EDPS

EUROPEAN DATA PROTECTION SUPERVISOR

Big data and the new EU data protection Regulation

The role of Big Data in Healthcare

Sophie LOUVEAUX
London 14-15 November 2016

Big Data Means Opportunities

Large Availability of Personal Data → Large Computing and Storage Capabilities → More Knowledge, Better Therapy, Greater Health

Let's Have a Look at the European Open Science Cloud

- "*...aims to give Europe a global lead in scientific data infrastructures, to ensure that European scientists reap the full benefits of data-driven science....*"

- 1.7 million European researchers and 70 million professionals in science and tech will have access to data.

- Free, open and seamless services for storage, management, analysis and re-use of research data, across borders and scientific disciplines.

3

(European *Commission, Communication on European Cloud Initiative*, COM(2016, 178))

A Beautiful World....

✓Additional insights on diseases and therapy;

✓Faster progress in scientific research;

✓Customised treatment of patients;

✓More efficiency;

✓Access to knowledge that appeared out of reach before.

....Where Data Protection Might Look Out of Place....

....But Change Is Underway...

- In May 2018, a **new General Data Protection Regulation (GDPR)** will replace Directive 95/46, consolidating and innovating data protection rules.

- "*The UK will continue to need clear and effective data protection laws, whether or not the country remains part of the EU*".

  (ICO statement of 19 April 2016)

....and the GDPR Will Mark a Difference

- **«All You Can Eat» approach**: feed as many data as possible to computers and process them fast. Regulation is a burden and user's trust irrelevant.

- **Sustainable approach**: facilitate the free flow of data and facilitate the internal market. Protect individuals. Regulation is an **investment** and users' trust is **value**.
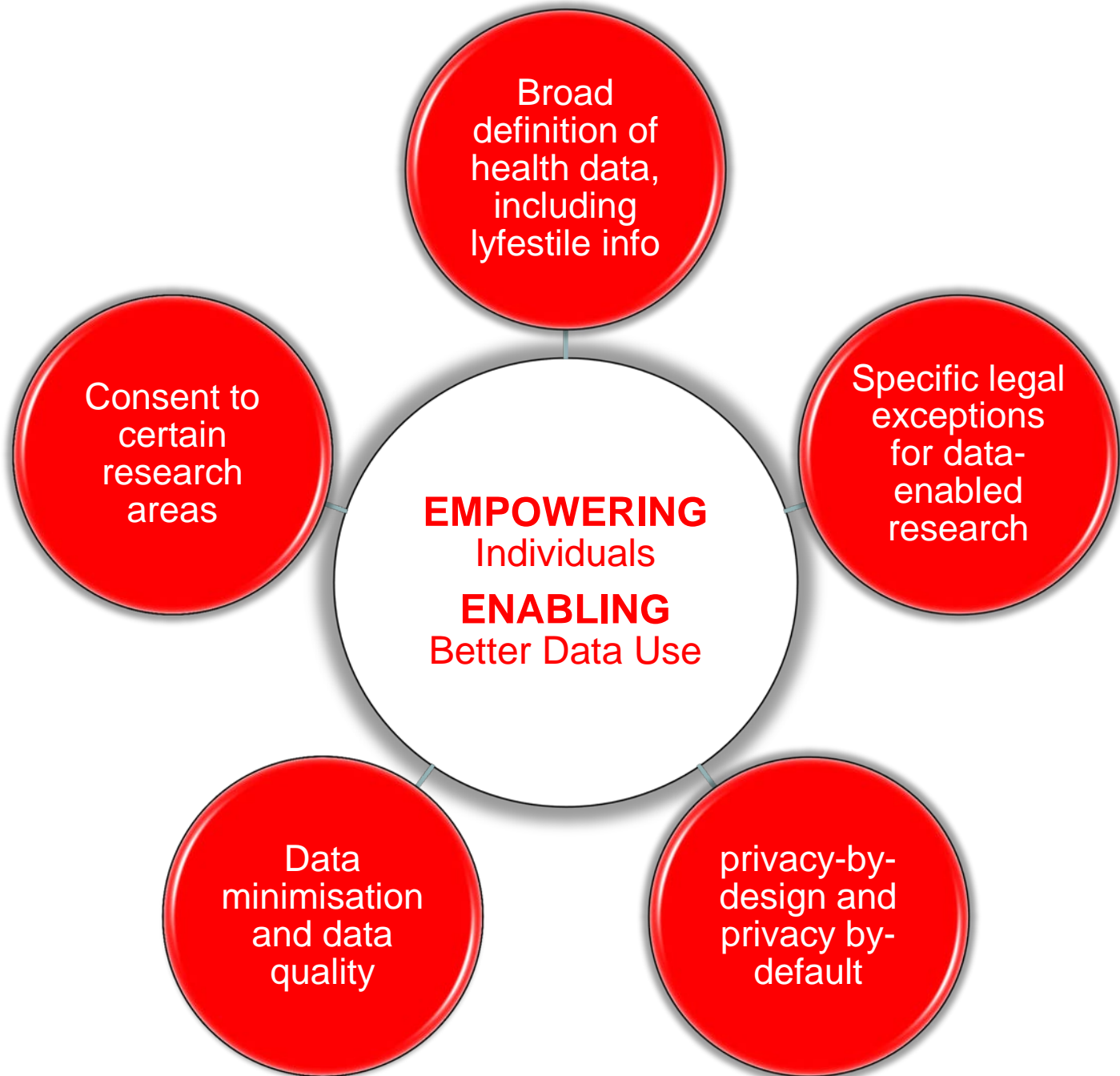
A Workable Definition of Health Data

- Article 4 («*personal data related to the physical or mental health of a natural person*») and recital (35) of GDPR include a comprehensive definition of health data.

- If lifestyle information **is used to determine health conditions of an individual**, then the notion of «health data» should also be deemed to include lifestyle and wellbeing information.

Consent to Certain Research Areas

- Data protection rules require consent to be **freely given, SPECIFIC and informed**.

- It is often difficult to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection.

- Therefore, data subjects should be allowed to give their consent to certain areas of scientific research.

- Risk that research purposes are defined too broadly and consent is undermined!

Interpreting Exceptions for Scientific Research:

- Article 89 of the GDPR allows the EU or Member States to limit certain individual rights, when necessary for scientific research.

- As an exception, it should be **strictly interpreted and applied**.

- We want to avoid that scientific purposes are used as a «loophole» to collect data for other purposes (see also Art. 89(4))

Privacy «by design» and «by default»

Compliance Might Be a Step Hard to Climb But Will Lead Us Higher

Important principles, but initially established ONLY IN PRACTICE.

The GDPR has now CODIFIED them. Privacy shall be embedded in the design phase.

In the future, we expect that PRIVACY is perceived AS A QUALITY FEATURE of products and services.

Data Minimisation and Data Quality: Sides of the Same Coin

- A large amount of data are available in the real world, but **not all of them are of good quality**.

- The GDPR introduces the concept of **data minimisation** (use just what you need)

- As minimisation is implemented, there is a **greater incentive to select data of good quality**.

- **Data quality is crucial in healthcare** (e.g. clinical trials, therapy evaluation, etc.)

A Sign of Maturity: Being Accountable for Data Processing

The GDPR introduces a shift in paradigm about compliance:

- The Controller has to adopt **suitable measures** to ensure and demonstrate compliance (Art. 24 of the GDPR)

- The Controller has to continously **assess, manage and minimize** risk associated to processing.

Non-exhaustive list of appropriate measures

- Documentation (art 30)

- Implement security requirements (art 32)

- DPIA impact assessment (art 35)

- Prior autorisation / consultation (art 36)

- Designation of a DPO (art 37)

- Data protection by Design / Default (art 25)

Reasons to be Accountable Now

- Heightened public concerns

- Reduce risks, **enhance trust of customers**

- Be **ready** for the future

- Respect existing rules

- Avoid **orders, sanctions and damages**

Two Reasons Why We Need Data Protection Using Big Data

Healthy or not, we remain human beings with fundamental rights!

Big data will run better, with built-in data protection safeguards!
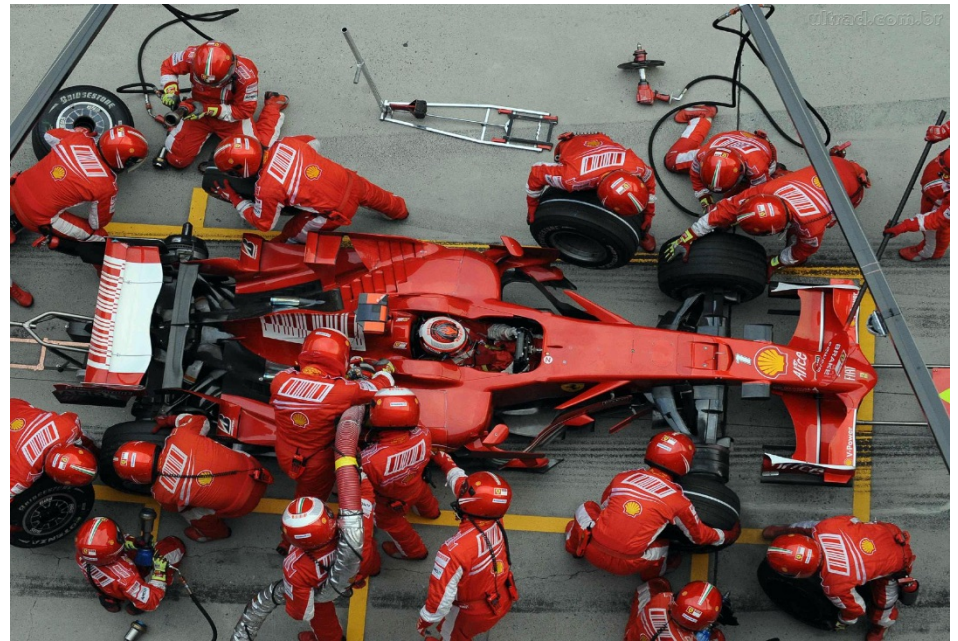
Thank you!

more at:

www.edps.europa.eu

edps@edps.europa.eu

@EU_EDPS