What will the impact be on patients and research for the next 20 years?

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Individual rights: safeguards and data protection

– “Health of my patient will be my first consideration” (Declaration of Helsinki)

APPROVAL
- Independent scientific approval
- Independent ethics committee review

DATA COLLECTION
- Key-coded data
- Operate to Binding Corporate Rules

RESEARCH CONDUCT
- Declaration of Helsinki
- ICH Good Clinical Practice.

– Safeguards apply to human subject research (‘private’ and ‘public’)
– Narrow or broad consent does not equal good data protection
– Narrow or broad consent does impact research and patients

Protecting trust in research

- Research = the highest ethical and scientific standards.

- Support Parliament amendments to safeguard research-only permission

*EP Recital 126...**The processing of personal data for historical, statistical and scientific research purposes should not result in personal data being processed for other purposes, unless with the consent of the data subject or on the basis of Union or Member State law.***

EP Article 5 1(e): ...personal data may be stored for longer periods insofar as the data will be processed **solely...**for...scientific research...in accordance with the rules and conditions of Articles 83 ***and 83a...and if appropriate technical and organizational measures are put in place to limit access to the data only for these purposes (storage minimisation)***

Interventional research


Clinical trials regulation — Independent ethics committee review


Key-coded data


Declaration of Helsinki — ICH Good Clinical Practice.

- **Clinical trials governed by strict regulation**
- **Informed consent a key responsibility.**

EP81(1a) "*consent may be given for **one or more specific and similar researches**"*

- **Secondary use of data important to maximising patient benefit:**

1. Scientific progress is unpredictable - benefits from re-using data
   e.g. new indications, avoiding duplicating trials
2. Sharing our research - providing greater access to trial data (www.clinicalstudydatarequest.com)

Observational research


Data access committees Independent ethics committee review


Key-coded data


Contractual agreements ICH Good Clinical Practice.

– **Understanding the use of medicines in the real world.**

EP81(1a) *"consent may be given for **one or more specific and similar researches"***

EP81(2) ***"Processing of personal data concerning health...for...scientific research purposes shall be permitted only with the consent** of the data subject...*

EP81(2a) ***"Member States law may provide for exceptions** to the requirement of consent for research...with regard to research that serves a high public interest"*

– **Use of data from electronic records and disease registers**

  - at the time of data collection not possible to describe all future uses.

– **Alternatives to consent needed (e.g. independent ethics approval) where re-consent not possible or practical.**

What will the impact be in 10 years?

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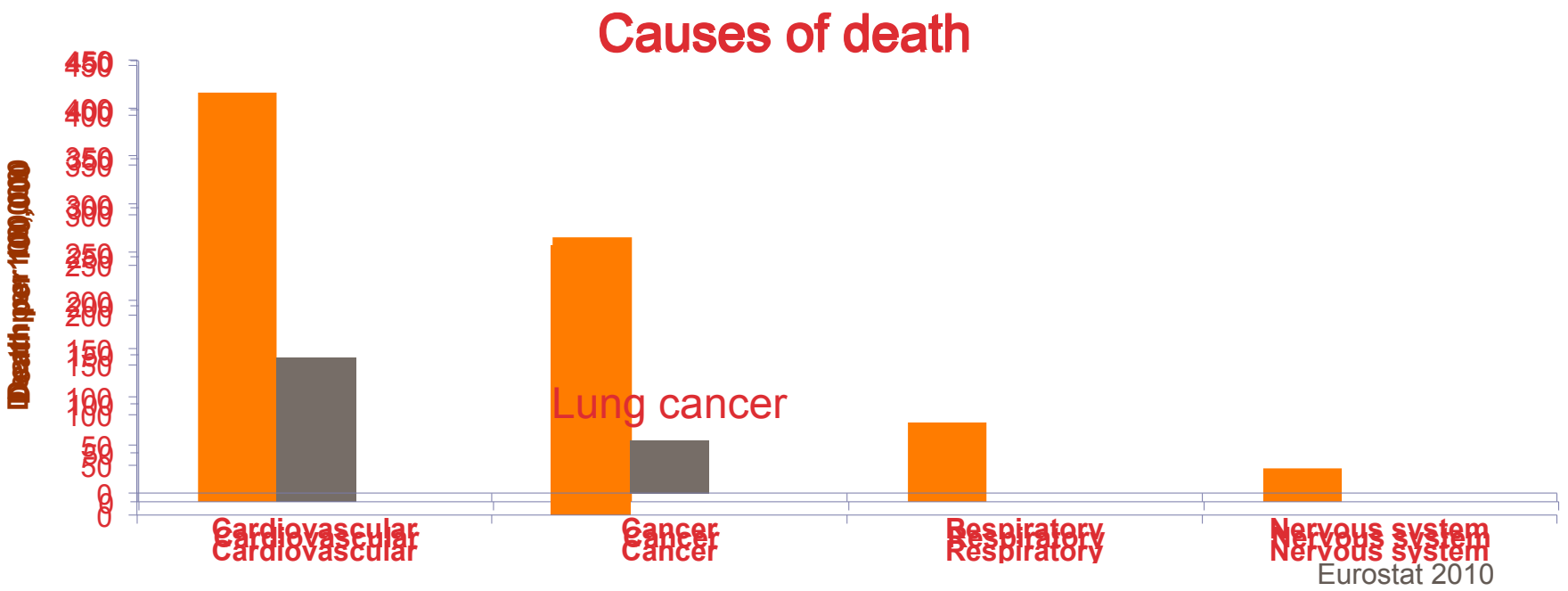
EP81(2a) *"**Member States law may provide for exceptions** to the requirement of consent for research...with regard to research that serves a high public interest"*



The solution

– Research is conducted under strict safeguards.

– Need solutions that work for different types of research.

– The data protection regulation needs to:

1. Allow for **broad consent** for use of personal data (subject to safeguards)

2. Provide clarity...including a **clear legal basis** for research use of data and alternatives to consent (where necessary).

3. **Harmonisation**– facilitate research in the best interests of current and future EU patients by adopting a common framework.

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GSK Binding Corporate Rules

1. We process PII fairly and lawfully
2. We collect and retain the minimum amount of PII necessary to pursue specific and legitimate business purposes
3. We explain to individuals how their PII will be used and their rights regarding their PII
4. We do not use PII in a way that is incompatible with what has been explained to individuals
5. We use appropriate security safeguards
6. We carefully control disclosure of PII to third parties
7. We have a Global Privacy Office and train our staff to ensure that we comply with the BCRs
8. We operate a complaints procedure and respect individuals' right to remedy
9. We audit our compliance and keep our BCRs under review
10. We cooperate with Data Protection Authorities