

# Our Global Policy Position on Clinical Research

## BeiGene's Position

Our mission is to ensure that more patients around the world have **access to innovative life-changing medicines**. This begins with our commitment to the discovery and clinical development of new treatments that improve and extend life.

We adopt a predominantly **in-house approach to clinical research** that leverages our world-class R&D team and international clinical development footprint. This enables us to efficiently develop innovative therapies that bring meaningful benefits to patients.

We are passionate about **improving diversity in clinical trials** and seek to conduct global studies that are representative of the patient populations eligible for our treatments. Furthermore, we recognize the importance of conducting trials safely and with integrity. We uphold the highest standards in clinical research no matter where our studies are conducted.

## BeiGene's Approach to Clinical Research

We focus on discovering and developing therapies that positively impact patients' lives. We know that creating the medicines of tomorrow requires a **world-class R&D team**. As such, we employ one of the largest oncology-research workforces<sup>1</sup>, comprised of industry-leading scientists, and invest in a diverse range of technologies that maximize our ability to develop new life-changing treatments. This is reflected in our broad research pipeline, which includes over 50 preclinical programs and covers 80% of the world's cancers by incidence.<sup>2</sup> Furthermore, half of our early stage therapeutic candidates have first-in-class or best-in-class potential, and we are currently conducting 30+ Phase 3 or registration-enabling trials.<sup>3</sup>

As part of our continuing commitment to develop innovative medicines, we have built an **international clinical development organization** with leading institutions and key opinion leaders. We conduct multiregional clinical trials, with more than 90 ongoing or planned in over 45 countries.<sup>4</sup> This includes Australia, China, Germany, South Korea, Spain and the U.S., as well as countries that have often been excluded in oncology trials such as Brazil, Mexico and Thailand. In addition, we work with community clinics and hospitals to help them prepare to run global trials.

Our multiregional approach **enables us to expand access to patients** that need innovative medicines in a broad range of countries. This is achieved through expedited clinical trial enrollment and by generating data to support regulatory approval and reimbursement in those markets.

In addition, **we offer compassionate use programs in many countries** for those who do not have access to our clinical trials and who have a disease with no satisfactory authorized therapies. Over the last few years, our compassionate use programs have facilitated access to treatment to over 400 patients in 50 countries. Furthermore, we are committed to the post-trial supply of our products to ensure the continuation of treatment until the product is available on the market.

---

<sup>1</sup> <https://www.beigene.com/wp-content/uploads/2022/04/2021-ESG-Report.pdf>

<sup>2</sup> [https://www.beigene.com/wp-content/uploads/2022/07/BeiGene-Global-PAP\\_FINAL\\_06.30.22.pdf](https://www.beigene.com/wp-content/uploads/2022/07/BeiGene-Global-PAP_FINAL_06.30.22.pdf)

<sup>3</sup> [https://www.beigene.com/wp-content/uploads/2022/06/BGNE-22-026-BeiGene-FactSheet-US-Final-\\_1\\_.pdf](https://www.beigene.com/wp-content/uploads/2022/06/BGNE-22-026-BeiGene-FactSheet-US-Final-_1_.pdf)

<sup>4</sup> <https://www.beigene.com/our-purpose/>

We conduct most of our clinical trials in-house rather than outsourcing to a clinical research organization. We believe this allows us to develop more effective collaborations with clinical trial sites, enroll patients faster, accelerate clinical development and exercise greater compliance oversight and quality control. We trust that **our clinical research model allows us to better understand** the clinical environment and the needs of patients, enabling us to quickly and efficiently develop new treatments that positively impact patients' lives.

We are committed to working with the best minds in the fight against cancer and seek **partnerships with world-class companies** to advance research and development. This is evidenced by our collaborations with companies such as Amgen, Novartis and Seagen.<sup>5,6,7</sup> In addition, we support independent research that aims to advance science such as investigator-sponsored research and investigator-initiated trials.

## Diversity in our Clinical Trials

At BeiGene, we are passionate about improving diversity in clinical trials. We believe that this is key to advancing health equity and providing healthcare decision-makers with the best possible information about our medicines. We recognize that people from different backgrounds may have varying responses to the same treatment. We **conduct clinical trials in multiple regions** with diverse patient populations that are representative of patients seen in clinical practice. Furthermore, we aspire to partner with clinical care experts, institutions and hospitals that share our goal of improving clinical trial diversity globally.

## Clinical Trial Integrity, Ethical Conduct and Safety

Our core values emphasize our promise to put **patients first and drive excellence with integrity**. These values are reflected in our commitment to conduct clinical trials with integrity and to the highest quality. We follow ICH<sup>8</sup> guidelines and uphold company-wide R&D standards that are often more stringent than industry requirements. For ethical conduct, we regularly hold audits and evaluate bioethics issues. We adhere to the 3R (replace, refine, reduce) principles and fully support the use of alternatives to pre-clinical animal research whenever possible.<sup>9</sup>

**Patient well-being** is paramount in our clinical trials. Our commitment starts before the first patient is enrolled, by putting safety at the heart of the clinical trial design and decision-making process. Furthermore, we ensure that our medicines are produced in accordance with high quality standards, have undergone robust testing and maintain strict compliance with the requirements of global regulatory authorities and our safety protocols.

## Clinical Trial Transparency

We believe clinical trial transparency and data sharing supports biomedical innovation, increases broader awareness in clinical research, and fosters **public trust in our products and treatments**. We proudly commit to the Biotechnology Industry Organization (BIO) Principles on Clinical Trial Data

<sup>5</sup> <https://ir.beigene.com/news/beigene-announces-global-strategic-oncology-collaboration-with-amgen/e32f497a-c505-474c-a98f-cd80c66ce0ad/>

<sup>6</sup> <https://www.businesswire.com/news/home/20191105005417/en/Seattle-Genetics-and-BeiGene-Announce-Global-License-Agreement-for-Advanced-Preclinical-Product-Candidate>

<sup>7</sup> <https://ir.beigene.com/news/beigene-expands-collaboration-with-novartis-to-develop-and-commercialize-beigene-s-tigit-inhibitor-and-market-five/90967044-2f65-4774-942e-7edbd880f12/>

<sup>8</sup> ICH = The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

<sup>9</sup> BeiGene 2020 ESG Report

Sharing and the responsible sharing of our trial data to help advance such research. To this end, BeiGene registers Phase 1 to 4 interventional trials and applicable non-interventional studies on publicly accessible websites (e.g., ClinicalTrials.gov) in accordance with regional and national regulatory and policy requirements worldwide.

## Enrolling in a BeiGene Clinical Trial

If you are interested in **enrolling in a BeiGene clinical trial**, you may be put in contact with the study team which includes the lead doctor, nurses, and research coordinators, who will assess your eligibility to participate in the trial. We welcome participation from people of all gender, race, ethnicity, and socioeconomic status in our clinical trials. This includes healthy volunteers and patients with specific diagnoses.<sup>10</sup>

*More information about our clinical trials can be found at <https://www.beigene.com/our-science-and-medicines/our-clinical-trials/> or by emailing [ClinicalTrials@BeiGene.com](mailto:ClinicalTrials@BeiGene.com)*

---

<sup>10</sup> <https://www.beigene.com/our-science-and-medicines/our-clinical-trials/>