The Learning Health System in Europe

IMI code of practice for the secondary use of health data

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Presentation Overview

- The issue
- The Code of Practice
- The Code's Article
- Status and Next Steps

What's the problem?

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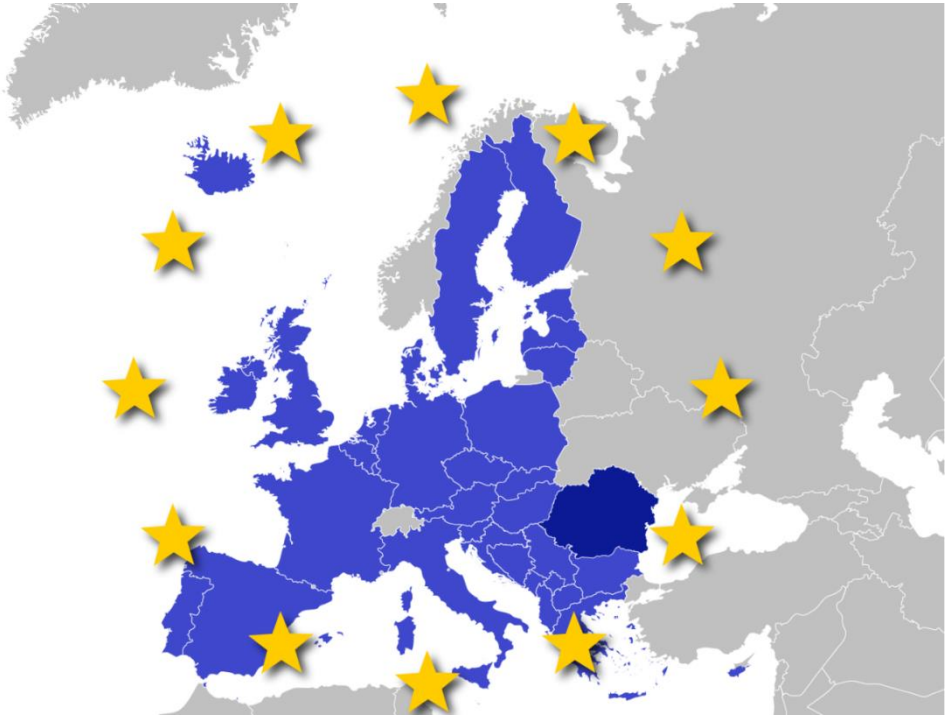
Common Privacy Rules… but…

- Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (24 October 1995)



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No harmonization

- Directives principles have been implement in each European country's local Law
  - **Each local law should contains the same Principles**
  - **But their implementation and interpretations differs**
  - **But some exceptions exist**

- The Directive is being revised
  - **Revised to become a Regulation (in early 2016 - Applicable 2 years after)**
  - **Unique text directly applicable after translation**
    - But many details to be defined at Member State level

Questionable Scope

- Applies to the processing of **personal data**
  - **Personal Data = Any information relating to an identified or identifiable natural person**
- Does not apply to **anonymous** data
  - **What is anonymous data?**
  - **Are clinical study data anonymous data?**
    - Not really (in the EU) but special regime in some EU countries
  - **No approved de-identification standard**
    - But some good proposals (see Khaled El Emam publications)

Questionable Rules

- Purpose
  - **Limited and defined**
- Collected Data
  - **Adequate, relevant and not excessive**
  - **Not kept for longer than necessary**
  - **Not transferred to other countries without adequate protection**
    - What about pseudonymised data?

Variable interpretations

- Consent
  - Is **consent** always needed to process health data?
  - **Exception** for scientific research purpose?
- Secondary use
  - Can **pseudonymised data** be used for another scientific purpose?
  - Does it require new **consent**?
  - Does it require **anonymisation**?
- Can HBS collected in clinical study be used for another purpose?
  - Many **guidelines** but no global one

The GDPR will not address these issues…

So What?

A Code of Practice for secondary use of Clinical data and Samples?

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Why developing a Code of Practice?

- Develop a unique - common across the EU - framework to reuse clinical (health) data
  - **Acceptable for EU collaborative research projects, IMI office, DPAs, Patients associations & Ethics Boards**

- Title: CODE of PRACTICE on SECONDARY USE of MEDICAL DATA in SCIENTIFIC RESEARCH PROJECTS
  - **Includes definition of terms (in the scientific context)**
  - **Built on articles and rules**
    - **Articles**: To organize the document by fields
    - **Rules**: What exactly is required to be done for each topic to comply with applicable regulations

Description of the Code

- **Collection**, **Use** and **Transfer** of Personal Medical Data
- **De-identification** and Protection of Anonymised Data
- **Information**, **Consent** and **Withdrawal**
  - Basic Information and Consent for Prospective Data Collection
  - Project Results
  - Incidental Findings
  - **Secondary Use** of **Health Care** Data in Research Projects
  - **Secondary Use** of **Research** Data
  - **Secondary Use** of **Genetic** Data
  - Consent Withdrawal

- Human Biological **Samples**
  - **Collection** of Human Biological Samples and Conduct of Genetic Analyses
  - **Secondary Use** of Human Biological Samples

Description of the Code (Cont.)

- Data **Security** & Involvement of Data **Processors**
- Documentation and Data **Retention**
- Medical Data **Disclosure**
- **Implementing** the Code's Rules
- **Modifying** the Code's Rules

- 5 APPENDICES (Adherence Agreement, Example of information sheets and consent forms, Examples of de-identification methods, Summary, Decision Tree

- Published on IMI eTRIKS project website and on IMI Office website

How to use this Code?

- This Code is **not a binding document as such** (yet)
  - **A guidance to be used by IMI projects to address multi-partners multi-countries issues for complying with Personal Data Protection regulations**
- This Code provides **EU harmonized operational solutions** to be compliant with the EU Privacy directive
  - **It does not plan for all local exception, but already includes some as examples.**
  - **It provides an harmonized solution to start from in multi-partners multi-countries, to be completed by applicable laws specificity where required**
- It proposes a secure framework for the **secondary use of genetic data** in RULE 22, which goes beyond what the laws currently allow
  - **As no solution exists yet when consent is not broad enough**
  - **As the EU can not afford not using all the knowledge currently produced with genetic data whereas the rest of the world will use it**

→ **RULE 22** needs **to be worked-out with Patients and Regulators**

You want to know more about the Code?

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Read our Article!

- **Code of practice on secondary use of medical data in European scientific research projects** - Anne Bahr & Irene Schlünder - International Data Privacy Law 2015 - *doi: 10.1093/idpl/ipv018 (free access)*

- Presents the Code, explains most questionable rules, discuss open issues
  - **Anonymization: definition and how to proceed**
  - **De-identification and Pseudonymization**
  - **DNA (in general) versus Genetic/biometric data "Rich-enough to single out a person"**
  - **Collecting informed consent**
  - **Using Human Biological Samples**
  - **Proposals to regulators to :**
    - Promote the use of broad consent
    - Allow the secondary use of pseudonymised data (without consent)
    - Support the development of a unique harmonized ICF template
    - Develop tools for forbid misuse of health data
    - Define means/ framework to reuse genetic data without consent
    - Balance exceptions for processing data with risk of harm

Status of the Code and Next Steps

- **Final draft** (dated August 27th, 2014) prepared with the 2 experts
  - **Submitted to the EDPS (as an IMI guidance/ tool) in Aug. 2014**
  - **Submitted to the CNIL (→ Art29WP) in Dec. 2014 + Belgian DPA**

- **Article** (published in Sep. 2015)

  → Both to be submitted directly to the Art.29 WP

- EFPIA to work on an industry-wide **CoC** based on this code

- EFPIA / IMI to propose a "Coordination and Support Action (CSA) for the Big Data for Better Outcomes (**BD4BO**) program" including data privacy topics ("Advice and requirements on legal, ethics, regulation, data privacy considerations").

Thank you for your attention

Questions?

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