

International Privacy + Security Forum, Washington, DC  
Transatlantic Trends in Genetic Privacy  
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Outline

- How a genetic testing company works
  - A patient submits a blood or saliva sample.
  - DNA is then extracted from that sample and then processed.
  - The DNA is then sequenced. Then, there is an analysis of whether there are any genetic variations.
  - The variations are then identified, and an analysis is made as to whether the variants are benign, pathogenic, or variants of unknown significance.
- Background of companies in the genetics space
  - Genetics is a rapidly expanding field. As our knowledge of genetics grows, the applications for genetics in medicine will continue to expand. For example, genetic information is today able to be used to diagnose diseases, identify appropriate drug treatment, and determine whether a prophylactic surgery is advisable.
  - There are different types of companies who use and process genetic information, including: medical providers, testing laboratories, pharmaceutical companies, data aggregators, and others. Pharma companies in particular are focused on how genetic information can be used to develop better drugs and more precisely target those drugs to the right individuals.
- Why genetic information is important to pharmaceutical companies
  - Significantly larger and more diverse range of genetic data make possible for researchers to observe and discover new patterns and connections. Researchers are enabled to better understand the role of genetic variation and therefore to help patients to find better therapies for cancer or rare diseases.
  - Some genetic testing companies offer sponsored testing programs in which pharma companies pay for the cost of genetic tests and in turn receive a de-identified report that indicates how many patients tested positive/negative for a genetic mutation along with prescriber contact information. The pharma company may then contact physicians to inform them about situations in which their drug treatments may be beneficial to patients.
- Global landscape regulating genetic privacy
  - Genetic information is generally treated by privacy laws, including GDPR, as a sensitive category of data requiring extra protection. This means that the most robust aspects of GDPR will apply to the use and management of genetic information. In addition, some countries and states impose additional, specific regulations regarding genetic information. Companies in the genetic space thus need to develop comprehensive global privacy compliance programs.
- EU approach to genetic privacy
  - GDPR + sectoral laws
  - GDPR introduces a new and seemingly quite far-reaching exemption to the processing of personal data for scientific research which might impact the legal framework in regard to the processing of genetic data for research purposes

- US approach to genetic privacy
  - HIPAA is the general US healthcare privacy law. Genetic information is one form of “Protected Health Information” that is subject to HIPAA. HIPAA has a detailed Privacy, Security and Breach Notification Rule.
  - HIPAA provides a floor of privacy protections but states can add additional protections and requirements for specific categories of health information, including genetic information. 10 states in the US have enacted such laws. These laws place additional limits and requirements on companies processing genetic data.
- Genetic editing and CRISPR
  - Crispr technology may help finding revolutionary treatments for a variety of human medical disorders
  - Most countries are struggling to assess whether gene editing may or may not be different from classical genetic engineering. In fact whether an organism manipulated by Crispr technology is genetically modified is a question that can be answered in different ways.
  - The Oviedo Convention impose certain restrictions on gene editing
- Anonymization/Pseudonymization
  - GDPR does not apply to the extent the personal data is anonymized and GDPR encourages pseudonymization as a risk mitigation measure. It can be difficult to apply these concepts to genetic data because genetic data frequently, on its face, does not identify an individual in an obvious way. A layperson could not look at genetic sequence data to determine the identify of an individual. But sophisticated individuals with genetic background could use genetic data to identify individuals, and could link the genetic data to other data sets in order to be able to reveal more information about an individual.
  - Indeed, even if not a full genetic sequence is available, but just a listing of genetic variants, if the variants are rare enough, can identify an individual. Thus, it is important to define clear standards as to when genetic data is appropriately de-identified.
  - In addition, it is important to address the steps to be taken to prevent re-identification of genetic data.
- Risk of harm
  - With various types of personal data, such as date of birth, email address, and credit card information, we can identify clear risk of harm and can understand how the data can be misused. In the genetic context, the risk of harm analysis is more complicated. We do not have a significant amount of background into how genetic data has been misused and thus the risk of harm calculation is more theoretical.
  - One concern individuals may have is that they are discriminated against based on their genetic information (e.g., denied for life insurance based on a genetic condition).