DGIP-CEDS

Data Governance and Intellectual Property Governance in Common European Data Spaces

Pravni fakultet u Rijeci

Intellectual Property (IP) Governance in the European Health Data Space (EHDS): Flexibilisation Raises Stakes for Healthcare Researchers and Innovators in the EU

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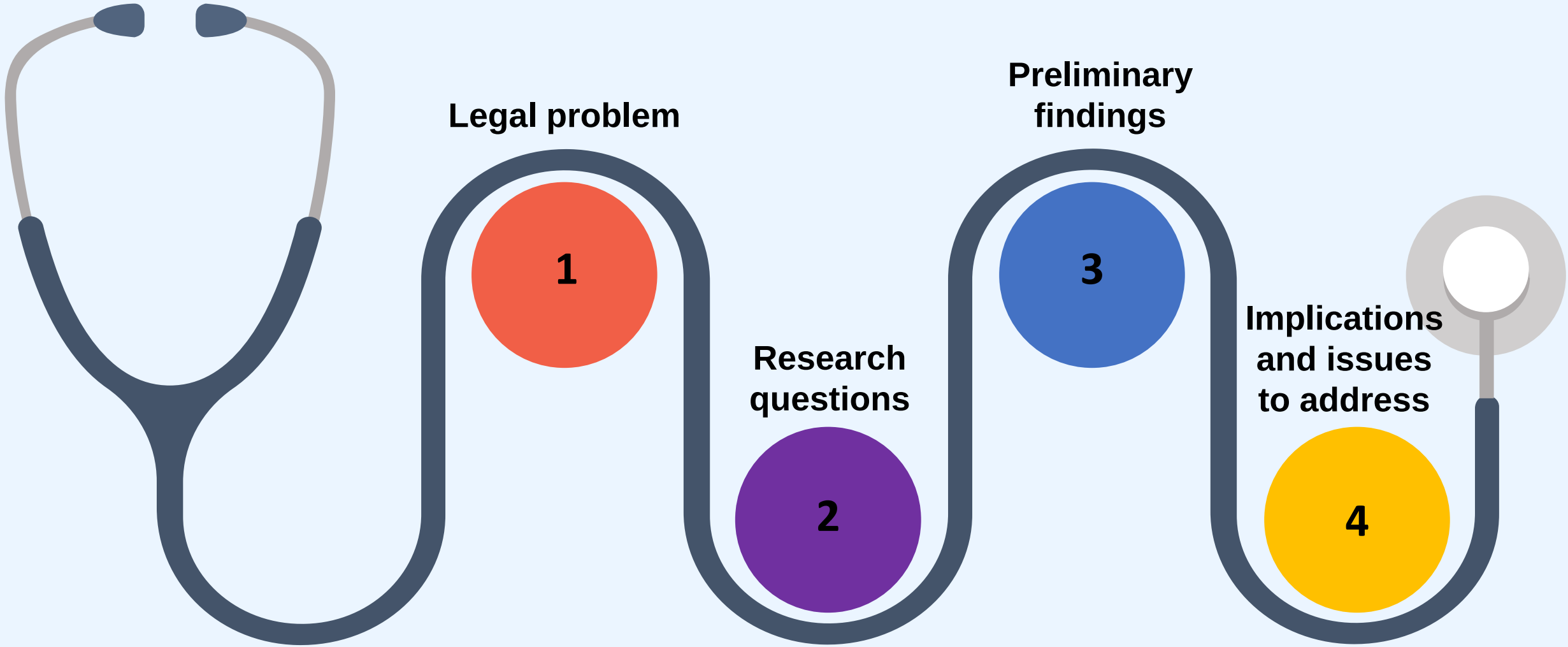
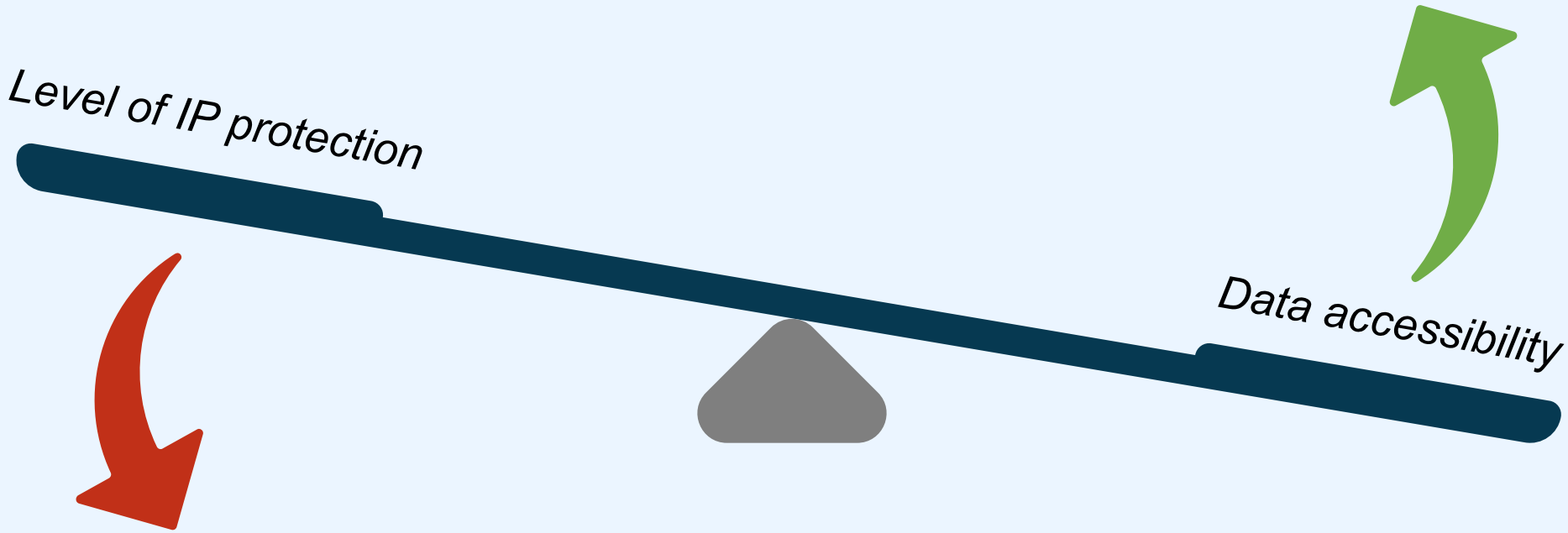
Presentation overview



1) Legal problem

Arguments concerning the secondary use of (personal and non-personal) electronic health data subject to IP rights in the European Health Data Space (EHDS) Regulation



1) Legal problem

IP governance rules in Chapter IV of the EHDS Regulation (applicable from 2029)

- Article 52(1): "**Electronic health data protected by intellectual property rights, trade secrets or** covered by the **regulatory data protection right** [.] **shall be made available for secondary use**."
- Article 52(2): "**Health data holders shall inform the health data access body** ["HDAB"] of any electronic health data containing content or information protected by intellectual property rights, trade secrets or covered by the regulatory data protection right [.]."
- Article 52(3): "**Health data access bodies shall take all specific appropriate and proportionate measures**, including of a legal, organisational and technical nature, they deem necessary to protect the intellectual property rights, trade secrets or the regulatory data protection right [.]."
- Article 52(5): "**Where** the granting of access to electronic health data for **secondary use entails a serious risk of infringing** intellectual property rights, trade secrets or the regulatory data protection right [.] which cannot be addressed in a satisfactory manner, the **health data access body shall refuse access to the health data applicant to such data**."

2) Research questions

I. **How may the new framework adopted under the EHDS Regulation interact with other international and EU legal instruments regulating IP rights?**

II. **How may the EHDS Regulation affect the exercise of specific IP rights and, by that, also the very foundations of IP policy in the EU?**

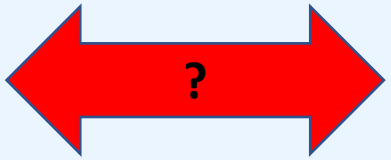
3/a) "Flexibilisation" of IP governance in the EHDS Regulation

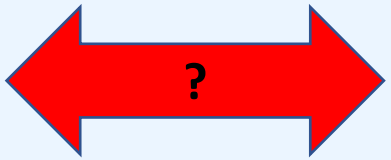
Electronic health data as excludable "private good" → **Electronic health data as non-excludable "public good"**

Utilitarian theory of IP protection → **Promotion of "open science"**

IP as a fundamental right → **"Overriding" rights** (e.g. right to health, right to personal data protection)

3/b) Frictions between EHDS and legally superior IP legal instruments

EHDS Regulation  **International IP rules**
(e.g. European Patent Convention,
WIPO Copyright Treaty,
TRIPS Agreement: unfair competition rules)

EHDS Regulation  **EU primary law**
(e.g. Charter of Fundamental Rights:
'right to property', 'freedom to conduct business')

3/c) Frictions between EHDS and other EU secondary legislation on IP

Article 1(3): EHDS is "**without prejudice to**" other legislative acts
"regarding access to, sharing of or secondary use of electronic health data [.]" - BUT:

EHDS Regulation ? **Trade Secrets Directive**
disclosure of trade secret data to HDABs and health data users may empty the essence of trade secrets protection

EHDS Regulation ? **Data Act (trade secrets rules)**
data holder may exceptionally "withhold or [.] suspend the sharing of data", if it "demonstrates that it is highly likely to suffer serious economic damage from the disclosure of trade secrets"

3/c) Frictions between EHDS and other EU secondary legislation on IP

EHDS Regulation ? **Database Directive**
sui generis database right
(right for database makers following substantial qualitative or quantitative investment)

EHDS Regulation ? **EU pharmaceutical legislation**
regulatory data protection
(exclusive right to pre-clinical and clinical trials data)

4) Implications and issues to address

- Legal uncertainties
  ↓
- Fragmented implementation?
  ↓
- Lack of safeguards for IP rights holders?
  ↓
- Unintentional IP leakages?
  ↓
- Unpredictable commercialisation paths?
  ↓
- Delayed innovation cycles?
  ↓
- Weakened global competitiveness?
  ↓
- Knock-on effect on pricing?
  ↓
- Hinder accessibility for patients and providers to state-of-the-art healthcare solutions?

Thank you for your attention!

For questions and potential collaborations:

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Project website:

https://pravri.uniri.hr/en/project/dgip-ceds/