Plan Overview

A Data Management Plan created using DMPonline

Title: Legal Challenges of Gene Editing

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Project abstract:

The spread of technological applications based on genetic research has become essential for every EU country, as they seek to ensure high quality of life for their population and make their economy sustainable. The advancement of knowledge and the technologies resulting from human genome sequencing have formed a medical revolution. The age of medical genetics – with a focus on chromosomal abnormalities, monogenic disorders, and genes – is giving a way to the era of clinical and public health genomics in the whole EU. As an outcome in many EU member states, traditional medicine has started to shift to personalized or precision medicine (hereinafter ,,PM"). PM is a way health care providers can offer and plan specific care for their patients, based on the person's genes (or the genes in their cancer cells). The so called ,,P4 medical approach", predictive, preventive, personalized and participatory medicine, will help to identify the right drug for the right patient at the right time, avoiding the prescription of costly and ineffective drugs and preventing potentially harmful side-effects. It promises an increase in quality-adjusted life-years, that from an economic standpoint can lead to direct and indirect positive outcomes.However, technologies, such pharmacogenomic drugs, pharmacogenetic tests, stem cell therapies, gene therapy, cancer vaccines face significant technical difficulties for now and they also have to overcome a number of commercial, clinical, ethical and regulatory difficulties. Genome editing has also regained attention following the discovery that CRISPR1 has the potential to make such editing more accurate in comparison to older technologies.Bioethicists and researchers generally believe that human genome editing for reproductive purposes should not be attempted, but that studies that would make gene therapy safe and effective should continue. Some researchers and bioethicists are concerned that any genome editing, even for therapeutic uses, will start us on a slippery slope to using it for non-therapeutic and enhancement purposes, which many view as controversial. Others argue that genome editing, once proved safe and effective, should be allowed to cure genetic disease (and indeed, that it is a moral imperative). They believe that concerns about enhancement should be managed through policy and regulation. There is also a concern that genome editing will only be accessible to the wealthy and will increase existing disparities in access to health care and other interventions. Some worry that taken to its extreme, germline editing could create classes of individuals defined by the quality of their engineered genome. It is essential to develop an up-to-date system for these tasks which is based on common European values and serves common European goals, but also provides the benefits for individuals and

ensures economic efficiency. The challenge is to find the balance between the benefit for the economic value and clinical merit for biomarker-based diagnostics.

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Legal Challenges of Gene Editing

Data Collection

What data will you collect or create?

- answers from questionnaires
- secondary research data
- publications, best practice manuals

How will the data be collected or created?

- questionnaires,
- *Surveys,*
- summaries,

Documentation and Metadata

What documentation and metadata will accompany the data?

readme

Ethics and Legal Compliance

How will you manage any ethical issues?

- Informed consent.
- Anonymisation.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Don't File Patents.
Open-Source It
Get Strong Non-Disclosure Agreements.

Storage and Backup

How will the data be stored and backed up during the research?

- documentation will be stored in a locked office
- electronic file will be stored in a computer

How will you manage access and security?

- using passwords
- closed office

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

all the sources and outcimes

What is the long-term preservation plan for the dataset?

10 years

Data Sharing

How will you share the data?

open acces

Are any restrictions on data sharing required?

no personal data will be collected and shared, except if scientific paper is published (name, affiliation, ORCID)

Responsibilities and Resources

Who will be responsible for data management?

Mónika Nogel JD, PhD

What resources will you require to deliver your plan?

Budged