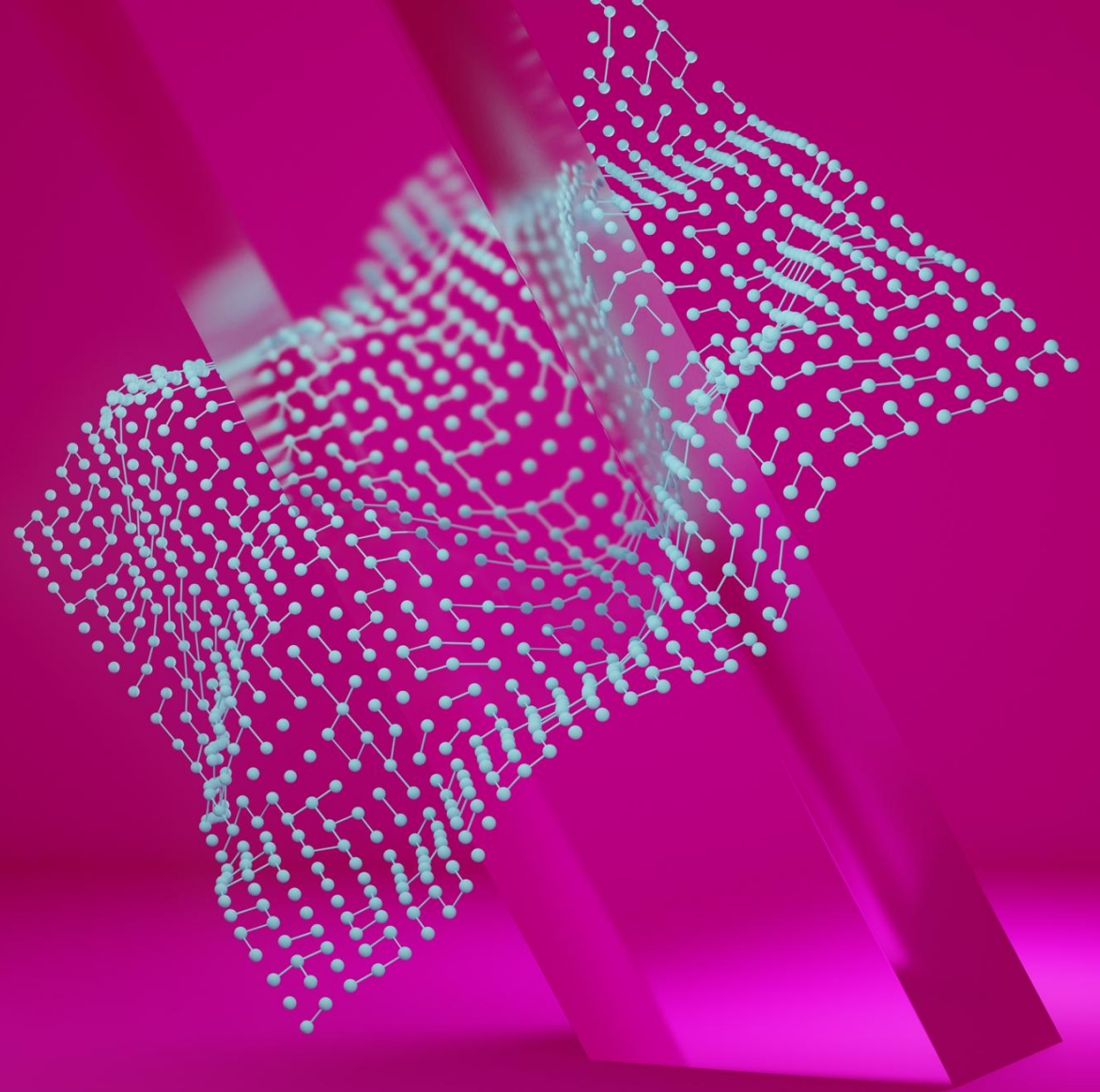


Welcome to Findata's
application clinic

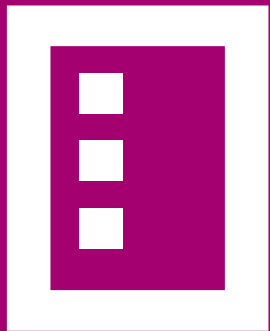
Regulatory changes

Senior specialists

Paula Nurmi & Rosa Juuti



Program



- Overview of regulatory changes
- Changes related to clinical research
- Invoicing and cost estimates
- Permit applications and data compilation in a decentralised model
- A risk-based approach to ensuring anonymity of results
- Data permits for processing in other secure environments
- Other
- Summary

Key services

Permits for the secondary use of social and health care data

Help Desk



Collecting, linking, pseudonymisation and anonymisation of data

Kapseli®
A secure processing environment for data analysis

- + Processing of applications and permits on behalf of data controller
- + Support for the preparation of data descriptions
- + Verifying the anonymity of results

Overview of regulatory changes

Changes related to clinical research

- The Act on Secondary Use no longer applies to datasets covered by the laws on clinical drug trials, medical devices, or medical research.
 - If you are conducting a research project based on these laws and need register data, apply for the data directly from the data controllers
 - Findata can not issue data permits for clinical studies

Permit applications in a decentralised model

- From 1 May onwards, applicants may continue to apply for permits through Findata as usual
- or
- alternatively apply separately to public data controllers.
- It is still possible to use Findata's centralised permit service in cases where a project involves data from two or more public data controllers and the data are combined into a single dataset.
 - Applicants can also opt to apply for separate permits from each public data controller.

When to apply from Findata in decantralised model

- Findata will act as the permitting authority, when data are requested from:
 - Kanta services
 - Private service providers
 - Organisations that have transferred their permitting authority to Findata (see list below)
 - Findata's ready-made data resources
- Permitting authority has been transferred to Findata by
 - Finnish Institute for Health and Welfare (THL)
 - Finnish Supervisory Agency
 - Wellbeing services county of Eastern Uusimaa
 - Finnish Center for Pensions
 - Finnish Medicines Agency

Data compilation in a decentralised model

- Where permits are obtained separately from multiple public data controllers, the organisations concerned will agree on a case-by-case basis on who is responsible for compiling the data.
 - This responsibility may be assigned either to Findata or to one of the permitting organisations.
- Findata will be responsible for compiling the data in cases where Findata has granted a permit (even if other organisations have also granted permits)

Invoicing and cost estimates

- Each organisation will invoice separately for its own contribution.
- As a result, for decisions issued after 1 May, permit holders will receive separate invoices from each participating organization
- For permit decisions made before 1 May 2026, centralized invoicing as usual

A risk-based approach to ensuring anonymity of results

- A new risk-based approach for ensuring the anonymity of results.
- Updated guidance and a new notification form is available on our website.

Data permits for processing data in other secure environments

- The amended Section 51c of the Secondary Use Act enables data disclosed under a data permit to be processed in other secure environments. Such environments must be operated by a trusted organisation, such as a recognised university or university hospital.
- This type of permit requires that
 - the risks associated with the data are low,
 - a Finnish research organisation is involved,
 - an adequate level of data protection and information security is ensured.
- A risk assessment will be carried out for each project.
- A data permit for processing data in other secure environments must always be applied for from Findata. Detailed guidance will be made available on our website.

Data permit application requesting the transfer of anonymised datasets outside of a secure operating environment

- The legislative change opens up the possibility to apply for anonymous, individual-level data to be released outside of a secure operating environment
- Anonymous individual-level data could e.g. mean data that has been processed with differential privacy tools

Other

- Kapseli is no longer the "mandatory option"
- Findata is currently developing a Finnish SPE catalogue
- Permit authorities are obliged to transparency regarding permit fees
- Findata has issued a regulation concerning the permit decisions

Summary

- You can apply centrally from Findata just like before.
- In certain cases, we will continue to be the permit authority.
- We still provide guidance on all matters related to the Secondary Use Act.
- A data permit for processing data in other secure environments must always be applied for from Findata.

Further info

- Check out recording of application clinic
<https://www.youtube.com/watch?v=iDHMIvmfy-0>
- Application assistant: findata.fi/application-assistant
- Data assistant: findata.fi/data-assistant
- Training portal: findata.fi/training-portal
- Appointment booking: findata.fi/booking

Public, private and occupational health care

Public healthcare

- Care provided by 21 wellbeing services counties, City of Helsinki, HUS Group and the Åland Islands
- Wellbeing services counties are self-governing organisations funded by the state. They are responsible for organising a wide range of services, including:
 - primary and specialised health care
 - social services
 - mental health and substance abuse services
 - family and disability services
 - rescue operations
 - emergency care

Private healthcare

- Public health care is complemented by private health services provided by companies, independent practitioners, organisations and foundations
- Common private healthcare services include:
 - general care
 - occupational healthcare
 - physiotherapy
 - oral health services
- Private health care can include both primary health care and specialised medical care.
- Around one in five persons in Finland choose to buy a private health insurance to receive compensation for the use of private services.

Occupational healthcare

- Employers are required to provide preventive occupational basic health care services for their employees.
- These services aim to
 - promote occupational health
 - promote the safety of work and the working environment
 - prevent occupational diseases.
- Many employers also arrange medical care for their employees, though this is not mandatory by legislation.
- Occupational health care services are typically purchased from private health care providers.

Data are recorded 1) in the caregiver's own records, 2) in the national Care Register, and 3) in the Kanta Patient repository

National data sources and controllers

Finnish Institute for Health and Welfare (THL) – thematic health care registers

- Care registers
- Cancer
- Infectious diseases
- Vaccinations
- Medical births
- Induced abortions
- Congenital malformations
- Etc.

Social Insurance Institution of Finland (Kela)

- Prescribed and dispensed medications
- Social benefits
- Kanta services

Digital and Population Data Services Agency (DVV)

- Population data
- Families
- Residence history
- Building information

Finnish Centre for Pensions (ETK)

- Pensions and benefits
- Incomes and careers

Finnish Medicines Agency Fimea

- Special permit register
- Adverse reaction register
- Incident report register

Finnish Institute of Occupational Health (TTL)

- Occupational diseases
- Exposure measurements

Statistics Finland

- Causes of death

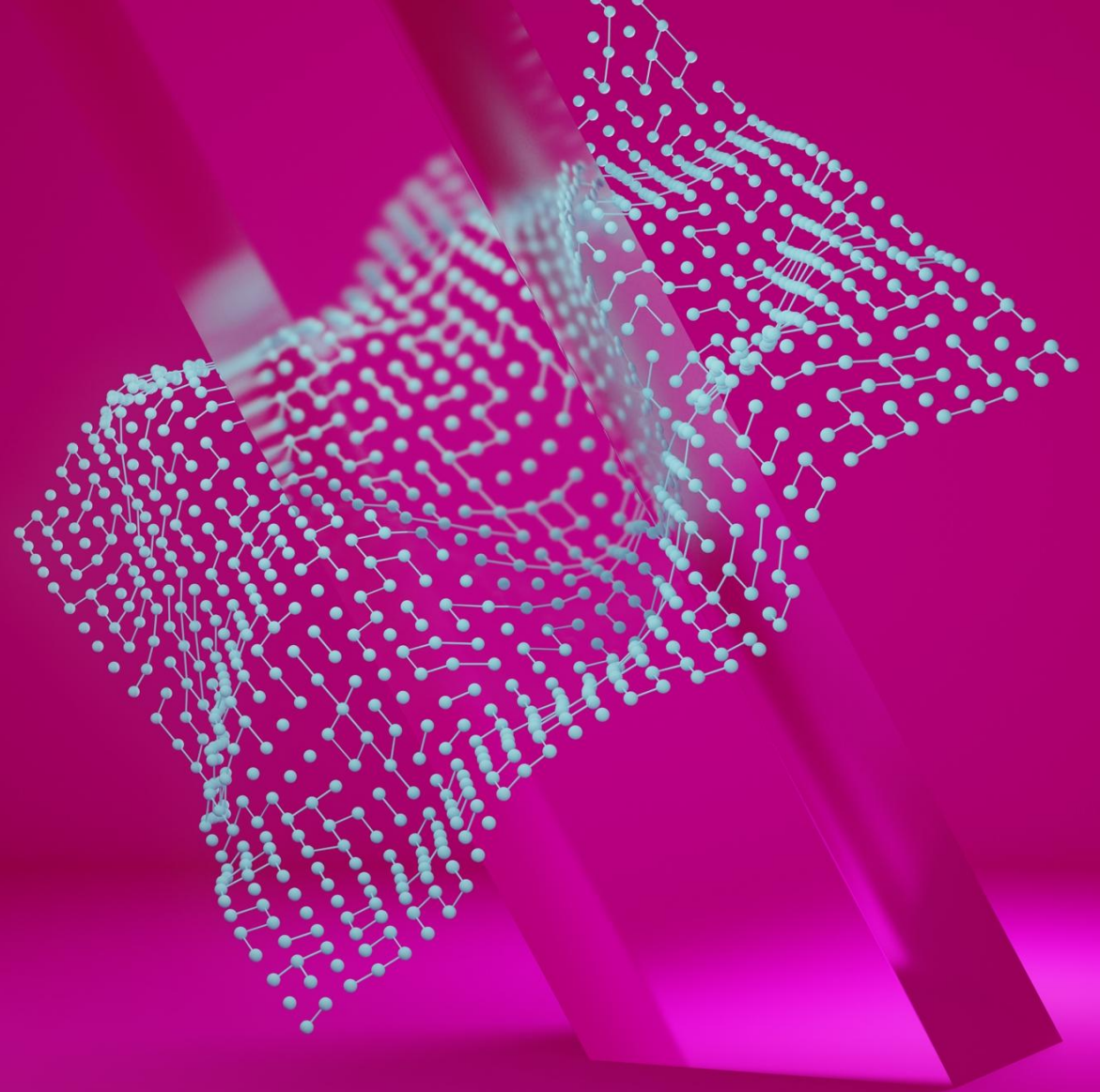
Finnish Supervisory Agency

- Social and healthcare professionals
- Private service providers
- Matters related to social and health care

Thank you!

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FINDATA



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