

Does Viatris participate in clinical trials?

Clinical operations, including clinical trials, are key to advancing access to medicine for patients across the world. We are committed to conducting clinical trials in an ethical way and to promoting patient safety and the protection of patient rights throughout the study's lifecycle. Our global program for clinical research and applicable standard operating procedures are designed to adhere to international best practice and good clinical practice (GCP) as defined in the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) framework.

Diversity in Clinical Trials

Viatris supports efforts focused on diversity in clinical trials and works to include diverse patient populations for global studies that will be submitted for approval to health authorities around the world. Considerations for diversity include both demographic criteria (e.g., gender, race and ethnicity) as well as non-demographic criteria (e.g., co-morbidities, organ dysfunction, the extremes of weight ranges). Viatris is committed to working with health authorities to enhance safety, scientific rigor and diversity in our clinical trials. Health authorities across the globe have called for increased pediatric research to support accurate labelling for pediatric populations. Viatris committed to comply with applicable GCP requirements to ensure that pediatric clinical trial requirements are implemented with a focus on patient safety and integrity.

In 2022, we continued research activities across diverse regions in which patients may experience various health care and/or economic challenges. Our research encompassed varied therapeutic areas, including mental health disorders, dermatologic conditions, ocular maladies and reproductive health, among others. Viatris has increased its focus on ophthalmology therapies, and several associated studies are planned for 2023 as this therapeutic area expands at Viatris.

Global Standards

Regardless of where the trials are conducted and whether they are performed in-house or by a qualified third party, adherence to Good Clinical Practice (GCP) applies, promoting adherence to applicable policies, procedures and regulatory requirements.

Informed Consent

The company's standard operating procedure governing the informed consent process is part of the QMS. It includes detailed procedures regarding the development, review, approval, implementation and confirmation of the informed consent process for adult and pediatric trials.

More comprehensive description of responsible clinical operations at Viatris is presented in the [2022 Sustainability Report](#).