INCREASING PATIENT PARTICIPATION IN CLINICAL TRIALS

PANEL 1

Diversity, Inclusion and Meaningful Participation

One of a series of live panels from the WCG Patient Advocacy Forum in Washington D.C. in October, 2019

Introduction

The lack of diversity in clinical trials occurs across many dimensions, including race/ethnicity, socioeconomic status, age, location, gender, disability status, and sexual orientation. While there have been Federal initiatives over the years to bring awareness and accessibility to these populations, both the medical community and the pharmaceutical companies need to partner to ensure that study participants are more representative of the disease population.

These discussions have been significantly edited for clarity and length.

The Panel

MODERATOR

Lori Abrams

Senior Director
Patient Advocacy
WCG

PARTICIPANTS

Jonca Bull

MD, Former Assistant Commissioner, FDA; history of advocacy and inclusion in clinical trials since late 1990s

Kimberly Richardson

Six year survivor of Ovarian Cancer; Research Advocate. Working with Cancer Survivors in the University of Illinois Cancer Center

Dorelia Rivera

Patient Advocate; Parent of a child with Ultra Rare Disease - NOMID (neonatal onset multisystem inflammatory disease); been in trials for 15 years

The Forum

Lori Abrams

We have an exciting lineup of panel members, and I'd like each one to introduce themselves and share a little bit about their background.

Dorelia Rivera

I wear several hats, but the reason I'm here is I'm a mom of a daughter with an ultra-rare disease. We've been in clinical trials since she was 1; she's now 15. She has an ultra-rare disease called NOMID, neonatal onset multisystem inflammatory disease, one of 67 in the world who has it.

Kimberly Richardson

I live in Chicago. I'm a six-year survivor of a rare ovarian cancer. I'm now basically a patient advocate. I work through the University of Illinois' Cancer Center and work with a bunch of cancer survivors who are very interested in research advocacy.

Jonca Bull

I have a very long history of advocacy around clinical trials and inclusion, which goes back to the earliest days of women in clinical trials, women and minorities in clinical trials back to the late 1990s. At that time there were prohibitions against women being in trials because of risk, fetal risk, as well as a lack of adequate attention to what a trial should look like.

Lori Abrams

What are the barriers to participation of diverse populations in clinical trials? How do we (the research community) begin to break down these barriers?

"...progress—if any—is slow. And as somebody who was in pharma for 20 years, I can say you can't do it alone."

—LORI ABRAMS

The situation is not improving. Over the years, since the 1980s, we've had some federal plans, discussions that we put into place to bring awareness of health disparities into the country. But the federal government doesn't actually do the work. The people who do the work are the pharmaceutical and biotech companies, the health communities, etc.

Without them getting together and working toward solutions, progress—if any—is slow. And as somebody who was in pharma for 20 years, I can say you can't do it alone. This is a big problem with no easy solution. Jonca, do you have any particular thoughts on this situation from your experience and former role?

Jonca Bull

Clinical research is structured in a way that does not drive inclusion for a number of reasons. Those reasons are why we're here as advocates today, to ensure that trials are designed in their earliest stages to drive meaningful inclusion.

I'll tell you about an encounter I had with a clinician: I was speaking at a meeting and a clinician came and he said, 'You know what, Jonca? I need to know that the clinical trials have patients in it like the ones I take care of.' That's really what our end game looks like.

Lori Abrams

The FDA has been trying to promote inclusion for years. For example, the FDA's Drug Trials Snapshots provide consumers with information—including demographics—about who participated in clinical trials for

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approved drugs. It highlights any differences in the benefits and side effects among sex, race and age groups.

Many of us in pharma felt, 'Aha! Finally, something might work.' If we saw the data, if we saw who actually participated in the trials, companies might become embarrassed. But there was no meaningful change. Can any of you comment on this?

Jonca Bull

I'll point out that the FDA has been working on this for years. In 2012, legislation required the agency to develop two reports, one on the state of inclusion across the medical product centers, and participation in clinical trials with medical approval. In a nutshell, it was abysmal.

That led to the development of the drug trial Snapshot. It shined a light on participation, and … here we are now in 2019, and it's still looks abysmal. I'm reminded of the 'Can you hear me now? Can you hear me now?' guy from the telephone commercials.

And the FDA realizes the industry is not really listening.

Lori Abrams

Let me cite a Genome Biology paper and share some distressing numbers: As of 2018 approximately 78% of individuals included in genome-wide associated studies were of European descent. African Americans and Hispanics were 2% and 1%, respectively.

"I had to become a nuclear physicist just to become an ambassador. What regular person would do that?"

—KIMBERLY RICHARDSON

Because the promise of precision medicine rests on effective engagement with subjects with diverse backgrounds, an inclusive research strategy should be a priority of everyone conducting clinical trials. We need to help patients gain access to genomic testing. That's really the issue.

It's not just that we need the results of the testing. We need to help drive it, because people do not have the same access to care, to testing, to treatment, to trials. Can you all share your experiences?

Kimberly Richardson

I'll recount my experience with a national initiative to get more people involved with genetic testing. Of course, I wanted to be an ambassador! I'm in advocacy. After the blood draw and the urine sample, two weeks passed. I reached out again, and they sent me a link with 14 modules of research and a quiz behind it.

Who in their right mind would want to be an ambassador? Let alone just a regular human being who thought this might be a cool thing to do. I thought I'd be encouraging more people to become involved in genetic testing. Instead, I had to become a nuclear physicist, in order just to become an ambassador. What regular person would do that?

Lori Abrams

Dorelia, I'd like to ask you the same question from earlier to get your perspective: What do you see as the barriers to participation of diverse populations in clinical trials? How do you think we, the research community, can begin to break down those barriers?

"Protections are now in place, but potential participants don't understand—or perhaps they don't believe it..."

—JONCA BULL

Dorelia Rivera

It starts with providing information. I can speak for the community I love, the Hispanic community. It's a very word-of-mouth type community. It goes back to 'What are you going to do with this information?'

The stories people hear about genetic testing are off-putting, even frightening. I think the first part would be access to information about genetic testing. The second is access to the testing itself. And that goes from just deciding to use a commercial genetics company but also working with insurers, Medicare, Medicaid - my mind goes to what they will cover and what they won't. And I think the access issue is really important in genomic and genetic testing.

But, it's essential to address misconceptions about trials in general. I remember when I first started going through the clinical trials with my daughter. In my own community, with my church, with my parents, they were like kind of aghast: 'You're going to give away all that information? You know, she's going to be a guinea pig!'

It's a matter of taking half a step back to explain what a clinical trial is and what it does. I think getting to the why of a clinical trial is just as important as the 'What is it?' It comes down to trust.

Lori Abrams

Let's switch gears for a second and talk about diversity as it relates to trust. We know that trust is an issue. Protections are now in place, but potential participants don't understand, or perhaps they don't believe it.

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—JONCA BULL

Can any of you shed light, or examples you've seen, on this topic?

Jonca Bull

I have participated in panels where issues around Tuskegee come up. And you must face that head on. What happened at Tuskegee certainly should give people pause. But a huge part of the legacy of Tuskegee is the protections for patients that we have in place now, IRBs—institutional review boards—and informed consent, which did not exist before Tuskegee.

Educating and reassuring patients about the levels of oversight is essential.

Lori Abrams

Great point. In your minds, who are the trust bearers? Where can the conversations begin?

Dorelia Rivera

They begin at the local level. Primary care physicians are trust bearers. And faith-based communities can play a tremendous role - they are essential.

Your priest tells you something, the community will react. They will. I started a nonprofit at her church called Casa Esperanza, which means house of hope. Physicians come in and do basic screenings and give talks on diabetes, heart health, other topics that the community asks for. It started with my church; it spread to all the churches around the area. Word of mouth is really huge, and the sense of trust is really

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—DORELIA RIVERA

"Genetic testing is tricky and complicated. But diversity in general shouldn't be."

—KIMBERLY RICHARDSON

important in the community that I work with.

Kimberly Richardson

Let me share perspective about both access and marketing. Most people will do 23 and Me and think nothing of it. But when discussing genetic testing, the conversation reverts to concerns about how information will be used. You've already spit in a tube, so what are you talking about?

It may be a matter of marketing. Maybe what we need to start thinking about is the need for slicker marketing on how we get genetic testing done.

To me, it starts with communicating with patients. What we do at the cancer center is start talking about how we unravel the information. Where do we start in terms of helping people understand why we ask them to give us the sample? Why are we asking for this information? What is it going to do for you today? What could it do for your family in the future?

That helps get to the question of why someone would spit in a tube and send it off to a consumer genetics company to perhaps learn their ancestry, but not be open to genetic testing. That's a crucial marketing question that must be answered. Genetic testing is tricky and complicated. But diversity in general shouldn't be.

Jonca Bull

Can I say something about data and diversity? We live in an age now

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where we know where the patients are. You can look at CDC data. You can look at a heat map of where the patients with, for example, heart disease, are. This is not rocket science. We know where the heat for whatever these diseases are. The question is, 'Is that where we are gathering the data?' One challenge is global trials. Sometimes, it's because sponsors plan to market in those countries. Other times, we gather data in areas because we need speedier recruitment.

I also hear complaints that trials are a bit too sanitized because the inclusion and exclusion criteria try to create this pristine population but oftentimes the population that's created isn't realistic. Frankly, I believe we have to be much more discerning in terms of what the trial looks like, and does it actually reflect the intended population: Patients that are going to use the product when it goes to market.

Kimberly Richardson

I can relate to this. Recently I was at a conference that featured a panel on diversity. Every panel member was male.

In Chicago, I participated in an event that decided to include a panel of all minority physicians. Of course, let's do it that way because then that'd be more relatable. It wasn't. When the physicians got an opportunity to speak, I think I was the only person in the room that understood what they were saying because I'm a research advocate. I learned a lot more in that conversation than everyone else in that room, and that was not the intention.

"...did you wonder that maybe the Aleve trial was all white men, and that's probably why it doesn't work for you?"

—KIMBERLY RICHARDSON

Lori Abrams
How could the panel have been more effective?

Kimberly Richardson
I think it's common sense. If you think it's so important for me to participate in clinical trials, then tell me like you would tell your grandmother, right?

Here's how I explain research and the importance of diversity in research to lay audiences: When you go to CVS or Walgreens, you see all this stuff on the counters. Did you know that every one of those things went through some sort of a process to be approved to be on this counter? And did you realize that, 'Okay, maybe I use Tylenol and you use Aleve,' and they all work differently for everybody. But did you wonder that maybe the Aleve trial was all white men, and that's probably why it doesn't work for you.

When we talk about clinical trials and we talk about safety and efficacy of drugs and a person's participation in that, we have to use examples that make sense to any individual. For instance, "Why did you pick this particular over-the-counter drug at CVS? Is it because your mom always used it? Does it really work for you?' These are the kinds of conversations we have with people to help them understand this is why you get involved in clinical trials. 'If you ever get sick or your family ever gets sick, do you want the old standard, or a "chemo" that we used a long time ago that made everybody toxic and sick, or do you want to use what's being produced now with more safety and less toxicity?'" I'll use that backbone to explain the importance of a blood or tissue sample:

"Social media offers a tremendous opportunity to connect... I never would have heard about the trial that is saving my daughter's life."

—DORELIA RIVERA

"Okay, let's look in the file, Kimberly Richardson. No data on her, so go get her what we used to give everybody. You're going to just get the over-the-counter stuff as opposed to the new innovative things." It's not a matter of 'dumbing it down', it's about talking about things that are relatable.

Everyone in this room is more interested in the clinical research, but the everyday lay person is just getting up, going to work, and then they realize they're sick. That's when they're more vulnerable. They're coming to the physician and expecting them to have the answer, and sometimes when they don't have the answer, then what happens? At some point, that person needs to be a little bit more educated about what's going on with clinical trials. How do we market that information to people before disease occurs?

To me, it comes down to meeting people where they are.

Dorelia Rivera

I'll relate your concept to social media, which offers a tremendous opportunity to connect. Without the Yahoo group I found years ago, I never would have heard about the trial that is saving my daughter's life.

There's another child in my community, Lexi, who died recently at age 6. Lexi's mother posted on Facebook; she said if it weren't for the social media and the internet her daughter wouldn't have lived those six years.That's how she found out where she needed to go. I certainly acknowledge that social media can be a "very, very big slippery slope," but it's essential to meet patients where they are.

I think if I had to drive anything home today it's that. And it could be elderly, it could be children, it could be diverse populations, but meeting them where they're at and starting with the community instead of starting with the person that says, 'I'm the researcher.' Because if you don't answer the 'why' for clinical trials, we're done with it.

Key Learnings

Combat lingering mistrust among minorities by educating on the dramatic improvements in ethics and patient protections

A general mistrust stemming from the Tuskegee Syphilis study still lingers among minority communities today. Education and reassurance about Independent Review Board protections that were created, in part, because of Tuskegee--are essential to the cultivation of trust moving forward.

Implement a more accurate representation of at-risk communities in trials by evaluating study criteria

Trials too often do not realistically represent their intended population. Stringent inclusion and exclusion criteria can often create a trial population that can be considered too "sanitized." The way a treatment worked for a person with a BMI of 22 and no other conditions may not be consistent with a person who has a BMI of 30 and a chronic condition.

Increase confidence in genetic testing among minority communities with full transparency

As of 2018, approximately 78% of individuals included in genome-wide associated studies were of European descent. African Americans and Hispanics were 2% and 1%, respectively. Transparency about the full usage of genetic information is needed. Why is this information useful? How it's going to be used now? How it's going to be used in the future?

Key Learnings continued...

These are questions that need to be addressed at the forefront of the process.

Improve participation in clinical research from minority communities by increasing representation in trial design and outreach efforts

A constant theme in clinical research is the dominance of the white male presence and perspective. Trials targeting underrepresented communities should have someone from their community involved in outreach and study design. Being able to “speak the language” and relate to a community is invaluable to increasing trust and participation.

Reach out to trusted leaders in underserved communities by considering faith-based institutions

Many faith-based institutions play an integral role in bringing accessible care options to underserved communities. Collaborating with these trusted community leaders can build the confidence of a community by allowing for further education on the misconceptions of clinical research.

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