Toisiolaki: Streamlining Secondary Uses of Health Data

Health data has long been seen as Finland's crown jewel and as a source of significant growth potential. The law governing secondary uses of health data and its associated data protection requirements have however played a significant role in holding Finland back in the perpetually accelerating R&D pipeline. In 2022, European pharmaceutical R&D investment to Finland totaled €0.26 billion, compared to €1.1 billion In Sweden and €1.5 billion in Denmark.[1,2] Long processing times, severe incompatibilities with international standards, as well as costly audit requirements each pose an existential risk to Finland's attractiveness as an investment environment.

The 2023 government program affirms Finland's four-percent national R&D target[3] and the need to reform the toisiolaki to foster future health research.[4,5] To advance this effort, members of Amcham Finland's Digitalization Working Group have developed a set of concrete, textual changes to the *toisiolaki* to alleviate bottlenecks in the R&D pipeline.

Read the full set of recommendations in Finnish here.

Overview of Recommendations

1) **The one-stop-shop model creates a significant bottleneck in the data permitting process.**"While well-intended, commercial actors are currently prevented from using their own data for research purposes without a government permit, even when patient consent has been obtained. Under the current model, a researcher is forced to set the terms of data use directly with each registry holder before applying for a permit with Findata. This is a clear violation of the one-stop-shop principle, adding months to the permitting timeline and, by extension, to the timeline of health care innovation.

   In contrast, registry holders are able to communicate directly with the organization requesting data and can therefore issue permits significantly faster than the Data Permit Authority (DPA). Formalizing the current process between registry holder and applicant and allowing the registry holder to issue permits also for joint-owned registries would remove a significant bottleneck from the R&D pipeline. Accordingly, the requirement for a Findata permit should be limited to cases in which data from the same patient is obtained from different registries.

2) **Long processing times for data permits risk repelling both EU-funded research projects and commercial R&D investors.**"The statutory three-month processing time is largely unenforced and in practice is closer to 14 months. This can be addressed through ensuring that academic and private sector

[1] EFPIA (2022) "Pharmaceutical Industry Research and Development in Europe"
[2] The *toisiolaki* is one of several factors that have contributed to this discrepancy.
[3] Valtioneuvosto (2023) "Vahva ja välittävä Suomi," p. 109
[4] Laki sosiaali- ja terveystietojen toissijaisesta käytöstä, 552/2019
[5] Valtioneuvosto (2023) "Vahva ja välittävä Suomi," p. 39

researchers are represented in the Data Permit Authority's senior-level specialist group.

Overseeing the DPA's key performance indicators and operating processes must be explicitly defined as part of the group's responsibility. The group must also ensure that DPA guidelines are compatible with EU standards and foster international research cooperation.

3) **Legally limited compatibility with international data catalogues means that Finland will be left out of research investments.** Both the European Health Data Space (EHDS) and EU DARWIN create catalogues through which researchers can search for suitable data sources for their projects. Ensuring compatibility with them is critical.

   Researchers also need the ability to obtain information about datasets to design their research. Hospitals can receive thousands of these data queries annually, so there must be a possibility to automate them. An automated advisory service generates aggregated, anonymous statistics through which individual patients cannot be identified. Registry holders must have the ability to link these advisory services to national and international data access services (*saatavuuspalvelu*).

4) **Researchers are currently required to analyze data only in operating environments that have been deemed secure by the Finnish government, which impedes international research cooperation and collaboration with pharmaceutical companies.** Approving an operating environment typically involves an audit, which is both costly and time-consuming. This incentivizes both national and international investors to move their projects to locations that recognize the significance of international cybersecurity standards, and for which previously conducted third-party audits are sufficient.

   Instead of reinventing the wheel and unnecessarily raising operational costs, the law must utilize established international standards and third-party audits within the same sector. Data use for innovation and development purposes must be allowed the same way it is currently permitted for scientific research.

5) **Current anonymization requirements render Finnish data essentially unusable for international research purposes, repelling cooperation and investments.** For example, U.S. law now requires artificial intelligence models to be trained on authentic data — a standard which Finnish datasets are currently unable to meet for innovation work. The current anonymization requirements are also in conflict with the EU's Medical Device Regulation standards.

   Instead of waiting for the DPA to carry out anonymization of all data, allowing the permit holder to anonymize data themselves would significantly ease these tensions. The permit holder may be required to submit the data to the DPA after the fact.

   Moreover, the law must recognize modern privacy preserving data analysis techniques, such as federated data analysis and artificial intelligence training, which significantly improve data privacy.