

CeMM position on genome editing in the light of recent reports about gene-edited babies

Following internal discussions at CeMM on human genome editing – prompted by recent reports on the birth of gene-edited babies using CRISPR technology in China – we distance ourselves from human trials performed without adequate ethical approval by the responsible institutions and in violation of both local regulations and the international consensus in the scientific community.

CeMM welcomes responsible research on understanding and advancing genome editing technology including CRISPR, which greatly benefits basic biomedical research and has great potential also for the treatment of many genetic diseases. Importantly, any such research must be performed in strict concordance with local, national, and international laws and regulations. Furthermore, it should be discussed and supported by the international scientific community, including biologists and medical researchers as well as ethicists, social scientists and various stakeholders of civil society, such as patients' organizations.

There is broad consensus within the scientific community that editing of the human germline for human enhancement is entirely unacceptable. In contrast, genome editing to correct severe genetic diseases may be acceptable if there is a clear positive risk-benefit ratio, no suitable alternatives, comprehensive preparatory work supporting feasibility, full legal and regulatory compliance, and strong framework of ethical guidance and supervision.

More specifically, CeMM takes the following position regarding potential uses of CRISPR technology for genome editing:

1. *CRISPR editing of cells growing in the laboratory* (e.g., genetic screening for potential drug targets in cell lines): Permissible and acceptable assuming that established practices for laboratory safety and genetic engineering are followed.
2. *CRISPR editing in model organisms* (e.g., creation and characterization of transgenic mouse models for research on human diseases): Permissible and acceptable within the highly stringent regulations of animal research in Austria and Europe.
3. *CRISPR editing for somatic gene therapy* (e.g., repairing diseased tissue): Permissible and acceptable within the very strict regulation of clinical trials in gene therapy, and only after CRISPR gene editing *in vivo* has been validated more extensively in preclinical models.
4. *CRISPR editing of the germline for gene therapy* (e.g., correcting a gene defect during *in vitro* fertilization to prevent a severe genetic disease): Currently not acceptable, highly premature, and illegal in large parts of the world. There is, however, the possibility that tightly regulated germline editing restricted to a small number of severe genetic diseases will eventually become acceptable within the next 10 to 20 years.
5. *CRISPR editing of the germline for human enhancement* (e.g., changing genes beyond their normal state to enhance the human body): Never acceptable and highly unethical because it creates unforeseeable risks not only for the individual and for its offspring (risk of side effects) but also for society (new sources of inequality and discrimination).

Researchers at CeMM currently use CRISPR technology in the scope of context one and two, but not any of the other applications. Early research on the third and fourth applications is ongoing at renowned and responsible institutions elsewhere. Finally, no responsible research institution would pursue, support, or tolerate work along the lines of CRISPR editing of the germline for human enhancement (point five in the list), and CeMM strongly condemns work along those lines.

CeMM is committed to participate in a broad societal dialog about CRISPR technology, genome editing, and other developments in the life sciences. It is important that these developments are not happening in perceived or actual secrecy at highly specialized research institutions, but that they are part of a broad discussion about chances and risks, and based on information, education and divulgation on all scientific, medical, ethical and societal aspects associated. CeMM is committed in fostering this debate and promoting genetic literacy in the general population.