UNITE US

Q&A:

Dr. Rodrigo Burgos on Clinical Trial Diversity

Introduction

Life sciences organizations are increasingly aware of the powerful role drivers of health (DOH) play in whole-person care. DOH are non-clinical contributors to whole-person health. Such behavioral, personal, lifestyle, socioeconomic, and environmental factors are responsible for around **80 percent** of an individual's overall health status. However, it's often a challenge for clinical research sponsors and life sciences organizations to identify DOH needs for the communities they serve and to successfully factor them into research and development efforts. Clinical trial diversity, in particular, has remained both a pressing challenge and a key priority.

Recently, **the FDA has heightened its focus** on increasing racial and ethnic diversity in clinical trials. According to a **recent study by Nature Reviews Disease Primers**, "in a 2020 analysis of the global participation in clinical trials, the FDA highlighted the vast difference between the enrolled participants and the global population. Of 292,537 participants in clinical trials globally, 76% were white, 11% were Asian and only 7% were Black. In comparison, the global population (~7.8 billion) is distributed with ~60% of the population in Asia, ~16% in Africa, ~10% in Europe and ~8% in Latin America (**World Population Review**)."

We interviewed industry expert **Dr. Rodrigo Burgos,** Clinical Assistant Professor and HIV PGY-2 Residency Co-Director at the University of Illinois Chicago, to share his thoughts on the evolving matter of clinical trial diversity. As an HIV pharmacotherapy specialist and pharmacy residency director, Dr. Burgos is committed to expanding opportunities to support pharmacists who serve marginalized communities.

Q&A

01 **Q: Can you tell us about your background in pharmacy and your work supporting historically underserved communities? In general, what has been your experience with drivers of health throughout your career?**

A: Absolutely. As far as my background, I completed a Doctor of Pharmacy program at University of Illinois Chicago (UIC) in 2005, and then residencies in general pharmacy practice and infectious diseases (ID)/HIV. I've been a part of the faculty at UIC since 2007, primarily focusing on three main areas:

1. **Serving patients in the clinical setting**
2. **Teaching students, residents, and fellows**
3. **Conducting research (the vast majority of which are clinical trials)**

Our infectious disease clinics are in areas of Chicago that have traditionally had limited access to healthcare. So, understanding and addressing drivers of health is definitely something that I come across in my daily work.

As far as the academic aspect to drivers of health—starting with the **Whitehall study** in the UK—there have been many studies that show how higher socioeconomic status is directly correlated to better health outcomes. From the on-the-ground perspective, I'd say there's been a large shift over the past 15 years or so in observing how we go from the scientific lens of, "How do we determine the best therapy for our patients?" to the broader social lens of, "How do we support our patients and make sure they have the resources they need to stay on with their treatments outside of choosing the best therapy for them?" Those are two different questions, but it's becoming increasingly apparent that we cannot afford to ignore these non-clinical factors, since they play a huge role in the overall impact on a person's health.

---

02 **Q: Thank you for sharing that perspective. To take a step back and address this more broadly, what are some ways that pharma organizations can expand clinical trials to be more diverse?**

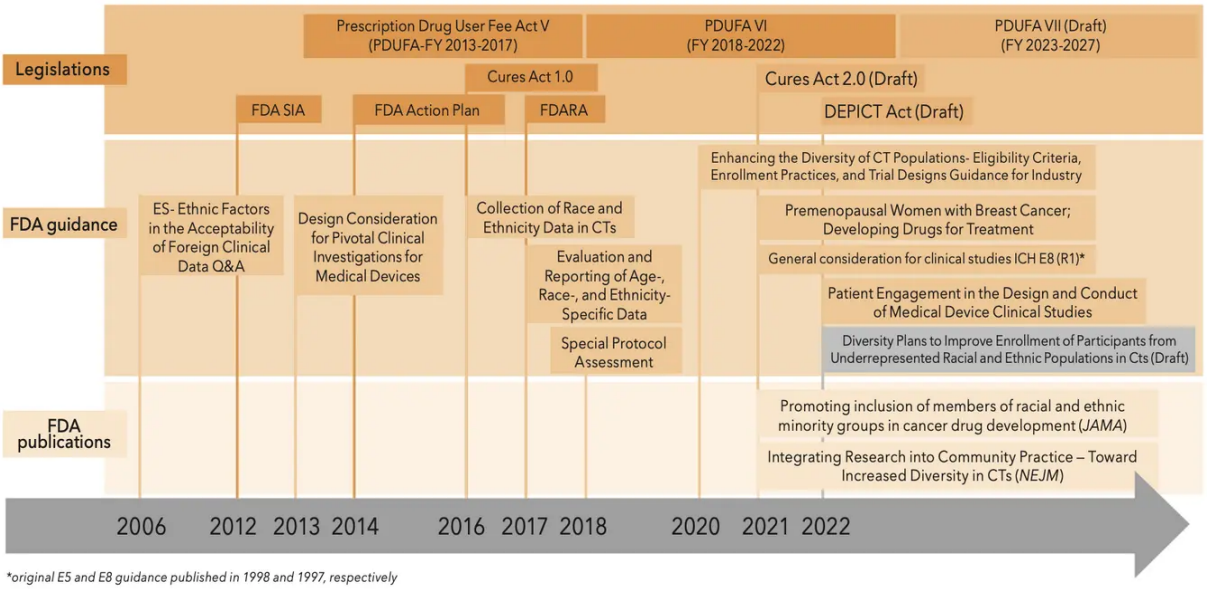
A: When thinking about ways for pharma to expand diversity in clinical trials, I think the first thing to note is that understanding diversity, equity, and inclusion (DEI) in clinical trials is complex. There is no single root-cause, nor a single solution. Expanding clinical trial diversity is a long-term commitment and ongoing effort that must come from all of us.

That said, there are some guidelines that many experts in this space recommend:

1. **Understand regulatory evolution:** Since around 2006, U.S. legislation such as the Prescription Drug User Fee Act (PDUFA), CURES Act, DEPICT Act (Diverse and Equitable Participation in Clinical Trials) and other laws have come into effect that incorporate aspects of diversity and inclusion in therapy development. (See Figure 1 below.) For instance, the **FDA Guidance on Collection of Race and Ethnicity Data in Clinical Trials; Evaluation and Reporting of Age, Race, Ethnicity Data** provides helpful guidance on this topic.

Question 02 continued

U.S. Snapshot: Diversity in Drug Development



*original E5 and E8 guidance published in 1998 and 1997, respectively

FIGURE 1: **A U.S. regulatory landscape overview on diversity in clinical trials, race, and ethnicity focus.**
SOURCE: TransCelerate BioPharma Inc.

2. **Incorporate a DEI team and sponsors:** Consider implementing a DEI team that keeps track of the regulatory landscape and assists with DEI implementation in clinical trials. **Sponsors** (a person, company, institution, group, or organization that oversees or pays for a clinical trial and collects and analyzes the data) can also work with sites on how to best approach their diverse patient populations. Having a dedicated support team for this work can go a long way in furthering clinical trial diversity.

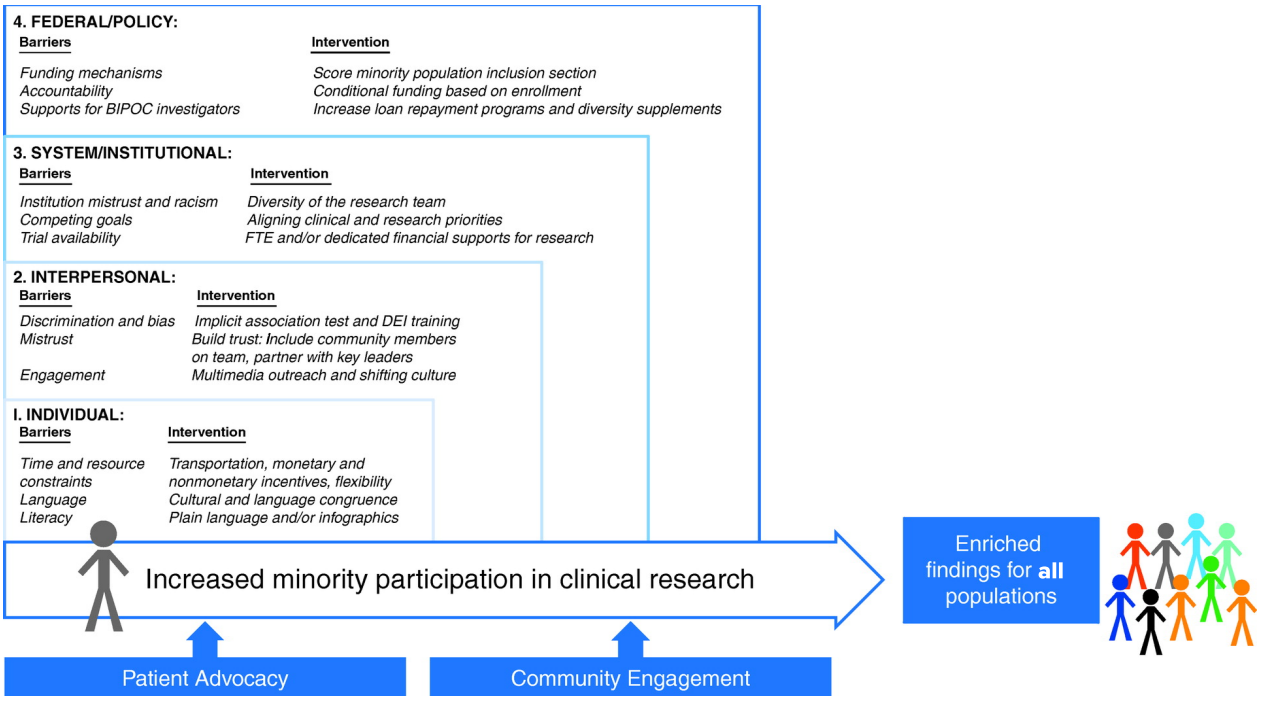
3. **Engage in collaborative data-sharing relationships:** The FDA requests sponsors define their enrollment goals for diverse populations as early as possible. Goals are established based on gold standards or benchmarks, which are defined based on epidemiological data. Many disease states have little to no epidemiological data to inform their gold standards, which can hinder research efforts in the long term.

4. **Take a human-centered design approach:** Putting real people at the center of the trial development process is critical. We must engage with communities and their leaders to understand the best ways to reach, educate, and communicate with prospective patients and study participants. Consider key areas such as:

   - **Communication methods:** What is the best way to reach this audience (social media, advertising, community events, etc.)?
   - **Messaging:** Is the messaging about the trial culturally sensitive? Does the community we're trying to reach understand the key message?
   - **Reading comprehension:** Is the reading level appropriate for this audience?
   - **Language:** Are we using the same language as the community we're trying to reach?
   - **Imagery:** Are the images in our outreach culturally sensitive and relevant?

03 Q: What are the biggest hurdles—whether for sponsors, CROs, trial sites, or patients—in creating more diverse clinical trial participation?

A: Certainly there are many barriers to address when it comes to creating a more diverse clinical trial population. The American Thoracic Society published a **statement paper** on recruitment and retention of diverse populations in clinical research that identifies common themes and proposes potential solutions. (See figure 2 below.)



I think at least trying to have these types of conversations to identify barriers is an important first step, and then it's about building the mechanics and the systems needed to provide even more support. It needs to be a shared effort between all of us: taxpayers, government, healthcare systems in general. For example, one of my colleagues at the College of Pharmacy has done quite a bit of research on the availability of pharmacies in communities. She found that Black communities in the south and west sides of Chicago have 40 percent fewer pharmacies available to them as compared to White communities in the city. So, for a sponsor to understand that data or hear that from the community itself—that is quite valuable.

04 **Q: Have you or other industry colleagues observed examples of effectively engaging with the community outside of the clinic? What role does the community play (or could potentially play) within trial recruitment?**

A: The community certainly plays a critical role in trial recruitment efforts. And yes, I've seen several instances of effectively engaging with the community. A few key suggestions come to mind here:

1. If possible, **work with a dedicated recruitment specialist** in your clinical trial recruitment efforts. This makes a big difference in both the volume and diversity of trial participants.
2. **Meet participants where they are.** They won't magically come to you, so it's up to the organization conducting the trial to proactively go out into the community and conduct outreach for trial recruitment.
3. **Be strategic about who goes into the community to recruit participants.** Ideally, it should be someone who looks like or who has some connection to the community.

Let's look at an example of this. When I was conducting HIV clinical trials, for instance, it was basically me running everything. From a resource standpoint, I was very limited on what I was able to do, including trial recruitment. Whoever was geographically close to me was essentially my pool of participants. But later, once we started doing COVID-19 clinical trials, we were able to hire a recruitment specialist. And this is all they do: They go out into the community, conduct social media outreach, talk to community leaders, and meet potential participants where they are. For our case in particular, working with these dedicated recruitment specialists was very successful, and they were able to recruit a diverse pool of participants for the trial.

Another example: Our friends and partners at a small community hospital down the street serve a large percentage of Chinese-American communities in Chicago. Their recruitment outreach specialist speaks Mandarin and Cantonese. She goes out into the community, talks to people in their native language, and is able to bring patients into the clinic not only for care, but also to participate in clinical trials.

So yes, I think it's a requirement that you have a recruitment specialist on the team if you expect decent numbers of participants within those diverse populations. And not only that, but having a person who has some type of connection to the community that you're recruiting within is crucial in building trust.

05 Q: Based on your experience, what do you see as the most common barriers to trial participation and retention?

A: In my particular experience, the population that I work with and the pool of patients that I recruit for these trials are fairly low income, if they have any income at all. As a clinician, I'm often working with a single mother of several children, or a head of household who provides for the entire family. To give you an example, let's say I'm working with somebody who has to go to work every day, and they cannot miss a day because they have an insecure work environment and could get fired easily. How can I entice this person to come in for a study visit for three hours on a Friday? They can't because they have to work. They don't have flexibility like that. Or maybe they're a single mother who has to care for other children—how can I bring her and all of the children to the clinic to be able to participate in this trial? It's very difficult.

The first aspect to consider is that this is not always an easy population to entice and recruit from. Another important aspect is trust in the system. Because I'm a Hispanic, Spanish-speaking male, it's more likely that Hispanic or Spanish-speaking patients will be open and receptive to what I have to say.

Other than initial trial participation, there are also barriers when it comes to trial retention. Up until 2020, the majority of the trials that I conducted were in HIV, and I drew from our patient population. They were people who I would regularly see in the clinic, and I had an established relationship with them. In general, those patients would stick with our study visits and had fairly strong rates of adherence. Occasionally, we would have a few dropouts or things would come up later on, like new diagnoses that eliminated them from the trial. But overall, it was a stable recruited population. Then we got into COVID-19 vaccine clinical trials.

These were trials where we recruited hundreds of patients. A handful of them were from our own patient populations, but many were people we had never seen before from the community. For our patients with whom we had established a relationship, we were able to keep them on board and engaged. But for newer patients, it was challenging. You have to be more engaging and in constant communication to keep reminding them that they're part of a clinical trial. At the beginning, for example, study visits are fairly close together, and they feel that they're a part of something. But as visits are spaced out further, let's say six months to a year, people forget. And even if you send a reminder, it can feel like, "Oh, well, who cares now? It's been so long." So, you definitely have to keep that relationship going, especially with those participants you don't have a prior relationship with. You have to help people remember that they're a part of something that is bigger than all of us.

06 **Q: Do you believe there is more that could be done to help patients stay enrolled in clinical trials? For example, addressing transportation and childcare as part of a trial to remove barriers that often impact underserved communities?**

A: Absolutely. We're fortunate in that our clinical team is interdisciplinary and includes outreach workers. Our outreach workers have university cars and can also provide bus passes, so we're able to provide transportation for a lot of our patients and study participants.

I also work in our obstetrics clinic for HIV-positive women. We used to have a fairly difficult time bringing our patients in for their OB visits. But recently, we've started scheduling Uber rides to bring them to and from their appointments. It was actually the medical center who started that initiative, which was very refreshing to see because, a lot of times, that's not the bottom line for an institution or administration. That was fantastic, and it's made a big difference in keeping people enrolled in studies and helping them get to their appointments.

However, there are still barriers, and it really depends on the trial. But as an example, one study I tried to do was a phase two clinical trial that required pharmacokinetic monitoring of pregnant women. This trial involved a lot of blood draws at different times throughout the day. That meant that I had to bring the mom in from around eight in the morning until eight at night. The mom would sometimes need to bring a child with her, as well, because she didn't have childcare. So, here I was trying to entertain a child throughout the entire day, and it really limits your ability to do anything else. Personally speaking, I did not feel like I had the resources or training for that. And that was how I learned that I'm not equipped to do phase two clinical trials. It's something that you wouldn't necessarily think about at first... But there are so many non-clinical barriers to doing that type of work.

Sometimes, it's even more basic than childcare or transportation—something like food. A patient might tell me, "I haven't eaten since last night. How long is this visit going to take? Can I go now?" And I'm trying to keep them at the clinic until we're done with the study visit. This has taught me and the clinic as a whole to become very flexible. We've had to open visits during the weekend or at night after patients were done with work, and maybe have a snack waiting for them. Being flexible in our approach was a huge part of how we were able to retain many of our participants.

But you also have to recognize that not every organization has that flexibility. Luckily, our team at that point was fairly large—we had about 60 colleagues participating in the trials. We had that flexibility to provide evening, weekend, or even home visits. Having the ability to do that was paramount to being able to conduct these visits and stay on course with the trial.

07 **Q: Thank you so much for sharing your perspective with us today. Is there anything else that you want to share about your work or any other thoughts on the state of clinical trial diversity?**

A: I do think it is important to acknowledge that barriers in diversity recruitment for clinical trials are not very different from those encountered in health care in general. This is not only a question of increasing diversity in clinical trials, but more broadly, a question of how we increase diversity in health care and in our systems as a whole.

There is also a lot of literature from scientific organizations that provide guidance on how to improve diverse population recruitment into clinical trials. And the vast majority, from what I have read, all essentially highlight the same points. I think one critical aspect worth reiterating is the need to increase diversity in the team of investigators, especially if you're trying to reach those diverse populations. And so you need to have someone who looks like you or has some sort of connection or appreciation to your community for that community to at least be receptive and open to information. A lot of these papers address that diversity in the research team is quite important for reaching these communities.

Lastly, I'll say that clinical trial diversity is a constantly developing field of study, and I'd encourage those who are interested to explore the literature and guidelines on this topic. As we've discussed, increasing clinical trial diversity is no one person's responsibility—and it's going to take all of us working together to really make a difference.

Additional Resources:

- The American Thoracic Society: Enhancing Recruitment and Retention of Minority Populations for Clinical Research in Pulmonary, Critical Care, and Sleep Medicine: An Official American Thoracic Society Research Statement
- Neurological Clinical Researchers from City University of New York SPH + College of Global Public Health + University of Wisconsin-Madison: Barriers and Strategies for Recruitment of Racial and Ethnic Minorities: Perspectives from Neurological Clinical Research Coordinators
- IDSA + HIVMA: Developing Therapeutics During the Coronavirus Pandemic and Future Public Health Emergencies
- FDA Draft Guidance for Industry: Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry
- Ashley Patcher, Program Director at TransCelerate Biopharma Inc. Article: Tips and Tools to Overcome DE&I Challenges in Clinical Trials