Consortium of European Social Science Data Archives

Managing Director
Paul Jackson

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Purpose of CESSDA in the ERA

Strategic Mission :

”To provide a comprehensive, distributed and integrated social science data research infrastructure, facilitating access to social science data resources for researchers regardless of the location of either researcher or data.”

Influenced by :

- Public Policies and Private lives
- Privacy By Design

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A non-invasive Mission

- A single European Data Protection Regulation is an important step to achieving this Mission - it addresses the geography problem
- CESSDA and the Social Sciences are not invasive
- Our regulatory controls should be about ensuring...

  - the non-invasive effect we have on individuals

  - our positive effect for an inclusive, reflective and innovative society right across the ERA

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Don’t swap geographical silos with purpose silos

- Achieving an *inclusive, reflective and innovative society* needs many actors to work together. The statisticians, scientists, economists, historians, involved in this purpose have the same non-invasive philosophy

- Please don’t divide us with different regulatory conditions in the Regulation. *Purpose is primary!*

- Please do divide us from any invasive purpose (including invasive scientific and medical purposes)

- Consider that where there is clear public *consensus* for a non-invasive purpose, private *consent* may not be necessary to uphold data protection rights.

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Dr Rob Frost
Policy Director,
Medical Policy,
GlaxoSmithKline

Alignment with existing safeguards

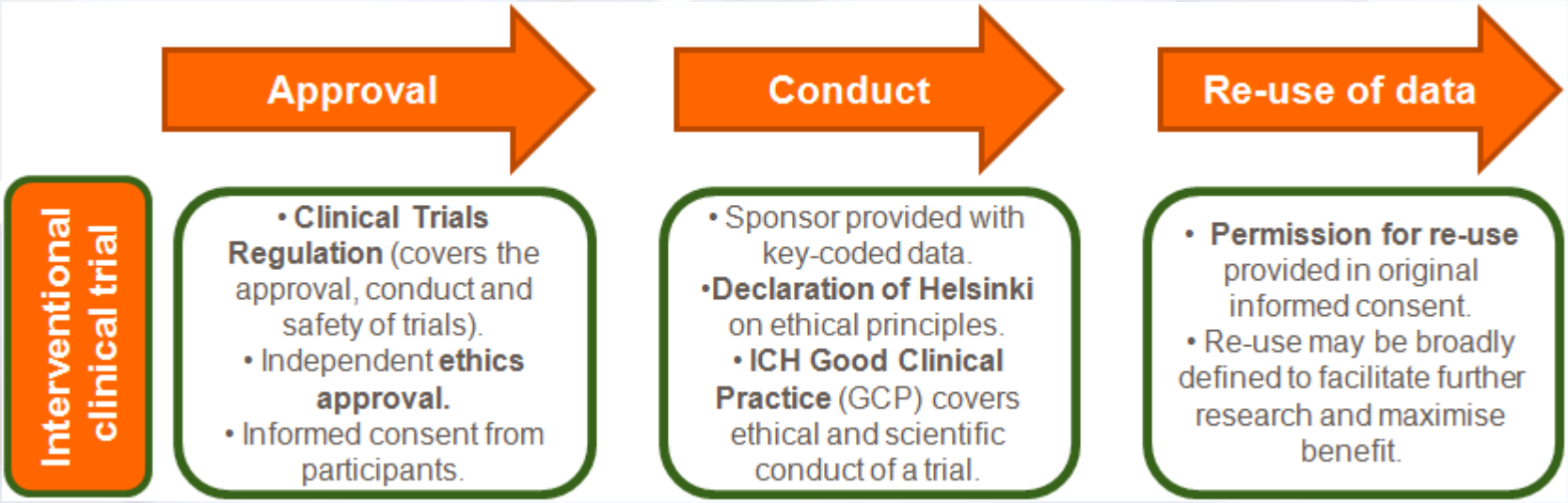
- Medical research delivers **important benefits** by helping to understand the causes of disease, develop new treatments and ensure the effective and safe use of medicines.

- European data protection legislation **covers use of data across all sectors** and for different purposes (i.e. not specific to medical research).

- The legislation must **'recognise' existing safeguards in place** to protect the use of data in medical research and not restrict research in the best interest of society and current and future patients

Interventional clinical trial

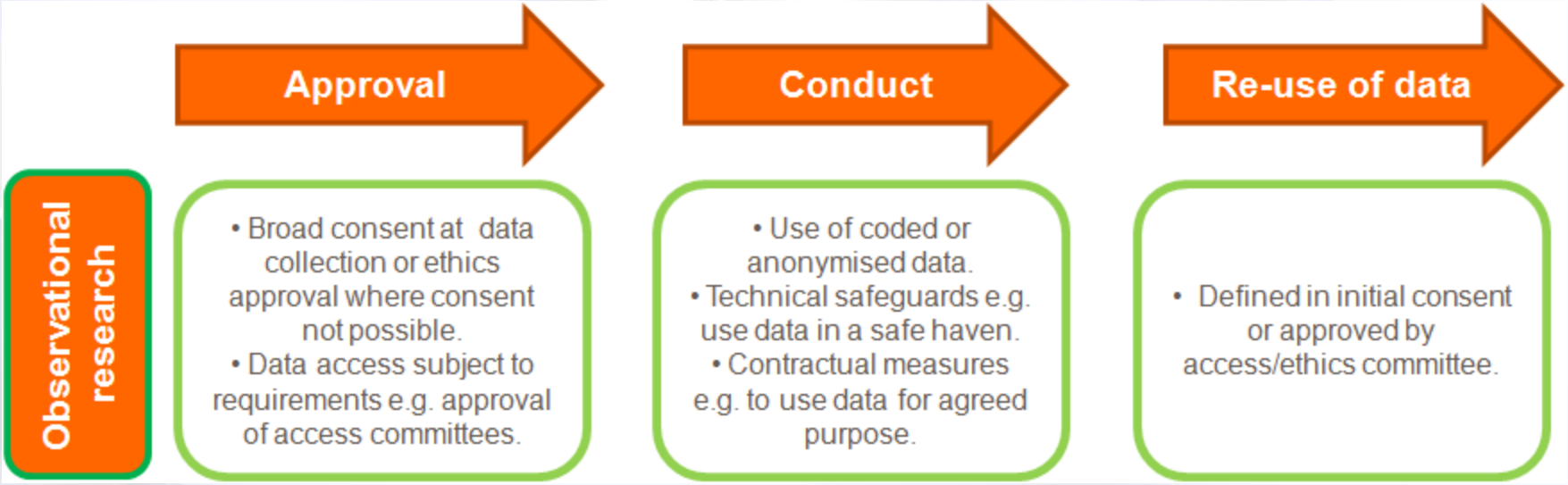
(e.g. testing a new potential treatment)



- "The interests of the subjects should always take priority over other interests" (CTR).
- Medical research must be conducted only by individuals with appropriate ethics and scientific education, training and qualification" (DoH).
- "International ethical and scientific quality standard for designing, conducting, recording and reporting trials…" (ICH-GCP).

Observational research

(e.g. monitoring the benefits and risks of marketed medicines)



- **Example of Clinical Practice Research Datalink (CPRD)**
- Independent Scientific Advisory Committee (ISAC) approval required for all research uses of individual level data.
- Legal agreement details the responsibilities placed on the researcher and their organisation for appropriate use of data.
- Rights of audit.

Protecting patients and delivering benefits.

- **Interventional clinical trial:** Detailed information on that study. Broad consent for re-use of data e.g. for research on the medicine/disease.

- **Observational research:** At the time of data collection e.g. when collecting information on treatment outcomes, it is not possible to describe all potential uses in detail. Broad consent or alternatives to consent (e.g. ethics approval needed).

- Appropriate access to data is crucial for public health, patient welfare and the development of new medicines and treatments.

- DPR must 'recognise' existing safeguards for medical research to support research in the best interests of society and current and future patients.

Personal data and cancer research – a case study

Catherine Guinard
EU Public Affairs Manager
Cancer Research UK

Cancer: research = progress

(or: personal data saves lives)

EPIC - the European Prospective Investigation into Cancer and Nutrition

- Investigates the relationships between diet and other lifestyle factors and cancer risk

- Involves over half a million men and women from ten European countries.

- **Results**

  Better grasp of the pre/post menopausal breast cancer as well as dietary factors affecting colon cancer.

- **Ongoing**

  EPIC centre in Oxford looking at the effect of diet on obesity and how nutritional and lifestyle factors affect the risk of bone fractures

Data Protection Regulation – what would the EP position mean for EPIC?

- The data collected within EPIC is **pseudonymised** when it is used in research.
  - There is no guarantee that the study would meet the tough requirements set for the use of pseudonymous data without consent.

- The study's success also relies on using **identifiable data** to build its dataset by linking its own findings with data from other sources like cancer registries.
  - Participants have given broad, not specific, consent for this linkage: going back to each participant in the study to ask for their specific consent would be incredibly burdensome in terms of time and cost, and this **extra burden could delay the study or even prevent it from happening.**

BBMRI-ERIC
Biobanking and BioMolecular resources Research Infrastructure

?

Thank you!


EUROPEAN DATA IN
HEALTH RESEARCH ALLIANCE
HOME
NEWS & RESOURCES
CASE STUDIES
WHO WE ARE
PERSONAL DATA SAVES LIVES
Researchers use personal data to make life better for all of us. It is vital that the Data Protection Regulation does not limit the use of this data.
> WHO WE ARE

Proposed solutions

Dr Beth Thompson
Policy Adviser, Wellcome Trust

Maintaining consent exemption

- Privileged position of research in the current Data Protection Directive is valued and must be maintained.
- The Commission's proposal and Council's position include important research exemptions, including alternative to consent for research.
- The Parliament's text tightly restricts the exemptions.

➢ **Essential that the final text includes the exemptions in the Commission's and Council's texts** to prevent severe unintended consequences for research.

Ensuring robust, proportionate safeguards

- Important ethical and governance safeguards ensure that data subjects are protected in research.
- Appreciate Parliament's concern that the Commission's proposal does not adequately reflect the importance of such safeguards.
- Welcome the emphasis on appropriate safeguards in the Council's position.

➢ **Further, proportionate safeguards should be included compared to the Commission's text, to ensure personal data are used safely and securely in research, and prevent misuse of research exemptions.**

Balancing harmonisation and flexibility

- The Parliament and Council have both delegated some research provisions to Member States leading to fragmentation.
- Harmonisation appropriate standards would be ideal to promote research collaboration...
- … but is challenging at this time due to national differences.
- Since the exemptions should not be compromised:

➢ **Accept that the final text may need to allow flexibility to allow Member States to implement culturally and socially acceptable rules**.