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Diving Into Diversity & Inclusion in Rheumatology Trials

**Announcer:**
You're listening to ReachMD. This episode of *Living Rheum*, titled "Diving Into Diversity & Inclusion in Rheumatology Trials" is sponsored by Novartis US Clinical Development and Medical Affairs. The host and speakers have been compensated for their time. This program is intended for health care professionals. Here's your host, Dr. Anisha Dua.

**Dr.Dua:**
Rheumatology is 1 of several medical fields that suffers from a lack of demographically representative patient data in clinical datasets and randomized clinical trials. This gap in representation can lead to increased health disparities and worse outcomes for our most vulnerable patients. But up until this point, efforts to increase awareness and participation from both researchers and patients had little impact on improving minority representation over a 10-year period.[1]

This is ReachMD and I'm Dr. Anisha Dua. Joining me to discuss diversity and inclusion in Rheumatology Clinical Trials are Dr. Grace Wright and Dr. Irene Blanco. Dr. Wright is a consultant rheumatologist in New York City and president of The Association of Women in Rheumatology, AWIR. Dr. Wright, thanks for joining us today.

**Dr. Wright:**
Thanks for having me, pleasure to be here.

**Dr.Dua:**
And Dr. Blanco is a professor and associate dean for diversity enhancement in the Department of Medicine at the Albert Einstein College of Medicine. Dr. Blanco, really looking forward to talking with you today, thanks for being here.

**Dr.Blanco:**
Thanks so much for having me.

**Dr.Dua:**
So, let's start off by taking a look at some of the populations that are underrepresented in clinical trials in rheumatology. Dr. Wright, what can you tell us about this?

**Dr. Wright:**
Absolutely. So, we normally think about underrepresentation simply in terms of race and ethnicity. But populations that are underrepresented extend to children, women, disabled individuals, pregnant women, really sort of covering all of those people that we don't normally include in clinical trials.

**Dr. Dua:**
Absolutely, and Dr. Blanco, what are some of the consequences we're facing due to the lack of diversity in those patient populations?

**Dr. Blanco:**
Well, we just don't really understand how many of our medicines actually work in said populations. So, for example, bioavailability would change in pregnancy, changes in bioavailability in children for example, who may metabolize drugs at different rates. So, you know, not having that data doesn't really help us understand just the broad swath of treatments available to all of our patients, um, across different groups. On top of it, we don't really know how people view how to take certain medications, how they tolerate different side effects, their cultural perspectives on such. And so, really once we exclude certain populations, we really don't know how medicines work across the gamut for different disease states.[2]

**Dr. Dua:**
Yeah, that completely makes sense. Dr. Wright, do you have any other things to add there?

**Dr. Wright:**
Yeah, sure, I mean, safety is a real issue in populations that are not accustomed to being parts of, sort of the cutting edge, and so if we don't include them in trials, we have no idea, number 1, about what the safety signals are in those patients. But I think in a more nuanced way, we also fail to build trust. And if we don't build trust in communities, then it really is difficult for us to then go and deliver something and convince a population that in fact, this drug is safe.[2] Often, I hear the comment was "It wasn't important enough to include me in the trials but now you want me to take the medication? I want to know that I counted in the very beginning."

We also know that the different comorbidities that have, different prevalences in different populations, so we, for instance, look at cardiovascular disease in women and the way it presents can be very different.[3] And often, we're looking at, is it the same disease? Is it a different manifestation? And we will never answer those questions if we don't actually study those populations and include them in our trials across all of our specialties.

**Dr. Dua:**
Absolutely, there are definitely consequences to not including these people in clinical trials and that you guys touched on some of the really important ones. And now that we have discussed some of that, can we talk about some ways that we can overcome this? Dr. Wright, what are some things we can do as a rheumatology community to address this problem of limited diversity and inclusion in our trials?

**Dr. Wright:**
Well, you know, I think we have to start to think about things in a culturally sensitive manner. We have to be curious enough to create content that is responsive to the various populations that we would like to access.So,culturally sensitive informed consent, so that people truly understand what they're consenting to not just sort of using the language that we typically use.So that's a big issue with informed consent. Shared decision-making really is an extension of that. And then, you know, there are other things that we can do.

So, for instance, bring the trial to the patient. A current paradigm really is we set up the trial and they come to us, and that itself becomes a huge barrier. So, can we have research coordinators, for instance, who go to the patient so that they can participate with a sort of being inclusive of them within their community? Number 1, that helps to build trust, going back to my earlier point and then think about those patients who are doing multiple things: they are taking care of parents, sometimes grandparents, children, other members of their community. We really need to create the support for the community and support for the patients. And so, having these kinds of patient coordinators that represent the population we need can really help to build rapport and get them included in the process of, you know, testing our therapies.

**Dr. Dua:**
Yeah, absolutely. And Dr. Blanco, do you have anything to add to that, in terms of how we sort of interface with these populations and try to get them more included in clinical trials?

**Dr. Blanco:**
I mean, I think what Dr. Wright was saying is so key to the crux of all of this. It's about making those relationships and building trust and really being centered in our patients. And we need to think about the inclusion of the patients in the trials but also how do we feed back the data to the community? You know, they're often times being asked to participate in all of these trials, and they never end up knowing happened to that data. You know, "Did the drug that I participated in, that I potentially received, did I get it? Did I not get it? Is that actually going to market? What's happening?" Right? And so, I mean that that's closing the loop helps to build that trust, because it's, you know, they're potentially going to be part of something big. You know, they want to know that they contributed as well.

And then going back to the point of having the whole research team being holistic and culturally humble and representing the communities that we're recruiting into these trials, because I think it adds just such a layer of nuance to the team and to the data that potentially we can get from our patients.

**Dr. Dua:**
Yeah, no, that makes complete sense and we do need to get it, do a better job of, sort of, getting out there, getting these patients involved, but also super importantly what Dr. Blanco was mentioning, closing that loop and actually making them aware of what were the outcomes, how did they impact this entire field moving forward and making them feel really a part of the process from the beginning to the end.

And so, do you think that a lot of this falls on our coordinators, right? So, do you think that our coordinators need to be better trained?

How can we help them, sort of do this important outreach and communication with these patients? Dr. Blanco?

**Dr. Blanco:**
I think our coordinators can definitely be better trained. I think potentially we can get coordinators from the communities that we're trying to recruit as well. You know, they're invested then in their community and could be an enormous bridge for investigators into said communities. I think, at the same time, we need tothink about how we train our investigators, right, to really understand the communities that they're studying, the communities that they're approaching so that they can engage with said communities as well.[2] I think, again, it goes back to the point of having the entire team really invested in these people as people and not necessarily as subjects or as, you know, data points and outcomes, right? We're really hoping to impact lives for the positive and so, you know, I think having the whole team really be patient centered and having a patient-centered training approach is going to lead to just better outcomes and better data, period.

**Dr. Dua:**
So, based on your experience, how do you think we can try to improve that? I know you talked a little bit about engaging the community and some different ways to try to do that. Can you expand on that a little bit, Dr. Blanco?

**Dr. Blanco:**
Sure, I think we need to build trust early and it has to be a constant conversation, right? So, if for example, you're part of a large medical center, right, think about how can you have a community board, right, be part of your clinical trial team, right? To say, you know, "What studies should we bring into this institution? What are the patients' perspectives from the get-go, right? Should we even launch this study? Would the study help anyone?" I think that, you know, oftentimes we talk about communities from a deficit-based model so we can come in with these ideas of we're going to save this community, when oftentimes if you talk to community organizers, community representatives, they know what they need and that may not necessarily be aligned to what we think they need, right?

And so, I think that those conversations need to be thought of early and you can think about not the deficits, what is this community lacking but really what are the resources, right? What are the rich things available within this community that potentially we can leverage as an infrastructure to disseminate this trial? An example for, is like, you know, use of barber shops and beauty salons for community health awareness. For example, in cardiovascular disease which we have seen work beautifully in Black and certain Brown communities, right, for dissemination of health data.[4]

And in addition, you know, we need to figure out how we structure our trials. I think Dr. Wright talked about this a little bit, right, where if, you know, your trial visits are only between 9 and 5 PM, anybody that works can't necessarily participate, right? So, then you are already skewing to a certain demographic. You are already skewing to a certain socioeconomic status where if you could have, for example, visits on the weekends, if you could have visits after hours, if you could really think about paying for childcare within a clinical trial within the budget, that could really help enrich the patient population that you're including.[2]

**Dr. Dua:**
Absolutely, those are such good points. I think, actually engaging with the community, asking them what they need, which seems so simple and basic. Doing those steps is really so important in building that this sort of level of trust.

I think this conversation has been super interesting in terms of figuring out how we can improve outreach to these communities and then try to just move this, all these fields forward.

But what are some ways that we can actually help educate and encourage our investigators and individual providers or trialists to help improve diversity in these clinical trials?

**Dr. Wright:**
Yes, I think, you know, 1 of the things that we have to always be aware of is that we all have bias. So, there is implicit bias that sort of walks around with us. It's how we were formed and if we approach a community without awareness that we have inherit biases that may come out in ways that are unintended but will have negative consequences, then, in fact as we do this outreach, we can be causing more harm than good. So, to improve diversity means that I understand this concept of vicarious racism, that talking to 1 person but making a slur about another actually negatively impacts them. And it's just as damaging to everybody, even the people who aren't part of the group that you are making a slur against. So, these are things about the way we speak, our body language, the metaphors, the jokes. It's that locker room joke that hurts everybody, even if they don't know it. They're all being impacted by it.

So, it's an idea of being conscious really of cultures, of understanding that, you know, there is the obvious aggressor but there is a micro aggressor and people are going to pick up on those terms, you know, like, "Oh, I didn't know you could inject yourself," "Oh, I didn't know." No, there is an implication that I think you were less than that I don't hold that population or those people in high regard. And so,

we immediately disenfranchise people by how we conduct ourselves by the absence of humility in understanding that we also come in with our deficiencies. So, I think really this is part of the approach, not just to doing the outreach but having people feel included and wanted within whatever our efforts are. So, again, critically important.

**Dr. Dua:**
Thank you so much. Yes, there's so many different facets for us to sort of touch on. And this conversation is so important, I'm just so glad that we're starting to have it more regularly. And so I really want to thank both of you, my guests, for helping us better understand diversity and inclusion in clinical trials. Dr. Wright, Dr. Blanco, it's really great speaking with you today and I look forward to continuing this conversation.

**Dr. Wright:**
Absolutely, happy to have been here.

**Dr. Blanco:**
Thanks so much for having me.

**Announcer:**
This industry podcast was sponsored by Novartis US Clinical Development and Medical Affairs. If you missed any part of this discussion or to find others in this series, visit reachmd.com/living-rheum.

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