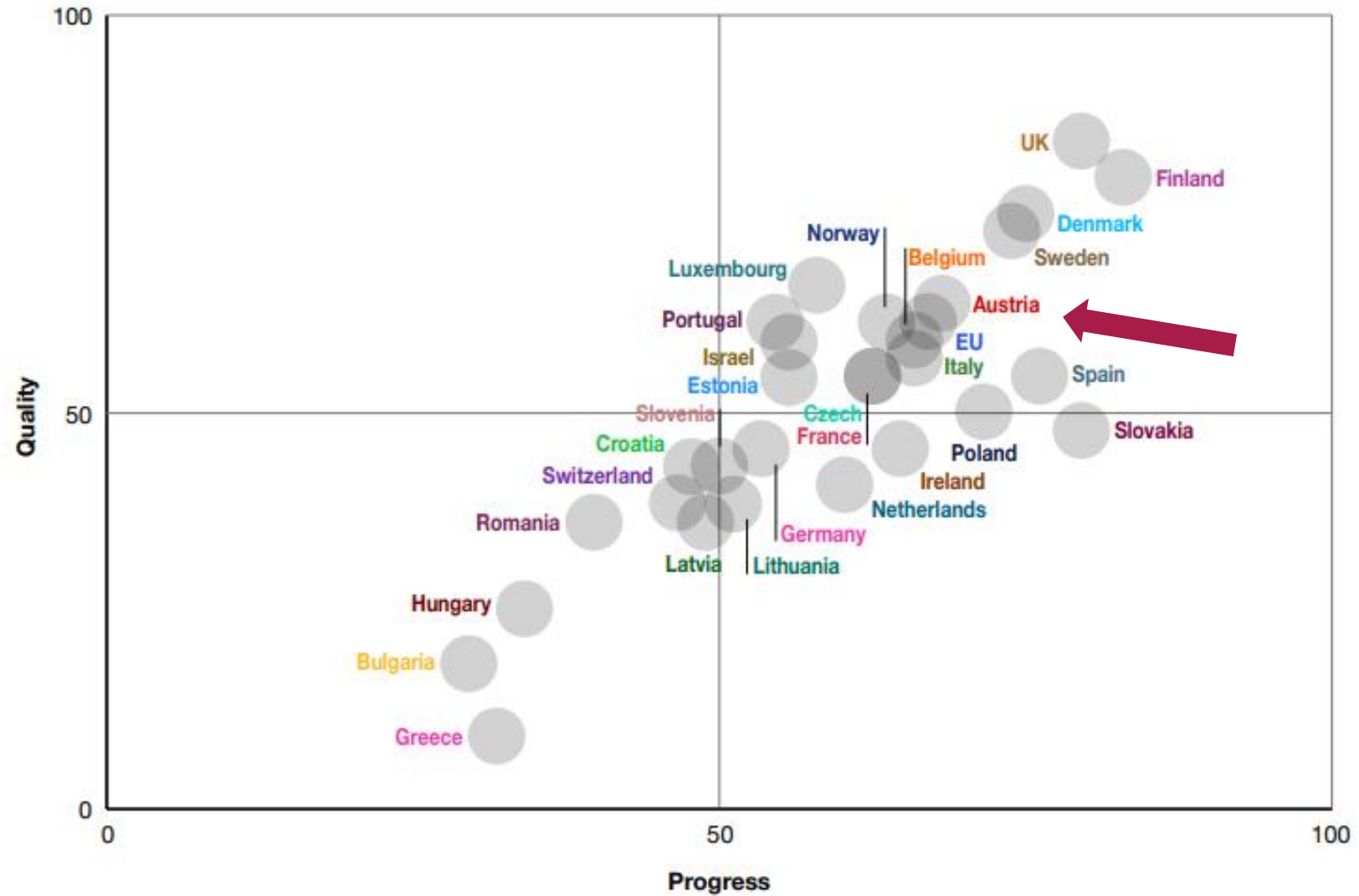


European Health Data Space (Act) – Will everything be completely different (again) in research based on medical data?

Dr. Žiga ŠKORJANC

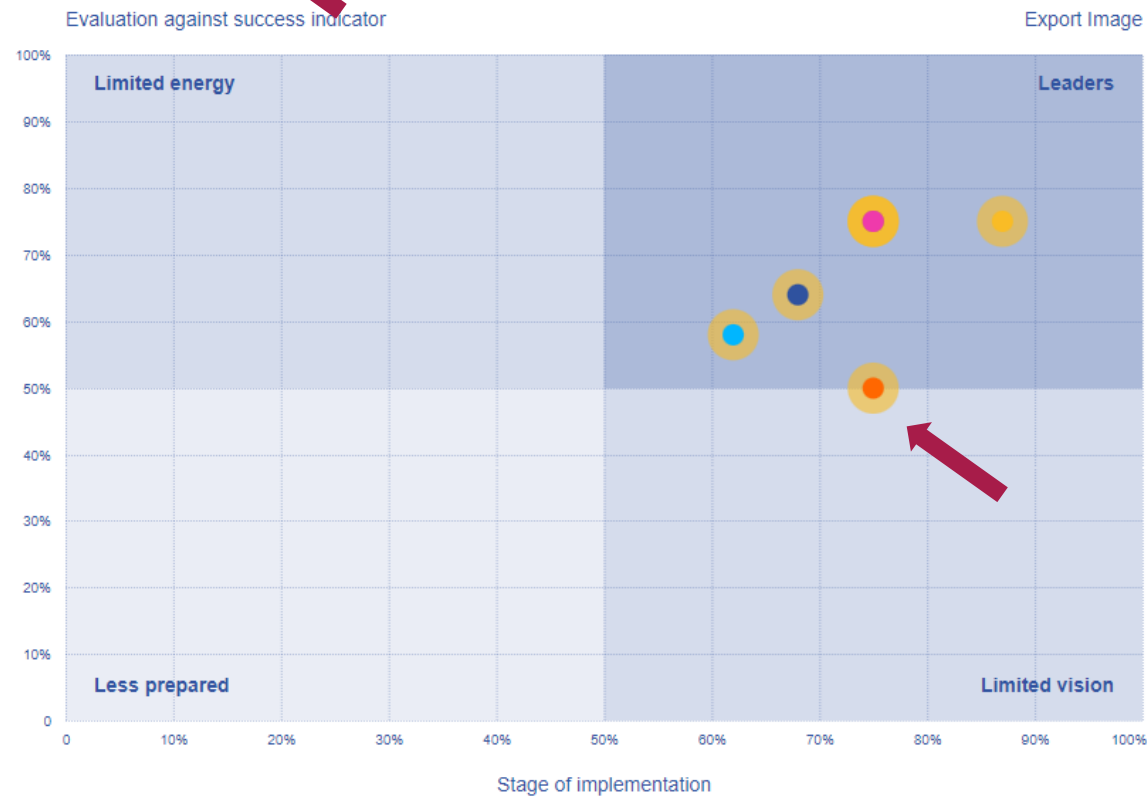


Figure 1: Secondary use of health data in Europe: country policy rankings



How well is your country doing on policy for secondary use of health data?

Overall Infrastructure **Capability** Innovation Equity Ethics Engagement Rank mode Comparison mode Good practice mode



Select the countries of your interest

Apply up to 2 regions

Alphabetical A-Z Alphabetical Z-A Deselect All

- | | |
|---|---|
| <input checked="" type="checkbox"/> Austria | <input type="checkbox"/> Italy |
| <input type="checkbox"/> Belgium | <input type="checkbox"/> Latvia |
| <input type="checkbox"/> Bulgaria | <input type="checkbox"/> Lithuania |
| <input type="checkbox"/> Croatia | <input type="checkbox"/> Luxembourg |
| <input type="checkbox"/> Czechia | <input type="checkbox"/> Netherlands |
| <input type="checkbox"/> Denmark | <input type="checkbox"/> Norway |
| <input type="checkbox"/> European Commi... | <input type="checkbox"/> Poland |
| <input type="checkbox"/> Estonia | <input type="checkbox"/> Portugal |
| <input type="checkbox"/> Finland | <input type="checkbox"/> Romania |
| <input type="checkbox"/> France | <input type="checkbox"/> Slovakia |
| <input type="checkbox"/> Germany | <input type="checkbox"/> Slovenia |
| <input type="checkbox"/> Greece | <input type="checkbox"/> Spain |
| <input type="checkbox"/> Hungary | <input type="checkbox"/> Sweden |
| <input type="checkbox"/> Ireland | <input type="checkbox"/> Switzerland |
| <input type="checkbox"/> Israel | <input type="checkbox"/> United Kingdom |

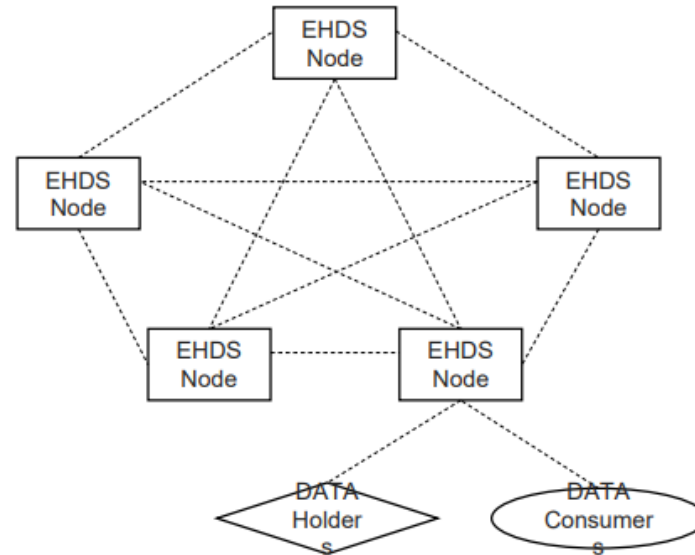
<https://secondary-use-health-data.theodi.org/tool/>

Effects of the European Health Data Space on research based on medical data (in Austria)

Regulation on the European Health Data Space

- General provisions (Chapter I)
- Primary use of electronic health data (Chapter II)
- EHR systems and wellness applications (Chapter III)
- **Secondary use of electronic health data** (Chapter IV)
- Additional actions (Chapter V)
- European governance and coordination (Chapter VI)
- Delegation and Committee (Chapter VII)
- Miscellaneous [Penalties, Evaluation and Review] (Chapter VIII)
- Deferred application and final provisions (Chapter IX)

EHDS concept



EHDS nodes = *Trust Anchors*

EHDS NODEs are resilient entry points for stakeholders into the EHDS

EHDS NODEs can be established by National or Trans-national stakeholders

EHDS NODEs follow common policies and interoperability specifications

DATA Holders make health data available for secondary use

DATA Consumers further process data for research, policy making or regulation

17th eHealth Network

EHDS concept – from a technical viewpoint

- For primary use: It is planned that all member states participate in **MyHealth@EU** by 2025.
- access bodies through which health data is made available for secondary use (**HealthData@EU**) will be connected to **the new decentralized EU infrastructure**.

EHDS „is a health specific ecosystem compromised of rules, common standards and practices, infrastructures and a governance framework“

- **Goal 1:** Improvement of medical care (primary use of data)
 - Exchange of „personal electronic health data“ with other health professionals in and between member states
 - A common European exchange format
 - Interoperable and secure electronic health record systems
- **Goal 2:** **Improvement of medical research** on the basis of data collected through medical care (secondary use of data)
 - „Access to large amounts of high-quality health data“
 - **1)** Currently great dependance on consent, therefore establishment of **health data access bodies in charge of an authorisation process**

Secondary use of data in medical research

- Researches gain access to
 - Only non-identifiable data – „containing information about illness, symptoms and medication, without revealing the identity of the person“.
 - An application must state, whether electronic health data is to be provided **in anonymised or pseudonymised form**.
- Only for specified purposes (e.g. scientific research or training, testing and assessment of algorithms)
- Data processing in an enclosed and secure environment (data and IT security).
- **2) Access to electronic health records of a single data holder**. Application for data access or a data request issued **directly to the data holder**.

„Trust is a fundamental enabler for success ...“

- The European Health Data Space should be a trustworthy environment, **and is based on the**
 - GDPR,
 - Data Governance Act,
 - Proposal for the Data Act and
 - Cybersecurity Directive („NIS-2“)
- Trust by law?
 - New regulation concerns several important risks and problems, and contains possible solutions (data transfers, security...)
 - **However**, trust is not directly connected to regulation (**do you put trust in medical law or in your doctor?**)

Thank you for your attention!

I look forward to the discussion!



Univ.-Ass. Dr. Žiga Škorjanc

- University Assistant and postdoctoral researcher at the Department of Innovation and Digitalisation in Law, University of Vienna (www.univie.ac.at/id)
- Managing Director lexICT – your data protection consulting firm (Vienna) (<https://lexict.de/home>)
- Member of the European Union Intellectual Property Office (EUIPO) Observatory Legal Expert Group (<https://euipo.europa.eu/ohimportal/en/web/observatory/about-us>)
- Email: ziga.skorjanc@univie.ac.at
- www.linkedin.com/in/ziga-skorjanc