Draft programme: FEAM one-day EU workshop on human genome editing

Possible meeting objectives

- 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.
- 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 academic experts to promote best practice, 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.

Background work

The workshop will be informed by a background paper that will outline what we know about the scientific and regulatory context across the EU – which might exist at either the EU or Member State level. The workshop itself will build on and enhance the content of this paper.

Draft programme structure

9h 15	**Welcome** To include aims of the meeting, a brief introduction to the scientific and medical context, why this topic is important, and why we are talking about it now.
9h 30	**Session 1: Context** European context – perspective from the European Commission, including the respective remits of the EU and Member States) (20 min lecture + 10 for questions)
10h 10h 10h 30	**Session 2: Research: current state, opportunities, and regulation** Ongoing and future possibilities in basic, preclinical research using genome editing methodologies (lecture – 20 mins, plus 10 for questions) – will cover: • What is the current state of basic scientific research into genome editing in the EU (i.e. what is done and where; examples)? Standpoint on basic research: roundtable with 3-5 members from various European countries/academies – selected based on the findings of the scoping work (5-10 minutes each to explain regulatory situation in their country and main driving factors, plus 30 mins discussion). Will cover: • What is the current state of the regulation of human genome editing used in basic research capacity (and related aspects such as access and storage of human embryos) across the EU?

	• Are there any areas where research regulation particularly differs within the EU? • Discussion will encourage identification of future possibilities of research using CRISPR etc. and areas where regulation or concerns might (or have) unnecessarily impeded on research.
11 h 30	Refreshments
12 h 12 h 12h 20	**Session 3: Clinical research and applications in human somatic cells: Current state, opportunities, and regulation** Ongoing and future possibilities for clinical research and applications in human somatic cells using genome editing methodologies (lecture – 15 mins, plus 5 for questions) – will cover: • What is the current state of clinical research and potential applications in the EU with respect to somatic human cells (i.e. what is done and where)? • Examples, if there are any, of applications – and potential benefits. Standpoint on human somatic cell genome editing (clinical research and applications): roundtable with 3-5 members from various European countries/academies – selected based on the findings of the scoping work (5 minutes each to explain regulatory situation around genome editing in their country and main driving factors, plus discussion). Will cover: • Identify current EU regulatory landscape, likely to particularly focus on gene therapy, and note any areas of variation among member states. • Discussion will encourage identification of future possibilities where regulation or concerns might impede research or applications.
13h	Lunch
13h 45 13h 45 14h 05	**Session 4: Clinical research and applications in germline cells: Current state, opportunities, challenges, and regulation** Ongoing and future possibilities for clinical research and applications in human germline cells using genome editing methodologies (lecture – 15 mins, plus 5 for questions) – will cover: • What is the current state of clinical research and potential applications in the EU with respect to somatic human cells (i.e. what is done and where; examples; potential benefits)? Standpoint on human germline cell genome editing (clinical research and applications): roundtable with 3-5 members from various European countries/academies – selected based on the findings of the scoping work (5-10 minutes each to explain regulatory situation around genome editing in their country and main driving factors, plus 30 minutes discussion). Will cover: • What is the current state of regulation of germline applications across the EU? Identify areas of conflicting regulation, or where countries have ambiguous laws/guidelines, and consider the implications (such as patient safety – e.g. if introduced, would people move across countries to have treatment?). • Identify concerns and areas in which EU level advice might be beneficial. • Discussion will encourage identification of future possibilities where regulation or concerns might impede research or applications.

15h05	Refreshments
15h 20	**Session 5: Cross-sector discussion** Including industry and patient perspectives, potentially involving members of the FEAM Forum
16h	**Conclusions and next steps** • Include discussion regarding the need, or not, for a European framework/guidelines – and the most pertinent considerations.
16h 30	**End**