The New European Data Protection Framework

Data For Health and Science
16 June 2015

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European Commission

Current legislation on Data Protection

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

Objectives:

- protect the right to personal data protection
- guarantee the free flow of personal data between Member States

DP Regulation maintains the same objectives!

New challenges for the protection of personal data

The challenge of technology, globalisation and societal change

Globalisation
Internet
Online social networking
E-commerce
Online databases
Electronic health records
Cloud computing
Big Data
Face recognition
Role of DPAs

Governance
Geo-location
Video surveillance
Profiling
Behavioural advertising
Biometric data
Genetic data
Law enforcement
Security breaches
Identity theft

No control over personal data → Lack of trust

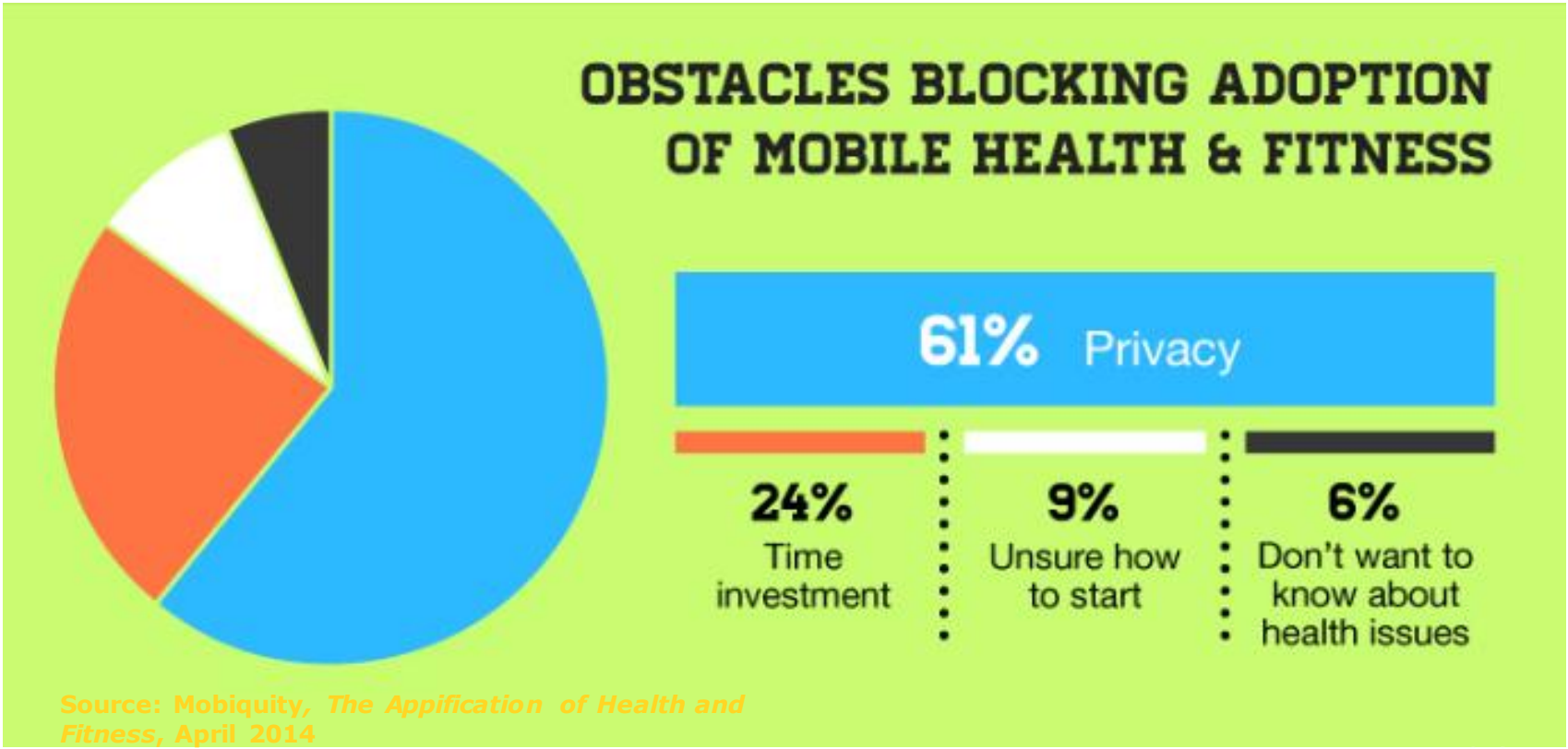
Insufficient awareness, loss of control and trust, particularly in the online environment:

75% of respondents in recent Eurobarometer say they have only partial or no control of their data online. 2 in 3 citizens say they are concerned about this.

Difficulties in exercising data protection rights:

- to exercise legal right of access to one's personal data;
- to have one's data deleted;
- to access effective remedies;
- to withdraw and transfer personal data from an application or service ("data portability")

Lack of trust in the health sector



Source: Mobiquity, *The Appification of Health and Fitness*, April 2014

A new legal framework

Lisbon Treaty

- **Fundamental right to the protection of personal data**

Article 8 of the EU Charter of Fundamental Rights

> *1. Everyone has the right to the protection of personal data concerning him or her.*
>
> *2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.*
>
> *3. Compliance with these rules shall be subject to control by an independent authority*.

- **New legal base**: Article 16 TFEU

Proposal for a General Data Protection Regulation, 25 January 2012

Replaces Data Protection Directive 95/46/EC ➲ new centrepiece of EU legislation on personal data protection

Objectives:

- strenghten data protection rights and to ensure that all individuals in the EU have the same data protection rights
- ensure data protection rules fit for the digital single market
- put individuals in control of their personal data
- strike the right balance between data protection rights and the need to support public health and medical research objectives

Data Protection Regulation – Main Changes

PUTTING INDIVIDUALS IN CONTROL OF THEIR DATA

- **Better information** to individuals about data processing
- **Consent** to be given **explicitly**, whenever this may be required
- Enhance "**right to be forgotten"**
- **Clearer rights** of access to individuals
- Generalise data **breach notifications**
- Reinforced **data security** obligations on controllers
- **Strengthened** national **DPAs**
- Enhanced and dissuasive **administrative** and **judicial remedies** for breaches of DP rights

Data Protection Regulation – Main Changes

RULES FIT FOR THE DIGITAL SINGLE MARKET

- Regulation is directly applicable and **removes legal fragmentation**
- **Cutting red tape** (e.g abolishing notifications to process the data)
- **One-stop shop system** for data protection in the EU: only one DPA checks compliance of a business, regardless of how many MS the business may be active in
- **Better enforcement and governance** and more **level playing field** through stronger national DPAs

Processing of Personal Data relating to Health and processing for research purposes

MAIN INNOVATIONS

- Definition of **data concerning health** (and biometric and genetic data) introduced
- **Better harmonisation** of legal provisions on Data Protection
- **Conditions for processing** of "sensitive data" including data concerning health (Articles 9, 81)
- **Specific Health Article** introduced – **Article 81** for processing of health data, including processing without consent
- **Targeted approach** to **Right to be Forgotten** for health data
- Introduction of **specific research article – Article 83**, ensures **complete harmonisation** of data protection safeguards
- Possibility for **delegated acts** specifying elements of Articles 81 and 83

Consent and other legal grounds

- Generally: sensitive data cannot be processed without explicit consent.
- BUT: Consent is **NOT** always required, nor is it the primary legal ground for processing personal data!
- Derogations for sensitive data:
  - Legitimate activities by associations or foundations that permit the exercise of fundamental freedoms;
  - **By a law, and subject to suitable safeguards;**
  - **Grounds of public interest particularly for health purposes, including public health, social protection and the management of health-care services,**
  - For procedures settling claims for benefits and services in health insurance
  - **For historical, statistical and scientific research purposes**.

Processing of Personal Data for Research Purposes

MAIN INNOVATIONS OF THE DP REFORM

- Introduction of **specific research article – Art 83**, ensures **harmonisation** of DP safeguards
- **Processing for research purposes allowed, within limits of Regulation, if purposes cannot be achieved by anonymized or pseudonymized data** (Art 83 (a) and (b)
- **Further processing**: processing of personal data for other purposes to be allowed only where the processing is **compatible** with those purposes for which the data have been initially collected. Where not compatible, **consent** is required, or **another legitimate ground** for lawful processing (Article 6 (4) and Recital 42
- **Enhanced responsibilities** (and liability) for the controller (Art 5 (f)

Other aspects of the reform facilitating health data processing and building trust

Mandatory appointment of independent **Data Protection Officers** (large undertakings)

Obligation for data controllers to carry out a **data protection impact assessment** in specific cases

Concept of "**Data protection by design and by default**"

Encouragement of self-regulatory initiatives, including the active promotion of **Codes of Conduct**.

Next steps

- Start of trilogues in June following the general approach by Council yesterday
- Final agreement by year end
- The Regulation will be enforceable in all Member States two years after it has been adopted

Link to EU Data Protection Reform Package:
http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm

Conditions for allowing research exceptions

Jane Reichel
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Informed consent in medical research

- Process personal data
- Store human biological samples
- Use data/sample in medical research

Administrative safeguard:

Ethical approval by national research ethic committees

Research exceptions from Data Privacy rules

- The Commission, European Parliament and the Council all accept exceptions, but in different ways

- Policy choice: A strict common rule or room for individual exceptions for the Member States?

- Constitutional issue: EU can fund medical research, but not regulate

Taking a comprehensive approach

- A common rule for exceptions from data privacy facilitates cross-border biobanking

- Complimentary soft law and governance tools for handling samples and research
  - Horizon 2020 ethics requirements
  - BBMRI-ERIC ethical, legal and societal issues
  - EU funded self-regulatory projects for a bottoms-up approach

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

Reuse of clinical trial data : the ECRIN perspective

Jacques Demotes

www.ecrin.org

Infrastructure for multinational, independent trials

(www.ecrin.org)

ECRIN IA 2012-15

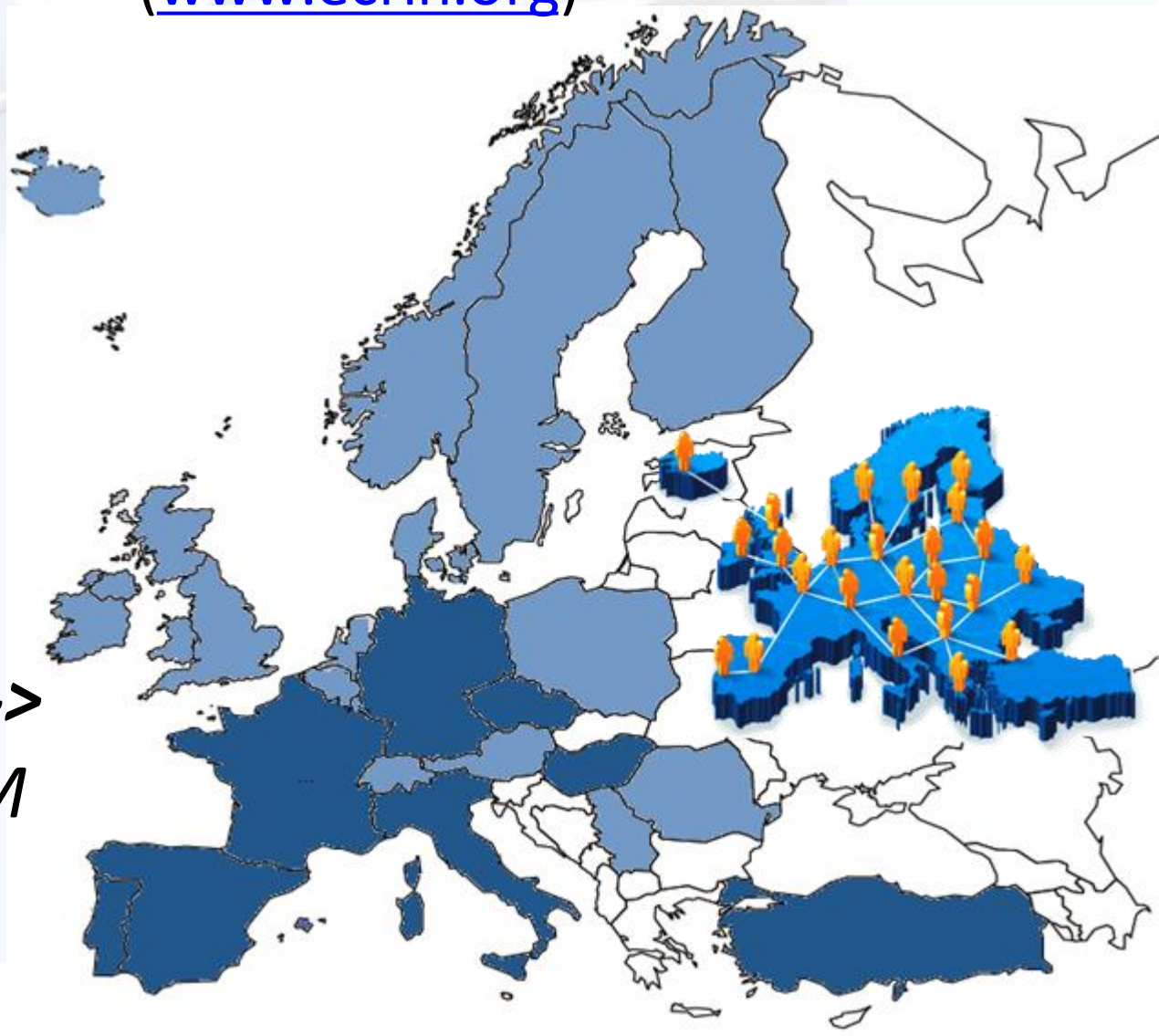
23 countries, 567M

Structuring user communities

ECRIN-ERIC 2013 ->

8 countries, 360M

Sustainable infrastructure



How does ECRIN support multinational trials ?

➢ Information before trial

- ➢regulatory ethical requirements
- ➢sites, recruitment
- ➢insurance
- ➢costs
- ➢funding
- ➢contracting
- ➢methodology

protocol

Scientific evaluation

Logistical assessment

Contract

➢ Services during trial

- ➢competent authorities
- ➢ethics committees
- ➢adverse events
- ➢monitoring
- ➢data management

ECRIN Scientific Board : Eligibility Criteria

- Multicentre trial run in at least two European countries.
- Rules for transparency:
  - Commitment to register the trial in a public register before inclusion of the first participant, for example on www.clinicaltrials.gov
  - Commitment to publish results irrespective of findings.
  - *Commitment to make raw anonymised data sets available to the scientific community upon request to the sponsor or principal investigator one year after the trial is completed (last follow up of the last patient) or, for registration trials, when registration is completed or the development is discontinued.*

Access to patient-level data of all clinical trials (H2020 Corbel)

- Procedure
  - ✓ personal data protection
  - ✓ anonymisation
  - ✓ restricted access
  - ✓ access procedure
  - ✓ contracting with dataset users
  - ✓ informed consent

- IT instrument:
  - ✓ repository ? extractor ?

Impact of access to clinical trial data

➢ Optimal use of data collected in clinical trials

(patients take personal risks to generate these data)

➢patient-level meta-analyses : pooling results from multiple trials to promote evidence-based medical practice

➢re-analyses : robustness of results

➢secondary analyses

➢group analyses

European Personal Data Regulation

➢ should not lock access to reuse of patient level clinical trial data

➢ « specific, informed and explicit consent » difficult to achieve for secondary use of clinical trial data

➢ exemption criteria for the reuse of clinical trials data : broad consent

➢ broad consent possible in Clinical Trial Regulation 536/2014

➢ reuse of healthcare data for clinical trials ?