

Our Approach | August 2024

Genetic Research and Use of Stem Cells



Genetic research

The rapid development of new technologies that interrogate variability in human DNA and RNA, combined with powerful computing hardware and software, has made it practical to investigate genetic and genomic determinants for risk of human disease or predictors of human response to drugs. We conduct genetic and genomic research within our clinical trials and in collaboration with external organizations that have collected human genetic and genomic samples and health data. We also conduct genetic and genomic analysis of our clinical trial samples, primarily to understand how genetic and genomic variation impact patient responses to medicines. This enables us to communicate information to regulatory authorities and prescribers that will improve the use of our medicines and the understanding of how genetics contribute to the underlying disease, which has the potential to identify new drug targets.

We obtain subject consent for use of genetic and genomic samples in accordance with ethical principles of human-subjects research, which include respect for persons/autonomy, beneficence and justice, consistent with [the Declaration of Helsinki](#), U.S. FDA requirements, [ICH E6 Good Clinical Practices guidelines](#) and [the 1997 UNESCO Declaration on the Human Genome and Human Rights](#). When collaborating with external organizations, we also ensure they've obtained consent from individuals who have contributed DNA, RNA and/or health-related data.

Use of stem cells

Together with the scientific community, we believe that research using stem cells has the potential to help identify medicines, therapies and vaccines to help treat, cure or prevent disease. Many of the most advanced scientific technologies in regenerative medicine involve animal or human embryonic stem cells. For more than a decade, we've applied advances in stem-cell technologies to support our research and development. The capacity of stem cells to differentiate into specific cell types underscores their versatility and utility, from early target validation and identification, to the screening and testing of potential new therapeutics, disease-modeling and pre-clinical proof of concept.

We conduct research using stem cells in full accordance with all applicable laws and regulations, and our own internal research policies. Our research policy involving stem cells adheres to [the U.S. National Academy of Sciences guidelines](#) as well as those of [the International Society for Stem Cell Research](#).

Our Regenerative Medicine Oversight Committee, which comprises both internal and external experts, oversees Company-sponsored research involving stem cells, including highly-targeted research using human embryonic stem cells and induced pluripotent stem cells. The committee is responsible for ensuring that all projects involving stem cells adhere to our policies.

For more information on our R&D efforts, please visit the [Research](#) page on our corporate website.