

Roche Position¹ on Human Stem Cells

Background

Stem cells and treating diseases. Stem cells and their applications offer an enormous potential for the treatment and even the cure of diseases, along with enhancing and extending the quality of life. Roche is highly interested in scientific developments in stem cell research and its related applications – both as a discovery tool and as a potential therapeutic modality. Roche is also fully aware of the important societal and ethical questions raised with regard to stem cell research and its potential applications.

As in all our activities, we follow applicable law and we are open to dialogue with all stakeholders surrounding this area of research.

About stem cells. Stem cells are particular cells that have the unique capability to renew themselves and to give rise to all specialized cell types such as heart cells or blood cells. Stem cells can be classified as follows:

- **Adult stem cells** are derived from tissues like bone marrow or cord blood. They are already successfully used for the treatment of patients with e.g. leukemia. The treatment of further diseases with adult stem cells is currently under evaluation. However, those cells only develop into a limited number of cell types. Hence the need remains for concomitant research with embryonic stem cells for specific applications.
- **Embryonic stem cells** are isolated from embryos. These cells are pluripotent, which means that they can develop into any fetal or adult cell type (blood, heart, brain cells, etc.), but they cannot develop into a complete organism.
- **Induced pluripotent stem cells (iPS)** are derived from adult cells, such as skin cells, and are being re-programmed to a pluripotent stage: once re-programmed, they exhibit similar properties as embryonic stem cells. If iPS cell technology develops as expected, it may eventually replace the need to derive stem cells from embryos.

¹ Pertains to SDGs 3 and 16

Stakeholders' Concerns and Expectations

Expectations and hopes within this area of research are high: stem cells and their applications may eventually enable researchers to find successful treatments for severe diseases for which we can offer few, if any, effective therapies today. Diseases or indications often mentioned in this context include Alzheimer's, multiple sclerosis, paraplegia, diabetes, Parkinson's and heart failure.

Ethical considerations on the use of stem cells vary widely and depend, to some extent, on an individual's cultural and religious background. The discussion centres on the following topics:

- The use of blastocysts (a blastocyst is a human embryo in a very early, pre-implantation stage of development from which embryonic stem cells can be isolated).
- Whether human embryonic stem cells should be used for research and/or as potential treatments for various diseases.
- Whether and how society should accommodate these diverse views in regulating the use of stem cells, with due consideration of the effect of such regulation on freedom of research and benefit for patients.

Roche's Position

Stem cell research is necessary. Worldwide progress in stem cell research over the past years has shown that scientific developments in pluripotent stem cell biology (i.e. the reprogramming of adult stem cells or somatic cells into pluripotent ones) provides a promising opportunity for the future and Roche is also engaged in using these technologies. However, the scientific understanding of these technologies is still at an early stage. Therefore, parallel research using both adult and embryonic stem cells is necessary to increase the understanding of diseases and develop treatments.

Roche conducts stem cell research, in-house as well as in cooperation with external partners, to become technically enabled in this research area, and with the ultimate aim to develop treatment strategies for incurable or inadequately treated severe diseases.

Roche is aware of the ethical concerns related to stem cell research. However, we believe that the vast potential and hope that stem cells might bring to patients to treat, prevent or diagnose a disease justifies this research, provided it is done responsibly, in compliance with laws and regulations, in dialogue with stakeholders, and with the ultimate aim of

developing new and more effective therapies for diseases that can currently not, or only partly, be treated.

Principles for using Human Stem Cells in research. Roche is committed to a responsible and transparent approach to stem cell research. For this reason, clear principles for the Use of Human Stem Cells in research have been developed.

The following principles apply to all research projects involving human stem cells, which Roche undertakes. They include:

- projects using stem cell research as a discovery tool
- projects looking into potential therapeutic modalities.

All Roche employees involved in human stem cell research are subject to these principles, which are designed to be applicable worldwide, subject to national laws and regulations.

General Principles for Human Stem Cells for Research

Principles 1-7 apply to research on all human stem cells.

- 1) The ultimate aim of Roche's research using stem cells is to increase the understanding of serious diseases and to develop effective diagnostic tools and treatments.
- 2) Each research project must have clear scientific objectives and design, in particular in accordance with good clinical practice.
- 3) Prior written, voluntary informed consent of the donor² of the genetic material³ must be obtained before human stem cell research is carried out.
- 4) Roche will not offer any inducements, financial or otherwise, to donors.
- 5) Roche will comply with all applicable national laws and regulations on stem cell research, which may differ from country to country.
- 6) Roche is committed to an open dialogue with stakeholders in this area of research.

²The term donor is generally understood as an individual who donates biological material, and, in the case of human embryo donation (in jurisdictions where applicable), the individual or couple for whose reproductive use embryos were created.

³Examples of genetic material: tissue, gametes (=eggs or sperm), embryos.

7) Roche will proactively encourage all its external contractors, who perform stem cell research for Roche, to abide by the same principles and conduct their research with the same high standards as Roche.

In addition to principles 1-7, principles 8-10 apply to research on human embryonic stem cells.

8) Roche intends to move increasingly toward using technologies such as induced Pluripotent Stem Cells (iPSCs) that could one day replace the need to derive stem cells from embryos. Until such technologies are fully developed, parallel research using both embryonic stem cells and iPSCs will remain necessary.

9) In the case of stem cell lines derived from embryos, Roche uses only embryos that have been created through *in vitro* fertilisation for reproductive purposes, that are no longer needed for those purposes, and that have been donated for research (with voluntary and informed consent).

10) Roche will not engage in human reproductive cloning.

Outlook

The Roche Science and Ethics Advisory Group (SEAG) offers advice and counsel on a broad range of ethical matters. It is a panel made up of independent external experts in bioethics and philosophy, and provides consultative feedback on ethical approaches to biomedical and clinical research, in particular on topics that are perceived as particularly sensitive or controversial by the public at large in order to take into account as many perspectives as possible. SEAG has also provided feedback to this Position Paper.

This updated position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on 13 May, 2013 and entered into force the same day. It was reviewed in March 2019.