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Diversity in Clinical Trials – Why it matters and how to achieve it

The Diversity Issue in Clinical Trials – an overview

Pharmaceutical industry discussions on Diversity, Equity, and Inclusion (DEI) all end in the same place—the need to build patient trust. However, there are few suggestions about how to build this trust and little recognition that it will take time. Additionally, trust is only the first step to ensuring DEI in clinical trials. Social determinants of health (SDoH) are often overlooked yet are key to patient willingness and ability to participate in a trial.

Rather than attempting to retrofit the old systems, is it time to build a new clinical trial patient infrastructure and create a new DEI pathway? While industry dialogue continues, RxE2 already knows how to increase diversity and has the means to do it now. We believe it is time to set aside the discussion and get to the how and now.

The history of diversity in clinical trials

The number of ethnic and racial minorities included in trials has not been representative of the national percentage of these populations. For decades, the industry standard has been a pool of clinical trial patients that were disproportionately white. Similarly, a gender bias leaned heavily in favor of men. Further reducing the possibility of diversity, Black and Hispanic patients were often not asked to participate in clinical trials because it was assumed they were not interested. The result is that trials are not strictly random because the selection process intentionally excludes a portion of the population with potentially significantly different outcomes. These combined factors create a knowledge gap in drug efficacy in the underrepresented populations.

Recently proposed Federal Drug Administration (FDA) guidelines recommend increasing diversity in clinical trials to better reflect the racial, ethnic, and gender breakdown of the country. While the guidelines are not compulsory, the industry is racing to create the necessary Race and Ethnicity Diversity Plans (Plan). Based on the protocol objectives of the trial, the Plan will identify the actions necessary to enroll and retain diverse participants.

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To date, most material addressing the FDA guidance lists the causes of inequity, the reasons why the inequity has remained for decades, and what needs to be included in the Plan to increase diversity. Few articles propose a means of solving the issue, and most end in the same place: the need to build trust. How will pharma companies do this in the limited window before their next trial?

Traditionally, primary care doctors inform patients about clinical trials and provide enrollment information. However, while primary care doctors may have a vast array of patients, the total number of patients fitting a trial-specific medical condition, disease stage, and demographic has proven to be limited. Furthermore, patients in underserved target areas may not have a primary care doctor or use a community clinic. These patients are likely to use urgent care and emergency rooms where they rarely see the same doctor twice. Under these circumstances, it is difficult to gain the number of diverse patients necessary to fulfill trial needs or sufficient patient trust to encourage participation.

With the hope of increasing clinical trial patient diversity, many organizations are creating new clinical sites and dispatching mobile units for decentralized clinical trials (DCTs) in underrepresented areas. While staff in the new clinics may racially and ethnically reflect the local population, they still need to build trust with the community and patients before successfully recruiting for trials and retaining participants. Similarly, expanded outreach in community centers and churches and via social media is touted as a means of increasing diversity. There is no identified segue between community outreach and potential clinical trial participants. Connecting with community centers and churches does not directly provide participants–you still must screen for the appropriate demographic, diseases, and willingness to participate. To be effective, these approaches still need to address the time factor.

The current conclusion is that gaining patient trust is the key means of increasing the ethnic and racial diversity necessary to make clinical trials more reflective of the population. Few articles offer insight into how to build the necessary trust, and fewer offer an adequate timeline to address both the need in the underserved communities and the FDA guidance. There is no how to build trust (trust gap) and no now in building trust (time gap).

The hope is that creating community engagement through DCTs and new or mobile clinics will translate directly into a diverse group of clinical trial participants. It is not sufficient to equate a community presence with creating patient rapport because patient trust still needs to be established. Additionally, the social determinants of health (SDoH), the final critical factors that decide patient participation, are often unknown in the currently suggested approaches–DCTs, new and mobile clinics, and community outreach. It is time to rethink the current model. Why create a new community clinic and introduce a new healthcare professional when thousands of local pharmacists have already established patient relationships in independent community pharmacies across the country?

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The RxE2 model to achieve clinical trial diversity

RxE2 proposes a different model. Whereas a doctor may have a handful of patients matching the criteria for any specific clinical trial, a pharmacist works with patients from dozens of doctors and can readily identify suitable patients for inclusion screening. The RxE2 platform includes 4,000–and growing–independent pharmacies already engaged in diverse communities across the country. Trust has been established between these pharmacists and their patients, creating the opportunity for open discussions about clinical trials. As trusted community healthcare providers, pharmacists connect directly with patients. With a clear understanding of community and patient SDoH, the key contributor to a patient's decision to participate, they offer counseling and follow-up, increasing compliance and retention.

RxE2's Diversity Now Plan is a referral and recruitment platform for underrepresented racial and ethnic populations that is currently in place and operational. The demographic for any clinical trial is at our fingertips, and compliance and retention programs are already in place.

RxE2's network of local independent community pharmacies across the country eliminates both the trust and time gaps

The six RxE2 steps to Diversity In Clinical Trials

1. **Identify pharmacies in underrepresented areas –** RxE2 has an extensive network of diverse community pharmacies already in areas of interest. There are 4,000 community pharmacies on the RxE2 platform; another 15,000 are readily available. This network is sufficient to provide a diverse population of clinical trial patients for almost any trial.
2. **Identify potential patients based on protocol requirements –** Using the prescription database and RxE2's AI-enabled technology, the pharmacist targets patients of the desired demographic and medical issue.
3. **Initiate patient contact to determine interest in clinical trials –** Considering patient SDoH and other factors, the pharmacist contacts potential patients.
4. **Perform inclusion/exclusion criteria for patients meeting the criteria –** Pharmacists provide the initial screening for patient suitability. This may be as simple as administering a questionnaire.
5. **Refer patients meeting the criteria to the Primary Investigator –** Pharmacists introduce patients to clinical doctors via a warm hand-off. Providing a personal introduction helps alleviate concerns about doctors unknown to the patient.
6. **Monitor underrepresented population enrollment –** Pharmacists follow patient participation and progress and adjust accordingly to meet protocol requirements.

Patients who move through these steps have a high probability of inclusion when they finally reach the clinical doctor. Additionally, retention rates are high because they know and trust their pharmacist and know that the pharmacist will continue to offer counseling and support throughout the trial.

Conclusion

The many articles addressing Diversity, Equity, and Inclusion have produced valuable dialogue and insight into the elements needed for improving diversity in clinical trials. What they lack is a means of implementing these necessary changes. Additionally, the current strategies potentially require years before results will be evident.

The current RxE2 platform engages over 4,000 community pharmacies. For most studies, this is more pharmacies than necessary. Compared to building and staffing new clinics, the required start-up time for identifying pharmacies in appropriate locations and selecting patients of the targeted demographic is months.

The how and now of building trust in underserved populations are at our fingertips. It's time to move beyond the discussion and begin implementation. It's time to move to the other trusted healthcare professionals—local community pharmacists.