GERMANY JOINS THE GENOMES INITIATIVE

In January, Germany joined the EU's "1+ Million Genomes Initiative". While the German government had previously declined to actively participate in the project and Germany had merely assumed the role of an observer, it can now become involved in sharing genome data across Europe for research purposes. Genome analysis is not only instrumental to the future diagnosis, prevention and treatment of rare diseases, it is also an important economic factor in digital health.

1. GENOME SEQUENCING

Human genomes are made up of at least 20,000 genes containing all our genetic information. Genome sequencing allows us to decode almost all mutations in human genomes. This enables us to identify individual gene defects causing diseases and thus to better diagnose and treat rare diseases. Increasingly, whole genome sequencing is being used in the field of tumours to identify mutations and tailor medication to the genetic makeup of a specific tumour.

But although the development of new technologies such as high throughput DNA sequencing over recent years has made it much easier and faster to carry out human genome research, the mutations that cause disease have been determined only for around 4,000 of the 20,000 protein-coding human genes. Medical researchers will probably need decades to identify all genetic causes of disease.

2. THE EU'S GENOME INITIATIVE: 1 MILLION GENOMES BY 2022

In order to produce reliable scientific findings, researchers need broad access to genomic data from both healthy and sick patients. The aim of the EU's Genome Initiative is to collect at least one million sets of genomic data by 2022 and make these accessible beyond EU borders. The initiative is part of the EU's agenda for the digital transformation of health and care, which is aimed at harnessing the potential of new digital technologies to improve healthcare. In a declaration published in April 2018, EU, EEA and EFTA countries agreed to work together to build up and link genome databases to form a suitable technical infrastructure. So far, 21 EU member states and

Norway have signed the declaration. Ten specialised working groups have been set up to look into ethical, legal and social issues, common data standards, best practices for sequencing, issues relating to health economics, research and public sector participation, as well as to analyse uses for rare diseases, cancer and common complex diseases.

3. CURRENT LEGAL SITUATION IN GERMANY

The current market leaders in genome analysis are the USA, China, the UK and some EU member states from Continental Europe. While other countries have already introduced whole genome sequencing as a standard procedure in genetic diagnostics and have produced millions of sets of data, Germany has only generated tens of thousands of data sets from whole genome sequencing. This cautious approach was put down to the particularly high level of interoperability required and restrictions due to data protection regulations.

There are certainly still some legal and also financial obstacles to be overcome in Germany. Although the German Genetic Diagnostics Act (*Gendiagnostikgesetz, "***GDA***"*) provides a legal framework for genome sequencing for medical purposes and establishing parenthood, there is no specific legislation governing genome analysis for research purposes.

Genetic Diagnostics Act on genome analysis for medical purposes and establishing parenthood

Genome analysis for **medical purposes** entails diagnostic and predicative genetic testing. Like genome analysis to establish parenthood, it is governed by the GDA. It stipulates that doctors have to provide genetic advice, restricts genome testing and analysis to doctors with appropriate training and provides for a patient's right "not to know" the results. Moreover, according to the GDA, patients must be given comprehensive information on the procedure beforehand and they must grant their consent.

Genome sequencing has already become part of standard care in Germany and since mid-2016 has been included in the German physicians' fee schedule. However, unlike in England, the German system does not cover sequencing of whole genomes but only of a very small gene panel of up to 25 kilobases, which corresponds to an average of four genes. For some diseases, up to 1,000 genes need to be analysed. Doctors wishing to perform larger sequencing projects have to apply for extra-budgetary services. Since such applications have often been rejected in the past due to the strict requirements, there is currently no incentive for physicians to perform medical genome analysis.

Pursuant to the GDA, genetic testing to **establish parenthood** requires the consent of the individuals providing the samples and can also be performed by specialists not qualified as doctors, for instance molecular biologists. Unlike in the USA, for example, analyses performed privately are not permissible.

No specific legislation on genome analysis for research purposes

The German legislator deliberately decided not to extend the scope of the GDA to cover genome analysis for research purposes, including general

research on the factors affecting human characteristics. By contrast to predictive genetic testing, such research is not aimed at developing specific treatment for specific individuals. This means there are no specific regulations in this field of research, so the general statutory provisions apply.

Therefore, for related clinical studies, the general German laws on medicinal products and medical devices apply. They require that participants be provided with full information on any testing and must grant their prior consent. Since genome analysis involves collecting personal data, the General Data Protection Regulation (GDPR) and national data protection regulations also apply. Article 9 of the GDPR classifies genetic data as sensitive data that may only be processed if the data subject has given their explicit consent or with special legal permission. However, the German legislator took advantage of the exemption clauses in Article 89 (2) GDPR. Article 89 states that genetic data may be processed for scientific research purposes even without consent if it would otherwise be impossible to fulfil such purposes and the interests of the party responsible for processing the data significantly outweigh the interests of the data subject in not having data processed. Given the significance of genome sequencing for research, the consent requirement could therefore be dispensed under data protection regulations.

However, this would breach the strict laws on medicinal products and medical devices which require consent to the use of data in clinical studies. Data protection law also entitles data subjects to request information on their data or have their data deleted. This may be difficult to put into practice if large amounts of data have been collected. Another point to be clarified is whether individuals have a right to know or not to know about random genetic findings.

Ultimately, in the absence of specific legislation on genome analysis for research purposes, many legal questions have yet to be answered. It remains to be seen whether the legislator will set out more precise regulations in future.

4. WHERE DO WE GO FROM HERE?

The Federal Ministry of Research (*Bundesforschungsministerium*) has announced that the next step will be to set up national working groups. A detailed schedule and set of requirements are to be drawn up by mid-2021. Only then will it be possible to develop strategies for the cross-border use of genomic and phenotypic data. According to the Ministry, the first locations for testing the secure sharing of genomic data are to be selected by the end of 2020. On that basis, it will be possible to donate genomes during clinical treatment.

By joining the Genome Initiative, Germany has taken an important step in terms of digital health. Now the task is to adjust the existing legal framework to cover whole genome sequencing and to clarify the remaining legal issues. In future, genome analysis will play a key role not only for major pharmaceutical companies, manufacturers of medical devices, hospitals and research institutes, which are directly or indirectly involved in researching rare diseases, but also for investors. To meet today's legal and regulatory challenges and any further challenges the future may bring, all players will have to keep a close eye on developments in this field.

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