Roche Position on Human Genetic and Genomic Research

Background

Genetics refers to the study of specific genes and how variations in their DNA sequence can affect certain traits, whereas genomics helps us to study genetic variability on a larger scale by examining the interaction of genes in an organism as well as with environmental factors. Human genomic data can be derived from various sources, such as germline (inherited), somatic (for example, mutations in tumor tissue), and mitochondrial DNA. Studying DNA sequence variations enables us to understand the potential contribution of genetic and genomic elements to the development of diseases such as cancer, dementia, autoimmune, and rare genetic diseases.

Genetics and genomics provide insights into the molecular description not only of single gene disorders, but also of complex human diseases, and have enabled the development of innovative approaches to prevent, diagnose and treat disease. Over the last decade, genetic testing has become increasingly relevant in the practice of medicine and scientific advances in this field are leading towards more personalized medicine. The completion of the first map of the human genome sequence transformed the way research is done and genomic data are now being generated through use of rapidly evolving technology. Genetic and genomic research have become indispensable tools for predicting the efficacy of drugs and for reducing the likelihood of adverse reactions on the basis of a patient's genetic makeup. In addition, pharmacogenomics has become an integral part of the drug discovery and development process so that a growing number of drugs can now be identified and tailored for defined sub-populations of patients with specific genetic profiles.

Stakeholders' Expectations and Concerns

Advances in genetics and genomics already have significant implications for our daily lives and will do so even more in the future. As with all new and emerging fields of science, there are high expectations surrounding their use and impact on human health. Innovative biopharmaceutical and diagnostic companies are expected to explore the enormous potential of genomics in order to find new opportunities to discover and develop novel and better diagnostics and therapeutics. These opportunities for scientific progress and medical applications in this field also bring with them ethical, legal, and societal questions and concerns, including those related to autonomy and informed consent, biobanks, quality assurance, access to research results, and data protection including confidentiality and privacy. Roche is fully committed to take these questions and concerns seriously and to address them in a professional and socially responsible way.

Roche's Position

Genetics and genomics benefit human health. Roche's ultimate goal and responsibility is to serve human health and well-being. Roche recognizes the importance of genetic predisposition and susceptibility to the pathogenesis of a broad range of disorders, and of the promise of using genetic and genomic information, including that obtained by using human specimens, biobanks and health records, for the discovery and delivery of new and improved diagnostics and therapeutics. Roche recognises the potential of applying aggregate results of these studies to the improvement of the human condition, and the increasing desire of participants in clinical trials to access and use their individual data. As a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives, we strive to employ the latest discoveries and technologies to deliver more personalized healthcare for the benefit of patients and families[1]. Careful reflection on genetics and genomics is needed in order to ensure benefits of potential innovative applications for individuals and society at large.

Genetic and genomic research, like all of Roche's research efforts, is conducted in accordance with the highest standards of scientific rigour and excellence[2]. In addition, in all present and future activities in this field, Roche will conduct activities by considering the public concerns and expectations as well as all applicable laws and regulations.

Roche is in particular committed to values that entail specific responsibilities and obligations:

- Respect specific social and ethical values affecting the use of genetic and genomic information.
- Uphold the obligation to inform research participants on the objectives and processes of collecting and analyzing genetic and genomic data
- Inform participants of the potential impact of any genetic or genomic information they might receive that is generated by Roche's research.
- Be especially sensitive to the duty to protect persons with diminished autonomy such as children or individuals with cognitive or mental disability.
- Respect and uphold the right of every individual to privacy and confidentiality regarding the use of their information.

[1] https://www.roche.com/about/priorities/personalised_healthcare.htm

[2] See Roche Position on Clinical Research

- Provide adequate data protection and appropriate safeguards when working with data from clinical trials and biobanks.[3]
- Communicate research results to the scientific community in a timely fashion [4] and the support of general educational activities in the area of genetics and genomics.
- Prevent the misuse of genetic and genomic information obtained in the course of research that would discriminate against or exploit individuals or groups
- Oppose in general any such misuse as a matter of principle.
- Abide by national and international research standards and applicable laws.
- Uphold the principle of providing appropriately considered benefits to communities contributing genetic and genomic material for research purposes[5].
- Not pursue the deliberate creation of genetically identical human beings.

Roche integrates these commitments to scientifically and socially responsible, accountable, and transparent use of genetic and genomic information into the development of new therapeutics and diagnostics.

Outlook

The evolution of genetics and genomics research has introduced an important new dimension to our understanding of disease mechanisms and pathways. It offers far-reaching opportunities to develop more accurate diagnostic tools and effective treatments. As a global pioneer in pharmaceuticals and diagnostics, Roche actively promotes developments to make the promise of genetics and genomics in healthcare a reality.

As in any rapidly advancing scientific discipline, new findings in genetic and genomic medicine have raised new ethical, societal and legal challenges and issues. Roche takes these issues very seriously and commits to the implementation of the guiding ethical principles.[6] Roche believes that informing society about the benefits as well as the limitations of genetic research will lead to greater understanding and fewer misconceptions.

It is clear that the full potential of genetics and genomics can only be realised by maintaining a high degree of communication, coordination and collaboration. Roche is committed to this, and actively encourages an open and transparent dialogue with all its stakeholders on this important matter to optimise future advances in human healthcare.

[3] See Roche Position on Biobanks
[4] See Roche Policy on Data Sharing
[5] See Roche Position on Biodiversity
[6] See https://www.roche.com/research_and_development/who_we_are_how_we_work/ethics_in_rd/genetics.htm

For further reading, please see:

- http://www.roche.com/research_and_development/who_we_are_how_we_work/ethics_in_rd/genetics.htm
- https://www.roche.com/about/priorities/personalised_healthcare.htm
- Roche Position on Biodiversity
- Roche Position on Clinical Research
- Data sharing policy
- Roche Position on Biobanks

This position paper was proposed by the Corporate Sustainability Committee, adopted by the Corporate Executive Committee on November 12, 2018 and entered into force the same day. It was reviewed in April 2020.