‘Data Protection Regulation:
Keeping health research alive in the EU’

Perspectives from Academia

Professor Richard Frackowiak
Chair of the Medical Sciences Committee
Science Europe

CRITICAL VALUE OF PERSONAL DATA
Perspectives from Academia

- **Access to personal data is vital in health research**:
  - observational studies
  - recruiting to and running clinical trials
  - research using biobanks, registries

- Past **successes** of EU research: eg. infectious disease – Understanding HIV natural history and development of effective therapy (30 years)

- EU **challenges** 21st century: ageing EU population – neurodegenerative diseases, eg- HBP - medical informatics

CRITICAL VALUE OF PERSONAL DATA
Perspectives from Academia

- **Proportionate** legal framework for data protection MUST:
  - Respect individual privacy
  - Facilitate medical research
  - Ensure society benefits from data collected with public money (social good) by fostering health research and innovation
- Cutting-edge European Academic research needs to continue
- DPR reform in context of scientific research (incl. health) is **PRIORITY** for Science Europe

SCIENCE EUROPE
Shaping the future of research

Science Europe (SE) Medical Sciences Committee

- Science-Policy Organisation **representing the collective interests of European Academic Research**
- **53 Member Organisations, 27 countries, approx €30 billion** invested in research annually
- **Medical Sciences Committee:** advisory body to Science Europe on **medical research science-policy activities**
- Fifteen **authoritative European academics**, broad medical expertise and research excellence

DPR, Science-Policy Activities SE Medical Sciences Committee

- Revision of the EU legal framework in context of health research is **key science-policy priority** for Science Europe and Medical Sciences Committee

- **Opinion paper** released, May 2013:

‘The benefits of personal data processing for medical research in the context of protection of patient privacy and safety’

DPR, Joint Science-Policy Activities

- Engagement with European academic collaborators (**Wellcome Trust, Federation of European Academies of Medicine, etc.**)
- co-signed **joint Science-Policy Statements / Recommendations on DPR**

Update: May 2013

Impact of the draft European Data Protection Regulation and proposed amendments from the rapporteur of the LIBE committee on scientific research

SUMMARY

We welcome the provisions in the European Commission's proposal for a Data Protection Regulation (2012/0011(COD)) to support research that is vital to improve the lives, health and wealth of people in the European Union. The Commission's proposal strikes an appropriate balance between protecting the rights and interests of individuals and facilitating scientific research for public good.

We are very concerned that amendments proposed by the rapporteur of the LIBE committee will prevent or severely impair scientific research studies using personal data.

To ensure that the Regulation does not inhibit ground-breaking medical and social research:

- it is essential that Article 83 and the associated derogations that facilitate research are maintained as the Regulation moves through the legislative process;
- amendments are needed to clarify the research provisions to ensure these achieve their intended purpose; and
- amendments are needed to clarify the scope of the Regulation and ensure that the use of pseudonymised data in scientific research is regulated proportionately.

LIBE AMENDMENTS TO THE GENERAL DATA PROTECTION REGULATION (2012/0011(COD))

VOTING RECOMMENDATIONS

May 2013

Key:

++ Strongly support
+ Support
- Oppose
-- Strongly oppose

Research in the DPR proposal from the EC (Jan 2012)

- **Special rules** for the processing of personal data for "historical, statistical and scientific research purposes"
  - Consent not the only legal basis
  - Indefinite storage
  - Exemption from 'right to be forgotten'

- **Conditions** set out in Article 83:
  - personal data should not be used if anonymous data would be sufficient
  - if possible, any identifying information should be kept separately from other information

- **We support Article 83 provisions and derogations**

LIBE draft report (Jan 2013)

- Jan Phillip Albrecht (DE, Greens)
  - Much stricter rules for data concerning health – very narrow MS exemption and authorisation
  - Note: always specific, explicit informed consent
  - All data ‘singling out’ an individual comes in the scope
  - If pass some approved current research will become **illegal!**

PRINCIPLES AND SAFEGUARDS health research

- Highly regulated field in EU with **privacy protection** built in and robust **ethical framework**
  - **EU Clinical Trials Directive**
  - **Consent**
    - specific, explicit, informed (norm)
    - 'broad-consent' (biobanks)
    - *No consent (exceptional)*
  - **Ethics Committees**

DPR & ANONYMISED DATA health research

- **Anonymised data cannot under any circumstance be associated with their individual donors**
- hence should be used and re-used for research (facilitated by modern data storage infrastructures and procedures)
- resource with potential savings for research expenditure and of researcher effort

- **Support that anonymisation is explicitly stated to be outside the scope of the Regulation**.

DPR & PSEUDONYMISED DATA health research

- **Most** used type of data in health research
- Cross **linkage** across database
- **Safe havens**, keeping key **separate**

- Recommend **risk-managed approach for pseudonymised data** processed for health research
- Require level of protection between identifiable and anonymised

Note: Pseudonymised data can often – but not always – be used in place of identifiable data.

DPR & IDENTFIABLE DATA health research

- **In general** : Use pseudonymised data or anonymised
- But exists special research circumstances where **identifiable data needed** (combination address, age, health condition).
- Use of identifiable health data **without consent** would become illegal under the rapporteur's proposals.
- **Vital that exception to consent includes identifiable data**. This should only be used when it is not possible to use pseudonymised data, where it is not practicable to seek consent and under the safeguards mentioned earlier

SCIENCE EUROPE
Shaping the future of research

CONCLUSIONS - DPR

- Objectives of **legal framework for data protection** MUST be to:
  - ensure patient **privacy and safety**

  AND
  - **facilitate** medical research in Europe to realise the **high societal benefits** that accrue from it.

CONCLUSIONS – DPR

- **Key for academia in the DPR** is:
  - Maintain **provisions and derogations** for health research (Art 83)
  - Clarify the case of **pseudonymised data** (risk-managed approach)
  - Processing of data **without consent** when needed has to be possible
  - Allow research under a **'broad consent'** (biobanks, registries …)
  - Limit unnecessary **administrative burden** put on researchers and administrators

Thank you