

# Diversity in Clinical Trials: UCB Strategy



Over 3.7 million patients globally use UCB medicines.<sup>1</sup> As a leading global biopharmaceutical company, we are continuously working to advance science and embrace new knowledge to solve the challenges that matter to people living with severe diseases.

One challenge of interest at UCB is diversification of clinical trials. At UCB, we are committed to working toward a clinical trial infrastructure that addresses health disparities and closes the gap in clinical trial diversity. The FDA continually shares that *“ensuring people from diverse backgrounds join clinical trials is key to advancing health equity.”*<sup>2</sup> We agree and actively seek diverse patients for our global clinical trials. We want to ensure diversity is represented in age, sex, gender, race, ethnicity, socioeconomic status, genetic disposition, and geographical location.

At UCB, we recognize this journey to diverse clinical trial will not be resolved immediately. By taking a variety of approaches to address and improve diversity in clinical trials we are learning and implementing new ideas that help us progress. We reviewed the UCB enrollment performance (2015–2020) in comparison to the FDA 2015–2019 Drug Trials Snapshots to understand our baseline data.<sup>3</sup>

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We studied the UCB global & US perspectives of the racial subgroups. From the global view, we need improvement for each of the racial subgroups other than White. In the US view, we are exceeding the US Census Data for Black/ African American and closely comparable to other subgroups.<sup>4</sup> However, to fulfill our commitment to diversity in clinical trials, we must continue to improve over our baseline.

We also looked at sex and age and found this was appropriately balanced for the UCB portfolio of clinical trial programs.

## UCB Global Data (2015–2020) vs. FDA Drug Trials Snapshots Summary Report

Race	FDA	UCB Global	UCB US
White	76.0%	87.2%	77.8%
Asian	11.0%	5.4%	3.3%
Black or African American	7.0%	4.5%	15.0%
American Indian or Alaska Native	1.0%	1.1%	0.8%
Native Hawaiian or Other Pacific Islander	NA	0.2%	0.7%
Other/Mixed	5.0%	1.6%	2.5%

FDA: Number of subjects = 292,537  
Drug Trials Snapshots / FDA 2015–2019 Drug Trials Snapshots Summary Report

UCB: Number of subjects = 8,852 in 36 studies

\*UCB Snapshot included all trials completed in period 2015–2020 with n>25 patients. Excluded APAC only & open label Extension studies



## Plans to increase diversity

It is our goal to improve health equity across the care continuum from research to the delivery of innovative medicines. Our commitment to working toward a clinical trial infrastructure that addresses health disparities and closes the gap in global clinical trial diversity has been reinforced within our clinical teams.

The training course addresses how to define diversity in a clinical trial as well as key areas to consider when designing and operationalizing a clinical trial.

Training on *"Enhancing Diversity Equity and Inclusion in our Clinical Trials"* was created for our global clinical team members and interested colleagues through the UCB learning platform. The training course addresses how to define diversity in a clinical trial as well as key areas to consider when designing and operationalizing a clinical trial. Topics of interest included protocol design, country and site considerations, data sources, patient engagement & advocacy, community engagement and external collaborations/partnerships. The training also includes a diversity planning checklist to guide clinical teams through the various actions they could pursue to increase diversity.

## Protocol Design

Protocol design is an important consideration when exploring ways to increase diversity and inclusion in clinical trials. UCB teams assess innovative approaches that include decentralized clinical trial (DCT) models, co-creating protocols with patients to leverage the voice of the patient and assessing protocol complexity to minimize patient burden.

The use of digital technology and the implementation of Decentralized Clinical Trials (DCT) has changed how we approach the design of our clinical trials. Today, approximately 46% of our trials have a DCT patient-centric component as they offer the opportunity to make clinical trials more accessible for patients. DCTs provide an alternative option for patients who may not have access to clinical trials in their area. Additionally, it can help us to reach patients living with specific disease states in underrepresented geographies.

We are hopeful approaches such as DCT can help ensure access to studies for a wider range of diverse study participants by removing barriers such as distance, transportation, and time required. We have learned that a trial does not have to be fully decentralized for patients to benefit. Simply reducing the number of in-person visits and replacing them with

remote, virtual, or telemedicine visits can go a long way to making a trial more attractive to patients.

In addition, co-creation of protocols with patients and patient advocacy groups (PAG) is an important step to understanding the patient population. Including the patient voice in the design and planning of our trials, especially from the different populations, is an advantageous approach. We proactively seek feedback from study participants during the trial so we can apply learnings to future studies. Patient insights allow us to update patient materials so that it is more meaningful to the populations of interest. Taking it a step further, through listening to diverse patients and PAG representatives, we can refine asset specific inclusion & exclusion criteria, thus broadening eligibility criteria for enrollment when scientifically and clinically appropriate.

Lastly, assessing protocol complexity and patient burden is now a standard process within our clinical protocol development. Any protocol concept that has a higher complexity than benchmarking data is actively challenged, and teams asked to reconsider their design and operational planning to ensure planned enrollment.

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## Country/Site Distribution Considerations

Through the work of the UCB Strategic Feasibility Team, clinical teams can discern:

- countries that support diverse recruitment.
- countries that have a high prevalence of the disease of interest.
- proactively identify sites in communities that serve the population of interest.

UCB leverages a data-driven approach to find under-represented patient groups using:

- disease prevalence and epidemiologic data to understand the target population.
- real-world data to identify and map areas with the patient clusters of interest.
- patient diversity data collected at site level for a more targeted site selection.

## Patient Engagement and Advocacy

Through patient engagement, UCB can maximize the creation of sustainable patient value for specific populations and support shaping the environment of health topics of shared interest. That is why we partner with global, national, and local patient advocacy groups who offer access to patient communities, individual patients/caregivers, patient advocates and patient groups.

Additionally, through sharing diverse imagery in our patient recruitment materials on popular digital platforms (*Facebook, Instagram, Google, Twitter, WeChat etc.*) UCB hopes to increase diversity in our clinical trials. We choose channels based on geolocation, patient population (*sex, gender, age groups, etc.*) to attract the targeted subgroup(s) to our trial information. Our Patient Engagement Team is mindful of tailoring each message for the desired demographic; careful to include tone of voice and relatable and interesting content.

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## Community Engagement

Our Community Engagement Partner Program was launched within the UCB Site Engagement Team. This approach was taken to support sites that have access to diverse patient populations. The goal was to collaborate directly with healthcare professionals and introduce them to their local communities creating opportunities to:



Listen to the needs of the community



Answer questions related to clinical research



Educate about clinical trials within the community



Engage proactively in activities such as walks, health fairs, public forums, and educational seminars



Provide information to patients about clinical trials in their area in an easy-to-understand format



Leverage Patient Referral networks



## External Engagement/Partnerships

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External collaborations are important to learning best practices for ensuring diversity in clinical trials. UCB recently worked with industry leaders as a member company of TransCelerate to launch their Sponsor Toolkit Program for Diversity, Equity and Inclusion of Participants in Clinical Trials as one part of their ongoing program to enhance diversity in clinical trials. In addition, UCB is a member of PhRMA who just launched Equitable Breakthroughs in Medicine Development to further innovation and collaboration, bringing together diverse communities, patients, providers, health partners, community organizations and academic institutions to pilot a network of sustainable, connected, community-based trial sites.

UCB, along with other peer pharmaceutical companies and CROs, partnered with Tufts Center for the Study of Drug Development to conduct a study to characterize and examine the relationship between investigative site personnel diversity and study participant diversity. The study concluded that a diverse clinical research workforce is associated with diversity among clinical trial volunteers. It also showed that diversity in the clinical research workforce still falls short of reflecting the diversity of the global patient population and identified key areas to support increased racial and ethnic representation among site staff.

As an industry we must continue, through partnerships and initiatives such as these, to build strong foundations to promote inclusion of underrepresented patients in clinical trials.



### Closing

UCB is serious about addressing Diversity, Equity, and Inclusion in clinical trials. The lack of diversity in clinical trials means that developed medications may not work as effectively for specific subgroups thus widening the gap to health equity. We are focused on closing the gap. Our first objective is to address race and ethnicity in the US and then take actions to do the same globally. We recognize the importance of seeking and employing new ways to connect to unique and diverse patient populations. We are also mindful of the FDA guidance that encourages us to create diversity plans in an effort to better represent underrepresented populations.<sup>1,2,5</sup> As we identify best practices for recruitment, we assess the key drivers such as scientific rigor, the power of analytics & data to broaden access, and simply addressing health inequities for each asset. By considering the needs of diverse populations globally and through meaningful conversations we can continue to improve upon our baseline goals of diverse clinical trials.



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