Workshop on human genome editing in the EU

Thursday 28 April 2016
French Academy of Medicine, 16 Rue Bonaparte, 75006 Paris

Meeting aims and format

This workshop will consider the landscape for human genome editing in the EU. The objectives of the meeting are to:

- Understand current scientific activities in the EU with respect to genome editing – focussing on human applications.
- Understand the current regulatory landscape for human genome editing research and clinical applications across the EU.
- Understand the ongoing debate on genome editing across the EU.
- Identify any areas where there are significant differences, e.g. between countries, and if possible consider the driving forces for these differences (e.g. ethics, public opinion).
- Discuss the need for a European regulatory framework to govern the safe and acceptable use of human genome editing.

In delivering these objectives, we will also:

- Foster discussion between experts to promote best practice, and to consider whether common European guidelines might be developed.
- Provide information to the public and stakeholders regarding these new scientific and medical possibilities, and the European landscape.

Discussions will be informed by a background paper that outlines what we know about the scientific and regulatory context across the EU. The workshop will build on and enhance the content of this paper, resulting in a written output that will provide insight into the EU context for human genome editing research and potential applications.

This workshop is jointly organised by the Federation of European Academies of Medicine (FEAM), the UK Academy of Medical Sciences and the Académie Nationale de Médecine, France. It is kindly supported by the InterAcademy Partnership for Health and the French Academy Foundation.

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Programme

8:30 - 9:00	Arrival and registration
9:00 - 9:15	**Welcome and introduction** • Professor Pierre Jouannet, Académie Nationale de Médecine, France • Professor Bernard Charpentier, President, FEAM
Session 1: EU context Chair: Professor Bernard Charpentier, President, FEAM	
9:15 - 9:35	**The perspective of the European Commission** Dr Charles Kessler, Principal Scientific Officer, DG Research & Innovation, Health E5, European Commission
9:35 - 9:45	Questions and discussion
Session 2: Research – current state, opportunities, and regulation Chair: Professor Virginijus Šikšnys, Member of the scientific steering committee	
9:45 - 10:10	**Introduction to the science of genome editing and its potential use in research and medicine** Dr Robin Lovell-Badge, Group Leader and Head of the Division of Stem Cell Biology and Developmental Genetics, Francis Crick Institute, UK
10:10 - 11:10	**Exploring different perspectives on using genome editing for basic research in the EU.** Panel discussion to: • Establish the current state of the regulation of human genome editing uses in basic research in a number of EU countries (and related aspects such as access and storage of human embryos). • Identify any significant areas where research regulation particularly differs between the EU countries. • Encourage identification of future possibilities of research using genome editing techniques and areas where regulation or concerns might (or have) unnecessarily impeded on research. Panel members: • Ruth Mampuys, Coordinator Ethics and Societal Aspects at the Netherlands commission on Genetic Modification (COGEM) • Professor Ernst-Ludwig Winnacker, Ludwigs-Maximilians-Universität München, Genzentrum, Germany • Dr Robin Lovell-Badge, Group Leader and Head of the Division of Stem Cell Biology and Developmental Genetics, Francis Crick Institute, UK • Professor Giuseppe Testa, Professor of Molecular Biology and Director, Laboratory of Stem Cell Epigenetics, European Institute of Oncology and European School of Molecular Medicine, Italy
11:10 - 11:35	**Refreshments**

Session 3: Clinical research and applications in human somatic cells – current state, opportunities, and regulation Chair: Professor Luigi Naldini, Member of the scientific steering committee	
11:35 - 11:45	Professor Naldini will introduce the current state of clinical research and potential applications of genome editing in human somatic cells.
11:45 - 12:30	**Exploring different perspectives on genome editing in human somatic cells in the EU.** Panel discussion to: • Establish the current regulatory landscape for research and applications in a number of EU countries, focusing on regulations around gene therapy and whether these are appropriate for genome editing, and note any areas of variation among member states. • Identify any significant areas where research regulation particularly differs between the EU countries. • Encourage identification of future possibilities where regulation or concerns might impede research or applications. **Panel members:** • Professor Nathalie Cartier-Lacave, Director of Research, INSERM and President, European Society of Gene and Cell Therapy, France • Professor José M García Sagredo, Professor of Clinical Genetics, University of Alcala and Member of the Spanish Royal Academy of Medicine • Dr Verónica Martínez-Ocaña, Scientific Officer, Ethics Sector, European Research Council
12:30 - 13:20	**Lunch**
Session 4: Clinical research and applications in germline cells – current state, opportunities, challenges, and regulation Chair: Dr Robin Lovell-Badge, Co-Chair of the scientific steering committee	
13:20 - 13:30	Professor Pierre Jouannet, Co-Chair of the scientific steering committee, will introduce the current state of clinical research and potential applications of genome editing in germline cells.
13:30 - 14:45	**Exploring different perspectives on genome editing in germline cells in the EU.** Panel discussion to: • Establish the current regulatory landscape for research and applications in a number of EU countries. • Identify any significant areas where research regulation particularly differs between the EU countries or where countries have ambiguous laws/guidelines, and consider the implications of such instances. • Encourage identification of future possibilities where regulation or concerns might impede research or applications. **Panel members:** • Professor Bernard Baertschi, Institute for Biomedical Ethics, University of Geneva, Switzerland • Dr Peter Mills, Assistant Director, Nuffield Council on Bioethics, UK • Professor Pierre Jouannet, Académie Nationale de Médecine, France • Dr Anna Veiga, Director, Stem Cell Bank, Center of Regenerative Medicine, Barcelona, Spain • Professor Ewa Bartnik, Professor of Molecular Biology and Human Genetics, University of Warsaw, Poland

14:45 - 15:00	**Refreshments**
Session 5: Cross-sector discussion of human genome editing Chair: Professor Ernst-Ludwig Winnacker, Member of the scientific steering committee	
15:00 - 16:00	Roundtable panel discussion that will consider various perspectives on the research into, and applications of, genome editing in humans. **Panel members will each provide the following**: • *Regulatory perspective (EMA)*: Dr Nicolas Ferry, Member of the Committee for Advanced Therapies, European Medicines Agency and Director of ANSM (French Medicinal Products Regulatory Agency) • *Preclinical Industry perspective*: Dr Lorenz Mayr, VP Discovery, Innovative Medicines and Early Development, Astra Zeneca, UK • *Research funder perspective*: Dr Katherine Littler, Senior Policy Adviser, Wellcome Trust, UK • *Patient perspective*: Dr Cor Oosterwijk, Secretary-general, The Patients Network for Medical Research and Health (EGAN) • *Public perspective*: Professor Jennifer Merchant, Faculty of Law, Université Panthéon-Assas Paris II, France
16:00 - 16:30	**Conclusions and next steps** Chairs: Dr Robin Lovell-Badge and Professor Pierre Jouannet, Co-Chairs of the scientific steering committee Open discussion to consider next steps for human genome editing in the EU. One aspect of the discussion may be to consider the need, or not, for a European framework/guidelines – and the most pertinent considerations that would need to underpin any such document.
16:30	**End**

Scientific steering committee membership

The meeting organisers are most grateful to the scientific steering committee for their support for this meeting.

- France: Professor Pierre Jouannet, Académie Nationale de Médecine, France (co-Chair)
- UK: Dr Robin Lovell-Badge, Group Leader and Head of the Division of Stem Cell Biology and Developmental Genetics, Francis Crick Institute, UK (co-Chair)
- Italy: Professor Luigi Naldini, Director, Division of Regenerative Medicine, Stem Cells and Gene Therapy, San Raffaele Scientific Institute, Italy
- Lithuania: Professor Virginijus Šikšnys, Biotechnology Institute, Vilnius University, Lithuania
- Germany: Professor Ernst-Ludwig Winnacker, Ludwigs-Maximilians-Universität München, Genzentrum, Germany
- Belgium: Professor Miikka Vikkula, Professor of Human Genetics, Laboratory of Human Molecular Genetics, Université catholique de Louvain, Belgium

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