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# Six ways to improve diversity in clinical trials

Diversity is becoming increasingly important as a focus of clinical trials. Studies routinely show that health conditions can affect different population groups in different ways, so trial designs that include a well represented mix of patients are vital. The data will be more robust, giving healthcare professionals confidence to treat patients once the therapeutic in question has successfully been brought to market.

Despite this, older people, those from under-served ethnic communities, differently abled people, and women are too often missing from research. Without their involvement, it is difficult to confirm if a treatment is truly effective for all patient populations.

The COVID-19 pandemic brought this issue of diversity into sharp focus. People from Black, Asian and minority ethnic groups have been disproportionately affected by the virus, but by June 2020 just 0.004 percent of the 1,518 COVID-19 trials registered on ClinicalTrials.gov were collecting data on ethnicity.

But change is happening. The Phase III trials for the COVID-19 vaccines developed by Moderna, Pfizer and BioNTech, and Oxford University and AstraZeneca each involved tens of thousands of people from racially or ethnically diverse backgrounds across the world. In the US, the FDA has issued guidelines to improve racial diversity in clinical trials and in the UK the Road to Equality campaign, co-founded by Innovative Trials in partnership with COUCH Health and Egality Health, is bringing together industry and patient representatives and academics to share best practice and discuss a way forward.

This short paper gives six approaches that could be implemented to help make diversity a bigger focus on your clinical trials.

### 1 Include targets for each population in the protocol and recruitment plan

If recruitment targets are not provided for every group of patients that the trial wants to include, and at levels that allow the data to be statistically relevant, there is a high chance that the final demographic spread will not encompass all groups to the desired levels. Including targets in the protocol and recruitment plan, then actively tracking these throughout the study, will ensure the final data includes the required levels of patients to confirm efficacy and efficiency when treating people of all backgrounds.

### 2 Actively promote diversity and include site level diversity plans

Having a clear approach to diversity promotion will help ensure the appropriate levels of different patient populations are achieved. This will differ according to the therapeutic area and locations of investigator and referral sites. Diversity plans and oversight should be considered at site, region and overall trial level to be most effective, and should include input from different demographics and local communities. Appropriate educational and promotional materials should be developed and made available in line with the diversity plan.

### 3 Include community outreach programs to educate and identify potential clinical trial participants

Building strong relationships with communities is important for engagement and gaining trust. This can take time but is worth the effort and patience. Developing relationships will enable a deeper understanding of people's views within communities local to clinical trial sites, and the creation of bespoke outreach programs. This could include working with patient groups, community organisations, religious groups, local businesses or places of leisure by offering education, knowledge and the opportunity to become involved in furthering healthcare within their communities and beyond. As part of this engagement exercise, materials should be created with the target population in mind. Materials and how they are delivered can make a big impact on both diversity and patient recruitment in general.

### 4 Patient referrals as an approach to expand into target demographics

Once a patient becomes involved in a trial, there may be others that the patient knows within their community network that may also be eligible. The type of trial and whether there are any sensitivities around the therapeutic area and/or within the patient population will determine if this is appropriate. Supporting patients to talk to others, and having materials to help them explain the trial and its benefits, can help bring forward others in the community that might want to be involved.

### 5 Make the reporting and publishing of diversity statistics a requirement

It is likely that there will eventually be a requirement to report and publish diversity data for each clinical development program. Currently this is not the case, but should be considered best practice. Implementing an approach where diversity data is published will mean trial designs will be future-proofed. This reporting will also mean a focus on ensuring diversity throughout the clinical trial is maintained.

### 6 Use a trusted vendor to support and enhance your recruitment strategy

Recruiting diverse patient populations into clinical trials can be time-consuming and challenging. One of the most effective and efficient methods to increase patient diversity in clinical trials is to partner with an experienced vendor such as Innovative Trials, which has expertise and proven success in this area. Working alongside you, your chosen vendor can provide training, support and practical tactics to ensure optimal recruitment across all appropriate patient populations to keep your clinical trials on track.

At Innovative Trials, our experts work with sites, primary care professionals and communities extensively to understand how recruitment can be enhanced by supporting, coaching and educating.

As such, we have a strong record of increasing recruitment rates, finding hard-to-reach patients and devising and implementing diversity strategies to support patient recruitment and retention.

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