

Clinical Trials

Clinical trials are research studies which test the most promising treatments, once they have been through pre-clinical testing. Clinical trials involving healthy volunteers and patients play a vital role in the development of new treatments and medical devices. With a focus on unmet medical need, our clinical trials are conducted to ensure that all investigational drugs are safe and effective. Clinical trials are divided into 4 phases that build on each other: While the treatment's safety and efficacy is monitored throughout each phase, each phase will seek to answer specific questions about a treatment. Over recent years, along with drug discovery, treatment development and the clinical trials essential to the process have benefitted from scientific and technological advancements, as well as greater diversity.

UCB's Values

At UCB we've moved away from seeing patients as just patients – they are participants. By really listening and engaging with them as partners we are striving for greater understanding of their needs & ways to make our clinical studies more participant friendly. We strive for our solutions to provide the best individual experience for patients, and we aim for the participants of our studies to be reflective of the populations that will ultimately benefit from our new medicines. This means considering the diversity of our trials beyond demographics such as race, gender, and other factors. In this essential step in the development of treatments, we are committed to working toward a clinical trials infrastructure that addresses health disparities and closes the gap in clinical trial diversity, to better reflect the intended treatment population.

UCB's Approach

Alongside our peers, we follow strict ethical and regulatory guidelines in all countries where we conduct clinical trials. To improve and accelerate development, we keep patients' needs front and center, leverage new technologies, and new clinical study designs to help improve the patient experience. We involve patients and caregivers in the design of our development plans right from the start and throughout the clinical development process. We participate in and support a range of cross-industry collaborations and initiatives that help move the needle on how clinical trials are designed and executed, and how we can maximize the use of the trial data to help reduce the burden on our study participants.

How we Focus on Patients

At UCB, we are taking many concrete steps to include the patient voice end to end in our clinical trials. We consult with Patient Advocacy Groups and caregivers from all over the world as we

design our clinical trials, and we also seek feedback from the study participants during the course of the study. Doing this brings together a diverse group of community representatives to ensure that we gather feedback from different perspectives. We have key steps in our study design where we challenge the number of visits and assessments to ensure that we reduce the burden on the participants. It is also important to us that participants in our clinical trials have a full and tangible understanding of the trial they are participating in without medical jargon, so we have implemented plain language versions of essential documents, such as consent forms and study summaries. For patients participating in our trials, the possible need for continued access until the medicine is approved is also a key consideration for UCB, and something that features in our design considerations.

Clinical Trial Diversity

At UCB, our vision is to ensure participants in UCB clinical trials are reflective of the populations that will ultimately benefit from our new medicines. As we continue to deliver value to patients, we look to find new approaches to clinical trials that encompass a broader spectrum of the population. One example of this approach is the implementation of decentralized clinical trials (DCT). DCTs offer the opportunity to make our clinical trials both more accessible and easier to participate in for patients. They provide an alternative option for patients who may not be able to easily access a clinical trial and helps us to reach patients living with specific disease states in underrepresented territories.

In another approach, UCB works directly with several partners 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. Although as an industry, we still have work to do, through partnerships and initiatives such as these, we are building on a strong foundation to promote inclusion of underrepresented patients in clinical trials.

Transparency

We collaborate with health care professionals, patients, and other stakeholders to increase transparency around our research and development work and improve knowledge of available treatments. At UCB, the results of our clinical trials are publicly available online via our **clinical studies index**. The regularly updated list discloses information regardless of the outcome of the study or where the study was conducted, and also includes information about UCB's ongoing clinical trials. To make sure that the results are comprehensible to everybody, we also publish **plain-language summaries of results** to help people outside of the scientific community to understand the conclusions. If you think you are an appropriate candidate to participate in one of our clinical trials, please contact your physician.