

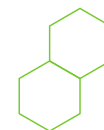
TEHDAS

**Towards
European
Health
Data
Space**



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National data governance models – findings of the TEHDAS country visits

Shona Cosgrove, Petronille Bogaert
EMA EU Big Data Stakeholder Forum, 1 December 2022



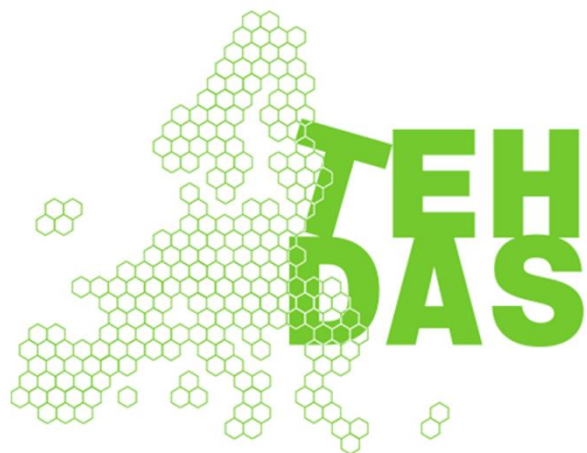
TEHDAS Joint Action helps the Members
States and the Commission in
**developing and promoting
concepts for sharing of data in
secondary use for purposes**
for citizens' health, public health, as well as
health research & innovation in Europe.



Country visits – Aim & scope

- To engage with national stakeholders and map the state-of-play of the national health data management systems in relation to a future European Health Data Space for secondary use (EHDS2)
- To reflect on needs and expectations at national level with regards to EHDS

Scope: data sources, data quality, data infrastructure, data governance, resources and capacity, EHDS preparedness

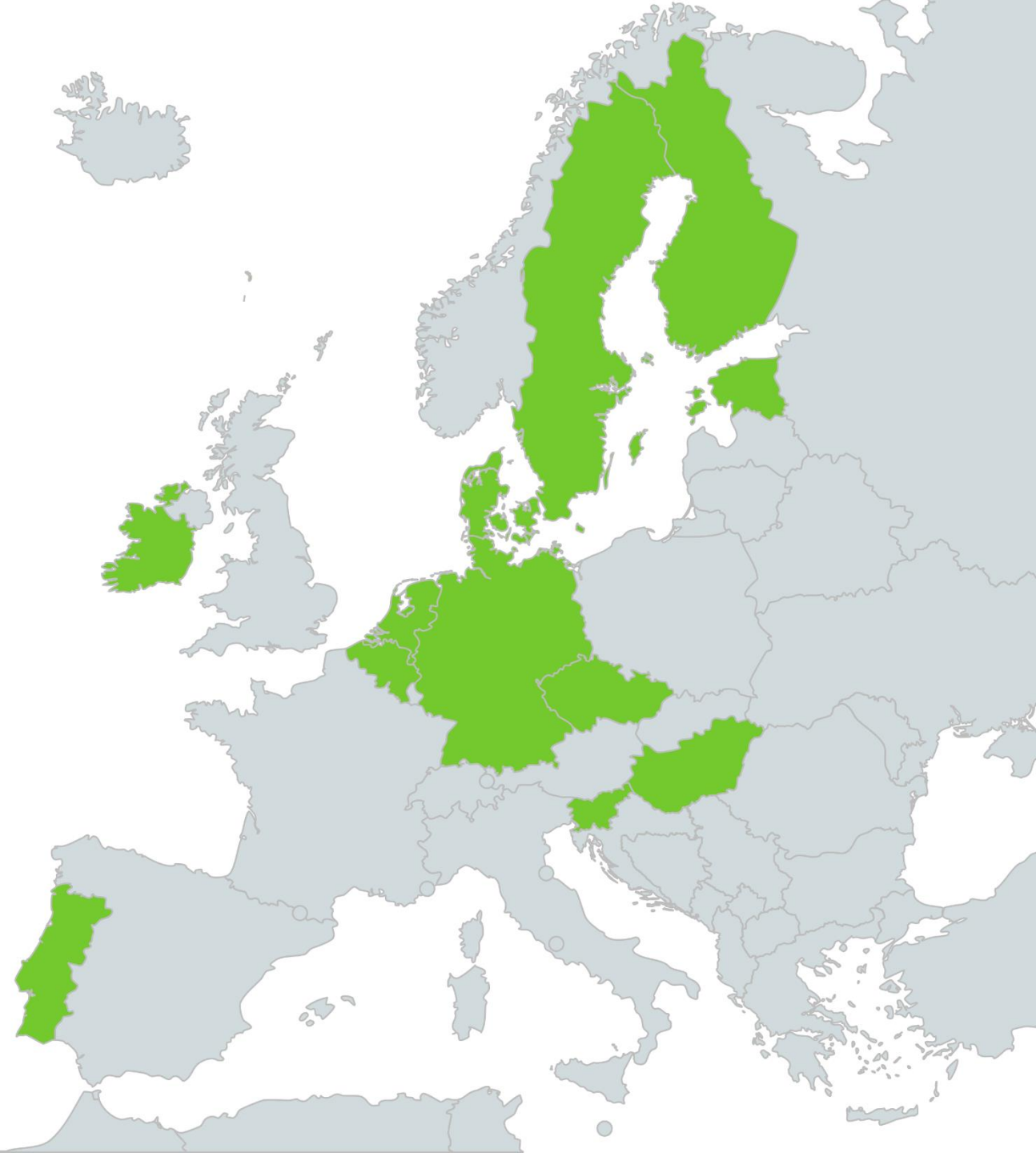


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Timeline:

December 2021 – December 2022



Methodology

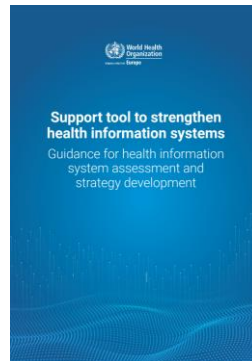
1. Preparatory desk review

- Preparatory report
- Stakeholders selection



2. Country visit

- Semi structured-interviews using adapted assessment tool



3. Debriefing meetings

- Multi-stakeholder meeting



4. Reporting

Report
[Factsheets](#)



Findings: Data governance



Data management

Decentralised

- Multiple data holders with own data governance system (regional, institutional etc.)
- Different data access procedures
- Some countries report legal barriers to data sharing between organisational levels or between data sources

Centralised

- Integrated, centralised systems
- Central data permit authority providing access to health data

Legal framework

Secondary use

- Most countries have legal framework for primary use
- Specific legal framework for re-use of data in place in some countries
- Some countries are working towards a legal framework for secondary use (e.g., drafting roadmap or legislation)
- Alignment of national laws with EHDS
- Unique identifier for health in place in most countries but barrier to its use in some

Privacy

- Strict laws on privacy in data sharing and processing, lack of transparency in some countries
- Need for additional approvals
- Sanctions in case of data breach

Access governance

Ethical

- Almost all countries require ethical approval for research using health data
- Need for consent for secondary use varies between countries and data types
- Need for consent noted as barrier to retrospective research
- Mechanism to allow research in public interest rather than consent
- Opt out mechanisms differ

Cross-border access

- Different approaches to sharing data across borders
- Access procedures and fees are often the same for local and foreign researchers
- Foreign researchers can only access data if affiliated to national researcher in some countries

Roles in the EHDS

- National contact point (NCP) for EHDS2:
 - Already established in some countries (e.g., Findata, Danish Health Data Authority, SPMS)
 - In other countries the NCP is not yet established or mandate not yet decided
 - In other countries establishment of new entity is ongoing (e.g., Ireland)
- Interesting roles noted during country visits:
 - ‘National data guardian’: ombudsman for citizens, representing citizens’ views on health data use and re-use
 - National Board for Health Data for shared decision-making and strategy setting



Needs & expectations from EHDS

Legal

- Legal framework for sharing and linking data
- Clearer distinction between EHDS and GDPR
- Guidelines for common GDPR interpretation
- Harmonised rules on how to anonymise and pseudonymise
- Code of conduct for secondary use to support DPOs
- Definition of requirements for trusted research environments
- Clear legislation for federated analysis

Organisational

- Guidance on how to implement the EHDS, clear roadmap of what to do when
- Platform within the EHDS where healthcare providers, citizens, patients, DPOs and legal officers can share best practices
- Manual with overview of national data management systems
- Transparency on roles of the data holders and access decisions
- Clarification on role of private actors in the EHDS

Human

- Legal experts
- Training on data protection and data privacy

Conclusion

In general, positive views on the impact and added value of the EHDS for secondary use, and political will to join. However, countries note that there is work needed to clarify the governance aspects of EHDS.

- ✓ Clear definition of responsibility and liability in the EHDS
- ✓ Consider diversity in current governance structures and local sensitivities
- ✓ Ensure equal benefit for all countries and stakeholders
- ✓ Focus on cybersecurity and trust
- ✓ Improve transparency in access processes and decisions
- ✓ Communicate with all stakeholders, including citizens

Thank you!

Contact us at:

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To keep up to date with the TEHDAS activities, you can sign up to the TEHDAS Newsletter via the website: **tehdas.eu/contact**



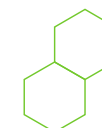
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