's only equitable if we get everybody up to the same level, not just a little bit of an improvement for someone who's behind, but actually getting everyone up to the same level. That's the difference between equity and equality. Equity means getting --doing the work necessary, particularly for the folks that are behind to move them up to the same place as everyone else.

Maybe let's move to the next slide, and I'll talk a little bit about ViiV and our mission, and I will talk to you specifically about our clinical trials of our long-acting cabotegravir for prevention as an example of when you do all of those things that we talked about how you can get the results that you desire.

So to talk a little bit about ViiV, ViiV is the only company that's 100% focused on development of drugs for HIV treatment and prep. And so our mission overall is to leave no person living with HIV behind. And our mission in R&D is to leave no person behind in our research. So we include diverse populations in our clinical trials. That means the populations that are disproportionately impacted by HIV.

And in order to be successful at doing that. We need to have partnerships. We need to have a broader participant and patient and provider experience of bringing in new HCPs, researchers who are taking care of the populations that are disproportionately impacted. And we need to respond to the community. We need to hear the communities' voice and be engaged with them constantly in order to understand exactly what they need in new medicines.

And then we have to address the challenges of the past. Historically, there have been a number of egregious examples of communities of color in particular mistreated in clinical trial settings. And so we need to be prepared to address those and make sure that we are making folks comfortable and providing the right kind of experience when they participate in our clinical trials.

Next slide. So I want to talk a little bit about the epidemiology of HIV globally to set the stage for the understanding about why we took the approach that we did to our PrEP clinical trials. So if you look at the global population of people living with HIV, which is the pie chart on the left, you can see that 72% of the people living with HIV around the world are black. 19% are other races, and 9% are white.

Now on the right, you see people who have participated in Phase III HIV randomized clinical trials, and this is a survey of roughly 19,000 individuals. And you can see that 65% are white, only 23% are black and 12% other races. And so clearly, you see here that while blacks are disproportionately represented among the individuals who are living with HIV, they are not adequately represented in the clinical trials that study drugs for treatment and prevention of HIV.

Next slide. The same thing is true for women. So here on the left, you see the global

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population of people living with HIV. Now 52%, a little bit more than half of the people in the world living with HIV are women.

If you look over to the right, again, you see only 1/4 of the people participating in Phase III HIV clinical trials, again, that same population, as I described in the last slide, only 25% are women. So women are not adequately represented. And often, they are very poorly represented in clinical trials. And so there remain questions at the end of the trial because there weren't a number -- weren't enough women included.

Next slide. So what are some of the barriers for participation in clinical trial among racial and ethnic minorities and women? I'll start out most specifically with HIV stigma. We know that HIV is a tremendously stigmatized disease. This has not changed over the last 40 years of the pandemic.

HIV stigma still lives with us. And so participation in clinical trial requires that individuals really be reached -- reach out to these individuals, and you give them a comfortable environment where they do not feel stigmatized. And you make sure that you're making all the steps necessary to keep their privacy and make sure that they don't have worries about the disclosure of various HIV stats.

Historical mistrust in the medical center, we all understand the things that have happened in the past that have impacted the trust of individuals in the medical center -- in the medical system overall. That has played a significant role in individuals being interested and being willing to participate in clinical trials. And we know many of the examples like the Tuskegee experiment in the past. So mistrust in the medical center is something we always have to be thinking about and looking to overcome.

But also just are we making our trials accessible to people? Are the clinical trials in the places where people are seeking care? And the answer to that is actually often it is not. And so clinical trials often take place in university settings and don't represent individuals who may need to come from a long way to get to them. And the ability to make sure that you have trial sites and hours of operation outside of sort of traditional working hours, we'll make it more possible for individuals who are working class or who work jobs that don't have the level of flexibility that might be needed to participate in clinical trials.

So we need to find a way to design our trials and make them accessible in a way that we can get broader population.

And then medication concerns. People often are worried about what is this medication going to do to me? Can we do a good job of explaining what the risks are to people, helping them to understand side effects and helping them to understand the efficacy risk that is associated with participating in clinical trials. So making sure that people are fully educated, where we have an informed consent that people are really informed.

And then the opportunity. Do people get the opportunity to participate? If you ask individuals to participate, actually, that's the only chance that you have to get them to be willing to participate. Many surveys have demonstrated when they've asked African-Americans in particular, about participating in clinical trials and why they've never participated in a clinical trial, even if they're in a clinic where clinical trials are available. The answer is most often that

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they were never asked.

And so some of the biases that exist in some of the providers and investigators may assume that people of color African Americans in particular, don't want to participate.

And so we have to make sure that we ask and if we do all of these other things, ask them, make sure that they can feel comfortable, make sure that they can feel safe and protected in the clinical trials and actually do a great job of explaining to them what the values of the clinical trials are. Then I think we have a better opportunity to have people participate.

Next slide. So I want to talk to you specifically about our clinical trials, our Phase III clinical trials that enabled the approval of cabotegravir long-acting for the PrEP. So cabotegravir LA is the first injectable for HIV prevention. And so what HIV PrEP is basically giving an HIV medicine to individuals that are not living with HIV in order to prevent HIV from happening. And so cabotegravir for PrEP is now approved in the United States, Australia, Zimbabwe and South Africa.

And I particularly underscore that Zimbabwe and South Africa.

So the first approval of cabotegravir for PrEP just happened a couple of years ago. Actually, we launched at the beginning of this year, actually in the beginning of 2022 is when we launched this product. So it's notable that you see countries like Zimbabwe and South Africa listed as already approved. And that's because we've placed a huge priority on these countries because of the disproportionate impact of HIV on those regions. So our studies, our approvals were based upon HPTN 083 and 084.

So we partnered with the HIV prevention trials network for HPTN to design these studies and to operationalize these studies. And so HPTN 083 included 4,570 cisgender men who have sex with men and transgender women. There were 43 sites in 8 countries. HPTN-084 included 3,200 cisgender women at 20 sites. And those sites were all located in Africa.

And the reason why is actually illustrated quite clearly on the right side of the slide in the gray box.

So 1.5 million new cases of HIV occur worldwide every year. 58% of those are in sub-Saharan Africa, 63% of those new infections in sub-Saharan Africa among young women and adolescent girls. That means thousands of young women and adolescent girls become HIV infected every year. That's why we focus the 084 study on that population of young women and adolescent girls in sub-Saharan Africa, so that we could go to the population most disproportionately impacted.

Now with regard to the enrollment in the 083 study, we also wanted to reach a population that's particularly vulnerable. And so in the United States, we enrolled roughly half of the 083 study. So again, this is the study of men who have sex with men and transgender women. We enrolled roughly half of that study in the United States, and we mandated that 50% of the enrollees in the United States be black MSM. And that's because black MSM make up the largest number of new cases of HIV in the United States every year.

Roughly 50% of men who have sex with men become HIV infected in the United States are

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African American. And so this is a particularly important group to address.

And so we went at the population who needed this the most. And the results actually were quite outstanding. So the data showed that we had superiority in both 083 and 084. In the 083 study, long-acting cabotegravir was 3x more effective at preventing HIV than a daily oral pill. And in the 084 study, it was 9x more effective in cisgender women at preventing HIV acquisition in comparison to a daily oral pill.

So in both cases, the studies were stopped prematurely and individuals who are part of the study were offered access to long-acting cabotegravir. And those studies are now currently in the open-label extension as more and more of the countries that participated in the trial get approval and access to the medicines.

And speaking of access to the medicine, there's one more point. It doesn't make sense to study these populations and make a point about diversity in clinical trials if we aren't going to make the medicines accessible to those populations that are impacted. And we certainly have every commitment to do that. And so what you see is that last bullet on the right in the gray box is that ViiV signed the voluntary license agreement with the Medicines Patent Pool for Cab long-acting for PrEP, and we're joined by a number of stakeholders around the world to create a health coalition to expedite access to long-acting cabotegravir or -- really in all of those reasons that are disproportionately impacted.

And so I think this is a perfect example of when you plan ahead, you make the overall commitment. You partner with the community to make sure that your trials are diverse and represent the populations that are most impacted. That's when you can really make a difference. And I think Alberto made the clear point that he's not just looking at the demographics of the country. He's actually looking at the demographics of the particular therapeutic area that should guide you when you're making decisions about enrolling clinical trials.

So with that, I'm going to turn it back to Alberto to summarize.

Alberto Fernandez Executive

Thank you. Thank you very much, Kimberly, for sharing the work that ViiV is doing to improve our diversity of clinical trials, so most of the people impacted by HIV are included. Phenomenal work and I am very aware about -- how difficult it is, but it's absolutely the right thing to do.

So for everybody, as a summary, today, we have shared how we have implemented systems and processes and other challenges to ensure that we do the right thing for our patients. We put them at the front, at the center of the design of our clinical trials. And while there is still a lot of work to do, we believe that we are well positioned for future U.S. regulations and also any other regulations coming from any other regulatory bodies elsewhere in the world.

GSK is committed to applying the insights from this published results that I mentioned earlier, in an ongoing effort to improve diversity in clinical trial enrollment, and we know we are not the only ones. We are also committed to working with regulators, with patients, with academia, with other biopharma companies and with a broader health care ecosystem to

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have the biggest impact for patients collectively.

Thank you for listening. And I will now hand over to Frannie to lead the Q&A portion of the session. So over to you, Frannie.

Frannie DeFranco Executive

Great. Thank you so much, Alberto and Kim. At this point, we're going to open up for Q&A. [Operator Instructions] Jimmy, I see that you have the first question. So I'm going to promote you to presenters.

Jimmy Muchechetere Analyst

Just a couple of questions. First one is I'm wondering how seeking more diversity impacts on the cost of clinical trials and the speed of executing those clinical trials. That's question one. And question two is, given that you work with many different organizations, CROs, et cetera, how do you engage with them to make sure that they are in keeping with what you want to do in terms of clinical data?

Alberto Fernandez Executive

Yes. Thanks for those 2 questions, Jimmy. So honestly, what we have been setting for ourselves that target and commitment about the increase in diversity in clinical trials, we have not been thinking about the cost, we have been thinking about what's right for the patients. It might be true that in some cases, it might increase some part of the clinical trial cost, but at the end of the day, we believe it is the right thing to do. So we have not done the analysis.

That is where we are.

Now the question about how do we engage with CROs? We have, first of all, made them very aware about our objectives. So they are running in part of our pipeline, obviously. And in their objectives, they know they have to put diversity plans in place.

Second, we are also learning with them. We are all on this path of learning, and we are sharing those experiences. What we have been also very clear is that we believe that the epidemiology of the disease is what should drive the availability of patients, and we are working with them when it comes to feasibility and where are the countries, as Kim has indicated. We think we should go to and also identify certain sites that we believe in certain countries are better positioned to actually attract more of those diverse population we are looking for. So that is what we are doing.

As we said, we are starting to create a stronger partnership. It's moving in the right direction. A lot of work to be done, no question. But so far, we have been welcomed to a partner with those CROs because they also understand it's important for them to make both steps in this area.

Kim, I don't know if you have anything to add...

Kimberly Smith Attendee

Maybe I'll just build on that and just say that the speed of the clinical trial really depends on

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the planning. And so if you do the right planning upfront and make sure that you have investigators at sites that have the population represented, then you can actually -- you can do things in your time frame, but it does require planning. If you decide at the last minute that you want to fix a problem that's already in place in your clinical trial, yes, it's going to take you longer. So it really is about planning.

And to answer your question about CRO engagement, that's a question that we ask upfront. When we talk to the CROs about the potential for operationalizing our trials, we let them know exactly what our intentions are, and they need to guarantee to us that they have a plan to be able to do that. That they have those types of -- that they have reach in those areas. And so I think your questions are exactly right, but it all comes down to planning it ahead of time.

Frannie DeFranco Executive

Aude, you are our next participant. I'm now promoting you to panelists.

Aude Scheuer Analyst

My question is actually also similar to Jimmy's in that I was wondering about cost but also the complexity as in it's -- I mean sometimes it's easy to get enough participants such as with HIV, I would think that, unfortunately, there's enough population to get as a candidate for the trials. But how do you see it in general? Because from what I understand, the diversity in trials has been a bit lower than it should be in general because a lot of the trials have been in places such as Ukraine, where there is a good infrastructure to do these and there's maybe a shortage in women having been represented because for some -- certain medication, it's difficult to include women of childbearing age due to the risk to the child. So I was just wondering, in terms of complexity, I mean, is it just a onetime change. As you said, you have to plan for it, then it's fine.

Or will there still be an increased complexity to this going in the future and as such, probably still an increased cost as Jimmy mentioned?

Alberto Fernandez Executive

So that is obviously a learning curve here, right? So the planning is definitely one of those aspects, as Kim indicated, the complexity of the design, the complexity of the diseases will evolve. And as it has been mentioned, depending on the global landscape and the nature of the clinical trials, different countries will have different opportunities and different situations. We believe in that.

In terms of costs, I think it is important to say that we are also looking into different alternatives to actually use technology to reach out to where those patients are. And in some cases, what we have found is that there are opportunities to actually decrease the cost because by using technologies like decentralization of clinical trials and putting the clinical trial assessments closer to where the patients are, we can actually find efficiencies, right? So in that sense, I think it is going to be a combination of, yes, the corporate planning plus the learnings we may have from the diseases we will be tackling, plus leveraging some of those opportunities that we have in terms of technology and data to find where those patients are instead of waiting for the patients to come to us.

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Kim, I don't know if you have anything to add to that.

Kimberly Smith Attendee

I think you answered that very well. Nothing to add.

Frannie DeFranco Executive

We have another question, that's from Ruchi.

Unknown Analyst Analyst

I'm substituting for Ruchi on this call. I'm [Brushni], and I'm part of Western Asset Management. A couple of questions, and that's already been raised by Aude and by the present -- presenter earlier as well. But I just wondered how do you try and address, A, some of the inherent issues into the clinical trials where you don't have people that participate as much? So how do you address inherent barriers, one.

In terms of the other question that Aude sort of raised earlier as well, are there any hard metrics that you published, particularly in, say, clinical diversity of, say, pre versus post menopausal women or so out of men as well across a whole range of child -- across all ranges of, sorry, age groups as well? And finally, how do your metrics compared with the peer group? Is that something that you're monitoring? Obviously, there isn't necessarily a standardized data set that's available, but is that something that will get monitored?

Alberto Fernandez Executive

Yes. So let me tackle first the barriers piece. So as Kim mentioned and I mentioned during the presentation, the barriers to start, first of all, with the education about clinical trials in those communities where the diversity is required, and we have a number of activities going into that space, right? So that's number one. Second, having investigators of diverse nature that can explain better to those patients, you know what the clinical trial is about.

I think also based on what Kim has experienced in ViiV and also some of our experiences helped in attracting those patients into the clinical trials. So they feel more comfortable about participation, understanding better the risks and benefits.

We have also identified that through the epidemiology, we can actually go to areas where traditionally not many sponsors have been going. By doing that, we can also help in educating the patient population, partnering with some patient association groups and helping those patients to be more interested in our trial. So there's a whole number of strategies that apply not only to the clinical trial diversity, but also -- peers, but also to a wider space on how to make sure that patients feel comfortable about participating in a clinical trial.

Now your second point about metrics. No, we don't have metrics right now on what you mentioned, but definitely based on your question, we could actually go and pull out the data and see if we can get anything in the history. And we know that peer groups are starting now to actually develop those metrics based on some of the publications that obviously we are part of. And we know also that companies, sponsors and CROs, listening to the guidance from the FDA are bringing up to life, many of the data sets they have and try to understand

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whether there is comparability in the different data sets that will be published. But for the time being, what we have is our data shows that the census is probably not the right choice to actually compare.

It's better to focus on the epidemiology.

Kimberly Smith Attendee

So let me just build on that a little bit and answer your question sort of from a ViiV perspective. You talked about women. And I think pre- and post-menopausal women and -- are we having problems because of childbearing women and maybe not that being a challenge, well, actually, one of the other initiatives is to try to actually be able to enroll more women of childbearing age and put fewer restrictions in. As soon as you know that you have good data that suggests that the drug that you're studying does not have a risk of sort of reproductive toxicities, then we should be looking to try to improve more women of childbearing age into those studies. So we sort of traditionally excluded them.

And that's a problem, because that means that we don't find out about women of childbearing age until way later.

And so it's an important priority for the industry as a whole. And I think actually regulatory agencies are starting to move in this direction, encouraging more women of childbearing potential as well as allowing women who become pregnant to even stay in trials, if you have a drug that you have no reason to believe has significant risk to them. So more flexibility in that space is extremely important.

And then I also wanted to talk about peer groups because we have actually compared to our peer group, our peer group being other companies that are doing work in HIV because it's easy to compare because there's so few of us. That's the reality. And we have unquestionably led in that space. So there's no question that we'll have a greater percentage of women in our clinical trials in comparison to other HIV research companies doing HIV research. And the PrEP example is a great example of the racial diversity and answering the question for cisgender women is critically important, and we did that upfront, not as an afterthought.

And so I also want to just point out that, that study that I talked about, where we enrolled such a large number of black men who have sex with men means that, that is actually the largest study of black MSM interventional study of black MSM that has ever been done. And so we are unquestionably leading in the diversity space. And I hope that, that creates a competition, and everybody really wants to do it. Because that's the only way we can lead to really just consistently getting these populations enrolled.

Unknown Analyst Analyst

That's very helpful. And I wonder whether it's possible to maybe you share the data as well or make it public if that's possible, because I think that does provide investors with some greater clarity.

Frannie DeFranco Executive

Okay. Great. Thank you very much. And I'm going to share my screen because we are out of

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time. So I want to thank everyone for attending and let you know that we have an upcoming investor education event, which will be on July 18.

As you probably know, the WHO has called antimicrobial resistance 1 of the top 10 threats to global health. So for this session, we're going to pull together a panel of GSK experts to provide insights on this space, including our commercial opportunities, an overview of R&D and importantly our approach to sustainability and access in this space.

So once again, I want to thank you all for attending. We had a great number of attendees come in. I want to thank Alberto and Kim for joining. And with that, I'm going to close the call, and thank everyone once more.

If you have any questions or feedback, we'd always love to hear it. But we'll see you all soon. Thank you once more. Bye.

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