

## EuropaBio position on germline genome editing

EuropaBio and its members strongly believe that genome editing will enable the development of many solutions to the grand challenges facing both people and planet. In medicine, genome editing offers the prospect of saving lives and tackling some of the most devastating genetic diseases.

It is crucial to note that all pre-clinical and human clinical testing by EuropaBio member companies, using genome editing for the treatment of genetically based diseases, is being done on non-heritable (somatic) cells. This means that it does not result in changes to the genes that a person passes on to their children. Clinical research with genome editing of human non-heritable (somatic) cells is currently seeking to develop treatments for HIV, leukaemia, haemophilia, Leber's congenital amaurosis 10, mucopolysaccharidosis, sickle cell disease and cystic fibrosis, amongst others.

Consistent with the principle of responsible stewardship of science, EuropaBio takes the position that it would be irresponsible at this time for anyone to proceed with clinical research for therapeutic use of genome editing of human germline (heritable) cells and embryos until (i) the consequences of such genome editing are more thoroughly studied and understood and (ii) a consensus on responsible and responsive global governance framework is reached. As it remains critically important that the current state of knowledge of genome editing is improved, such stay of clinical research with human germline genome editing should be limited in time and revised on a regular basis, along with the advancement of understanding of the scientific and technical environment, as well as the consensus on governance arrangements across the globe.

It is crucial that the global community, involving government, academia, industry, and society at large, gathers to discuss the technical, scientific, medical, legal, societal, and ethical issues associated with genome editing of human germline cells and embryos, with a view to establishing an international governance framework. It is also highly desirable that the international community of bioethicists steps up the research on the ethical dimensions of germline genome editing.

EuropaBio takes the view that once an established governance framework will allow clinical research in genome editing of human germline cells and embryos, such research should be carried out only with the intention to potentially provide therapies to serious and unmet patient needs. EuropaBio does not support the conduct of research in germline genome editing aimed at achieving human enhancement.

EuropaBio notes that the WHO convened an advisory committee to develop global standards for governance of human genome editing. This expert panel is currently working to set up a registry of research and development involving human genome editing. In this context, we would like to stress the importance of differentiating between genome editing of human somatic *versus* human germline cells. Remarkable progress has already been made in genome editing of human somatic (non-heritable) cells to treat diseases. All phases of clinical research involving genome editing of somatic cells are already registered in established databases, including the WHO International Clinical Trials Registry Platform (ICTRP), which the WHO plans to use for the new registry. Pre-clinical research on somatic genome editing should be excluded from any proposed registry.

EuropaBio's members adhere to a clear set of core ethical values and condemn, in the strongest terms, any actions that violate laws and regulations. We stand united with scientific and political leaders across the globe in our intention to contribute towards setting, following and enforcing guidelines and policies for the responsible research and application of genome editing of the human germline.