

The VTT logo consists of the letters 'VTT' in a bold, white, sans-serif font, centered within a solid black square. The background of the slide features a repeating geometric pattern of interlocking shapes in blue, orange, white, and grey, with semi-circular elements.

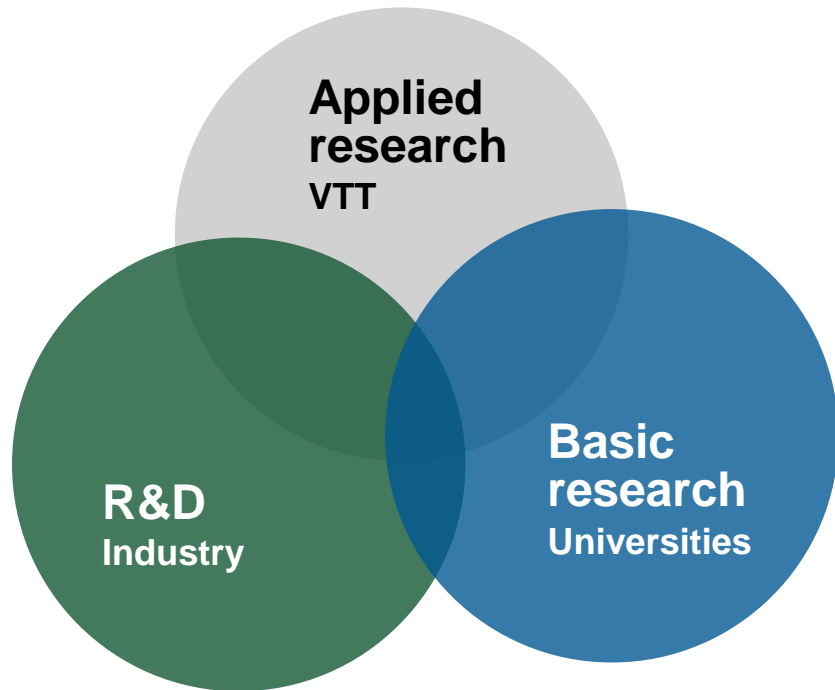
Regulatory challenges in healthcare innovation development

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VTT - practical innovations from science



254 M€

turnover and other
operating income

2,093

employees

45%

of the net turnover
from abroad

32%

a doctorate or a
licentiate's degree

Establishment year

1942

Steered by Ministry
of Economic Affairs
and Employment

Impact of regulation on innovation development

General Data Protection Regulation (GDPR)

Medical Device Regulation (MDR)

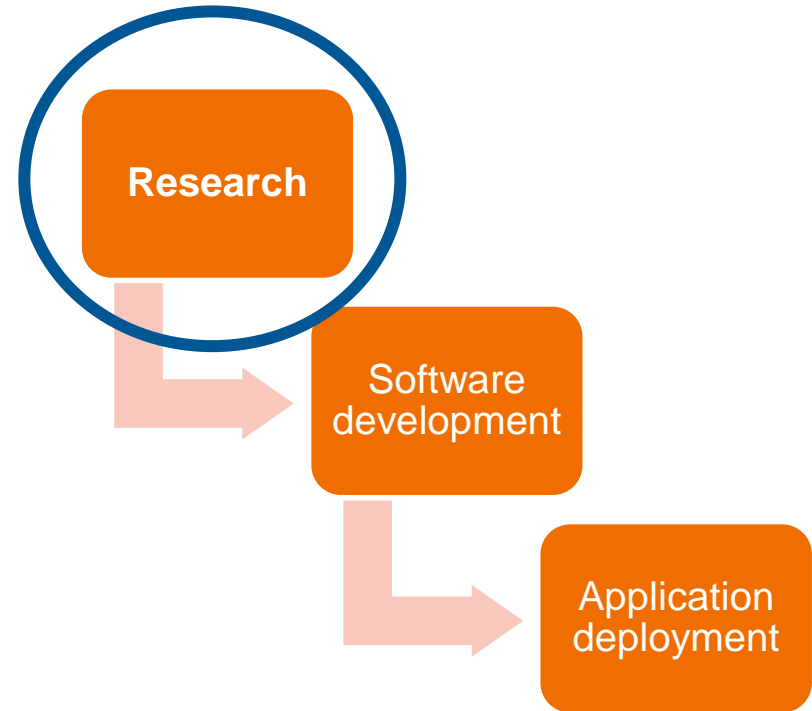
EU regulation under development

- Artificial Intelligence Act
- European Health Data Space (EHDS)
- Data Act

National regulation concerning:

- secondary use of data
- deployment in health and social services (e.g. apps connected to Kanta)

Regulation affects all development phases



Artificial intelligence application areas in healthcare

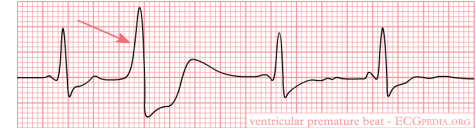
Imaging

tumor detection
dermatology
ophthalmology



Biosignals

signal interpretation
(e.g. ECG, EEG, PPG)



Patient and customer data


epidemiology
diagnosis, prognosis
identification of risk groups
service need prediction and anticipation
planning of personalized services



Use cases addressed by VTT in AHMED

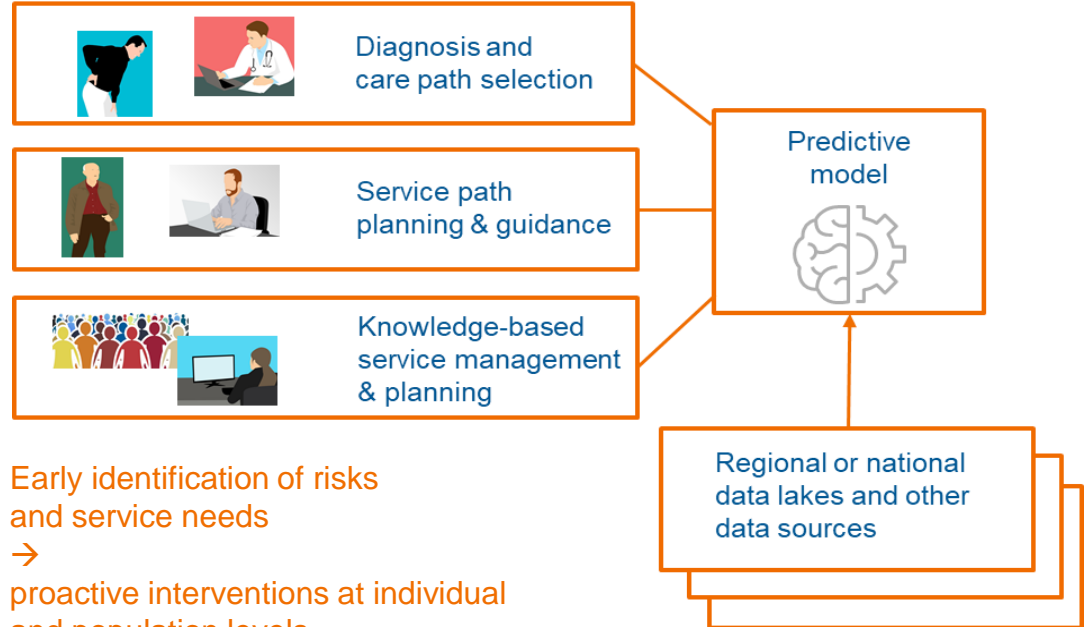
- Imaging: Deep neural network based image enhancement
- Biosignals: Machine learning based health monitoring solution

Focus of the presentation

- 
- Patient and customer data:
Machine learning model using sensitive personal data

Research example (MAITE project*): ML-based prediction/anticipation of elderly services need

Decision support applications



Population: ~200k
+65 yrs: 26,6%



Pilot region:
Päijät-Häme Joint
Authority for Health and
Wellbeing

Early identification of risks
and service needs



proactive interventions at individual
and population levels

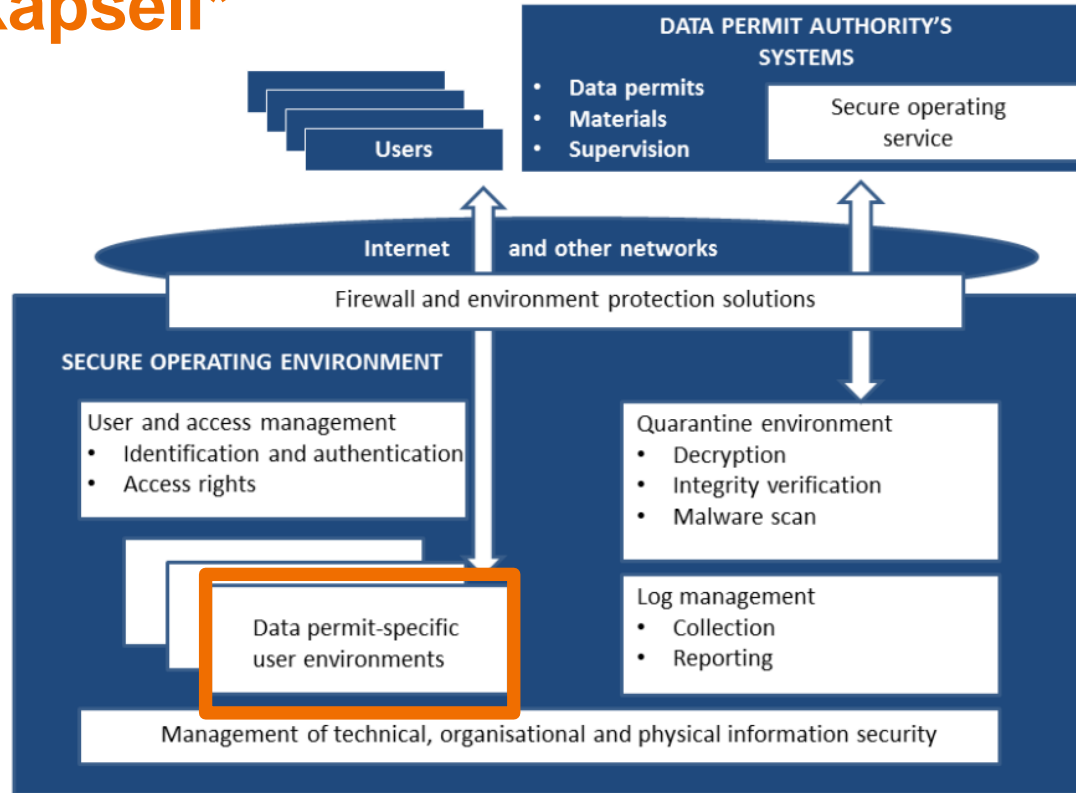
MAITE data resources

- Target group: elderly individuals
- Cohort size: ~ 37000
- Data contents:
 - Health and social services encounter data (diagnoses, operations, selected laboratory tests and medications)
 - Social services decision (rehabilitation, elderly housing service, caregiver support, homecare, transportation services)
 - Service need and physical function assessments (RAI)

Data usage in MAITE

- Basis for data processing: scientific research
- Data permit authority: Päijät-Häme (PHHYKY)
- Data usage in pseudonymized form (no personal identifiers)
- Data processing environment: Findata / Kapseli

Findata/Kapseli*



Challenges in individual level data access and processing

Phase	Challenge	Solution
Data access	Slow/laborious data permit process	<ul style="list-style-type: none"> Permit authority (FINDATA) resourcing and process streamlining
	Data extraction from operational systems	<ul style="list-style-type: none"> Investment in data holders' IT infrastructure
	Variable practices between countries	<ul style="list-style-type: none"> EHDS legislation
	Accessing data after data permit has expired (e.g. for verification and ML model updating)	<ul style="list-style-type: none"> Enable data set archival for re-use Data set anonymization*
Data processing (in SPE)	Usability	<ul style="list-style-type: none"> Improving remote desktop functionalities
	Complicated upload/download	<ul style="list-style-type: none"> Automated functionality for controlling inputs/outputs Standardized trustworthy scripts
	Fulfillment of specific requirements (e.g. computing power)	<ul style="list-style-type: none"> SPE's with different capabilities shall be available
	Traceability	<ul style="list-style-type: none"> Version control of SW and data in SPE*
	Co-creation/co-operation (end-users and stakeholders)	<ul style="list-style-type: none"> Synthesized data for continuous demonstration and testing*

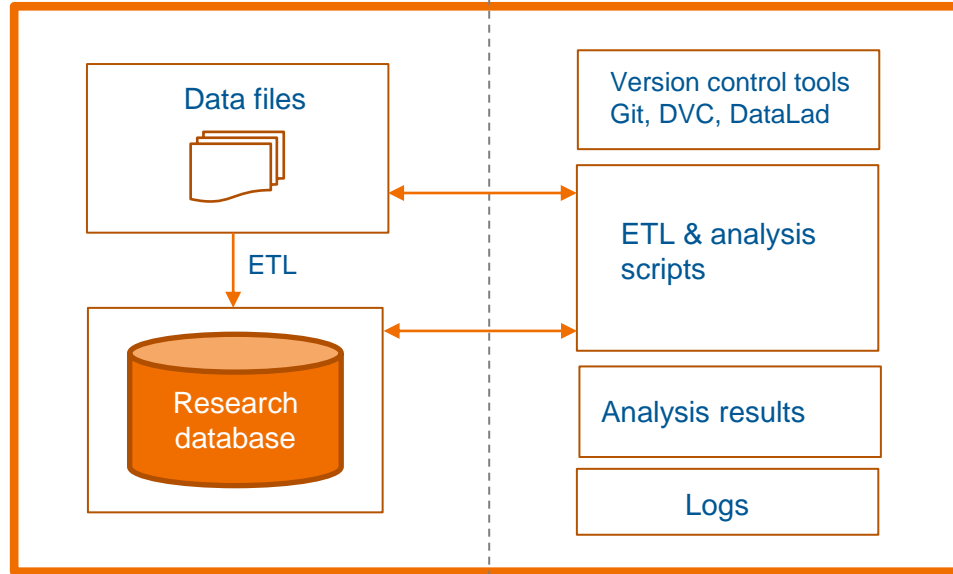
* actions under control of the data user

MAITE data processing in Kapseli

Data permit specific user environment

personal data | anonymous data (exportable)

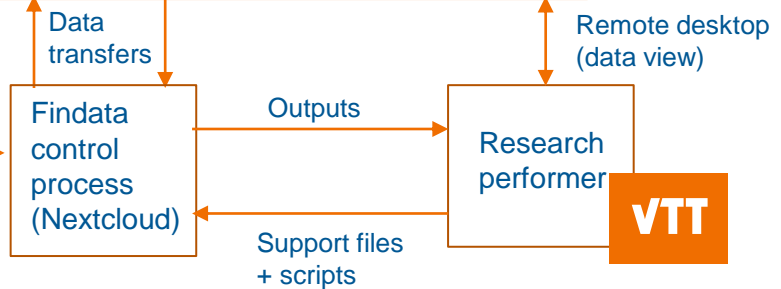
FINDATA



päijät  sote

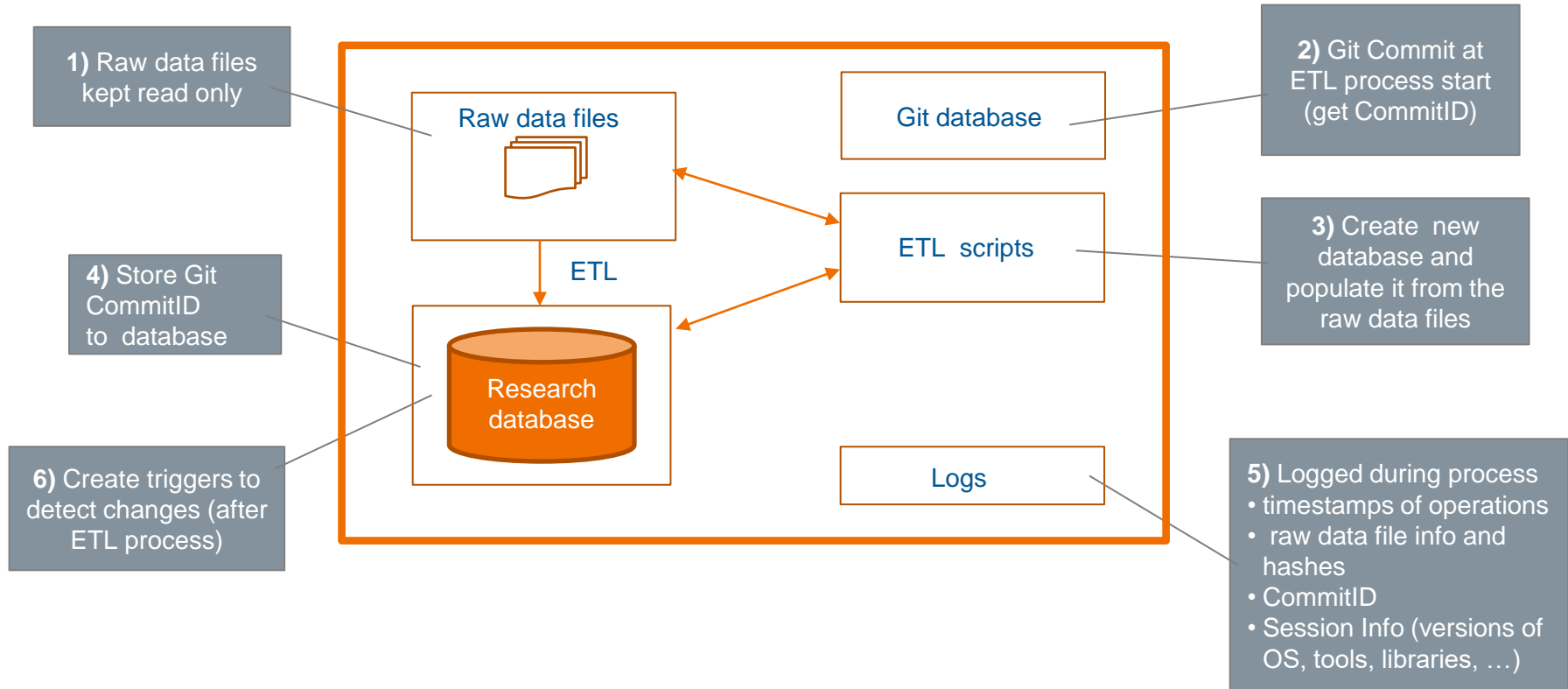


Pseudonymized raw data (CSV Files)



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Example: ensuring traceability of the ETL process in Kapseli



Conclusions

- Impact of regulation should be identified and understood already in the research phase of innovation development
- Usage of individual-level personal data brings challenges to data access and processing
- Fulfilling traceability requirements in a secure processing environment needs special consideration

bey⁰nd

the obvious

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