The IMIA initiatives on Trustworthy Reuse of Health Data: a report

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An IMIA “project”

2012 European Summit on Trustworthy Reuse of Health Data

2013 Transnational Summit on Trustworthy Use of Data for Health
3-4 June • Brussels, Belgium
http://dataforhealth.imia.info

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Agenda

• Charles Safran
• Iain Buchan
• Steve Labkoff
• Riccardo Bellazzi
• Antoine Geissbuhler
• Q&A
Discussion

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Open or closed?

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EC wants to unify data protection within the EU with a single law, the General Data Protection Regulation (GDPR) that will substitute the current EU Data Protection Directive 95/46/EC

A proposal released on 25 January 2012.

- Mid-September to mid-October 2013: Orientation vote.
- The adoption is aimed for in 2014 and take effect in 2016.
• **Scope:** "personal data is any information relating to an individual". The regulation applies if the data controller/processor (organization) or the data subject (person) is based in the EU

• **Single Set of Rule:** One single set of rules applies to all EU member states; one Single Data Protection Authority for each company.
• **Consent**: Valid consent must be explicit for data collected and purposes data used (Article 7; Article 4). Data controllers must manage opt-ins and opt-outs.

• **Right to rectification**: The “right to rectification” gives a patient in a study the right to go back to their records (Article 16) and revise them to reflect changes in their medical situation, or address errors.
• **Right to be Forgotten**: Personal data has to be deleted when the individual withdraws consent or the data is no longer necessary and there is no legitimate reason for an organization to keep it (Article 17).

• **Data Portability**: A user shall be able to request a copy of personal data being processed and be able to transmit it electronically to another processing system (Article 18).
Amendments for biomedical research

- Enabling broad consent for research
- Eliminating the “Right to Be Forgotten” Provision
- Clarifying the Definition of Genetic Data
- Addressing the Right to Rectification and Right to Information
- Clarifying aspects concerning anonymised and Pseudonymised Data (Key-coded data)
A system for data reuse should thus prove its trustworthiness by fulfilling the responsibility of dealing with the data within the limits of a social contract, regulated by policies, between the citizens and the organizations handling such a system.
Components

Technology

Research

Implementation

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Technologies

eTRIKS: European Translational Information & Knowledge Management Services (IMI)

Informatics for Integrating Biology & the Bedside

Electronic Health Records for Clinical Research

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Good Research for Comparative Effectiveness (GRACE)
Implementation ... ?

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The discussion groups

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Ensuring public trust and confidence

A broad consent, dynamically managed by citizens

– IT architecture: transparency, security
– Citizens Education / Empowerment
– Governance

Principles of safeguarding instead of maximum security option
Trusted business practices

• Opportunities:
  – Trusted data brokers
    • To act as a ‘Curator’ of data
    • To convert the Data into Information
    • To deliver electronic consent processes
  – Transparent support to the recruitment of patients in clinical trials

• Challenges: Independence, transparency, public private partnership

• Recommendations: Quality, Transparency, Governance and Accountability

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Trusted scientific practices

Trusted science, trusted processes, trusted systems, trusted people

- Opportunities: Closing the research to healthcare gap, Large scale science
- Challenges: Publication biases, Reproducibility, Regulations, sharing data is not a given
- Recommendations: Education, Standards and quality, Open data and open methods

Shared standards and guidelines for trusted scientific research and research governance are needed
Summary

• it is mandatory to involve citizens and patients' organizations in the process of defining a trustworthy system to:
  – clarify the benefits
  – take into account the concerns

• Transparency is needed, transparency is trust

• Governance is essential
International efforts

Research Data Sharing without barriers

Registration for the Research Data Alliance Second Plenary is now open! View the event details and register now!

Big Data Analytics IG

Status: Pending Action

The Big Data Analytics (BDA) Interest Groups seeks to develop community based recommendations on feasible data analytics approaches to address scientific community needs of utilizing large quantities of data. BDA seeks to analyze different scientific domain applications and their potential use of various big data analytics techniques.

Agricultural Data Interoperability IG

Big Data Analytics IG

Brokering IG

Certification of Digital Repositories IG

Community Capability Model WG

Data Citation WG

Data Foundation and Terminology WG
The road ahead

• The road has been drawn but it still remains long and winding.
• IMIA will act as an independent convener, able to provide a forum and to foster initiatives to overcome difficulties
• The goal is to provide benefits to all stakeholders involved in data sharing and reuse, from citizens to companies.

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Closing

“In a Connected world, we are no longer responsible for what is reasonably known, we become responsible for what could have been reasonably known had we collected and organized the data appropriately.”

- Dr. Brigitte Piniewski, Peacehealthlabs
- Dr Petra Wilson, Cisco