EU data reforms & research: an industry perspective

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Industry perspective

- Medical research – many advances, but much to do. Data crucial to responding to patient needs.
- Data underpins the research ecosystem: electronic health records, mobile technologies.
- We need much closer collaboration between the public and private sector.

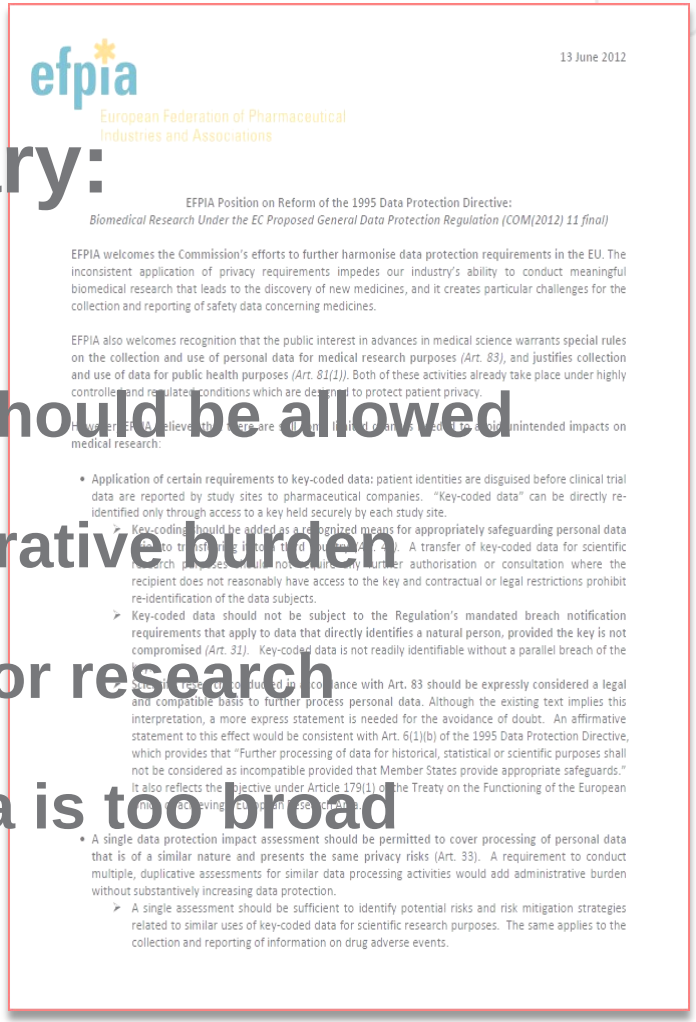
Patient information is essential for medical research

- **The use of patient information (predominately in key coded or anonymous form) is vital for the discovery, development and safety monitoring of medicines:**
  - Observational research e.g. identifies the causes of disease
  - Clinical trials for the development of new medicines
  - Monitoring the safety and efficacy of prescribed drugs

- **Protecting privacy: integral to medical research**
  - EU Clinical Trials Directive.
  - Independent ethics review
  - Informed consent of individuals.
  - Good clinical practice & confidentiality

The Commission's proposal is pretty good

- A few changes necessary:
  - Transfer of key-coded data should be allowed
  - Avoid unnecessary administrative burden
  - Enabling the re-use of data for research
  - The definition of genetic data is too broad



efpia

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European Federation of Pharmaceutical Industries and Associations

EFPIA Position on Reform of the 1995 Data Protection Directive:
Biomedical Research Under the EC Proposed General Data Protection Regulation (COM(2012) 11 final)

EFPIA welcomes the Commission's efforts to further harmonise data protection requirements in the EU. The inconsistent application of privacy requirements impedes our industry's ability to conduct meaningful biomedical research that leads to the discovery of new medicines, and it creates particular challenges for the collection and reporting of safety data concerning medicines.

EFPIA also welcomes recognition that the public interest in advances in medical science warrants special rules on the collection and use of personal data for medical research purposes *(Art. 83)*, and justifies collection and use of data for public health purposes *(Art. 81(1))*. Both of these activities already take place under highly controlled and regulated conditions which are designed to protect patient privacy.

EFPIA believes that there are certain [illegible] to avoid unintended impacts on medical research:

- **Application of certain requirements to key-coded data:** patient identities are disguised before clinical trial data are reported by study sites to pharmaceutical companies. "Key-coded data" can be directly re-identified only through access to a key held securely by each study site.
  - Key-coding should be added as a recognized means for appropriately safeguarding personal data [illegible] to transfer key-coded data for scientific research purposes [illegible] not require any further authorisation or consultation where the recipient does not reasonably have access to the key and contractual or legal restrictions prohibit re-identification of the data subjects.
  - Key-coded data should not be subject to the Regulation's mandated breach notification requirements that apply to data that directly identifies a natural person, provided the key is not compromised *(Art. 31)*. Key-coded data is not readily identifiable without a parallel breach of the [illegible]
  - [illegible] conducted in accordance with Art. 83 should be expressly considered a legal and compatible basis to further process personal data. Although the existing text implies this interpretation, a more express statement is needed for the avoidance of doubt. An affirmative statement to this effect would be consistent with Art. 6(1)(b) of the 1995 Data Protection Directive, which provides that "Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards." It also reflects the objective under Article 179(1) of the Treaty on the Functioning of the European Union of [illegible]
- **A single data protection impact assessment should be permitted to cover processing of personal data that is of a similar nature and presents the same privacy risks** (Art. 33). A requirement to conduct multiple, duplicative assessments for similar data processing activities would add administrative burden without substantively increasing data protection.
  - A single assessment should be sufficient to identify potential risks and risk mitigation strategies related to similar uses of key-coded data for scientific research purposes. The same applies to the collection and reporting of information on drug adverse events.

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