« Data Protection Regulation:
Keeping Health Research Alive in the EU »
European Parliament Brussels, September 17th, 2013

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Ethical and Societal Perspective

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Conflict of interest : none

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We all benefit, and will benefit, from medical research ;

Health should be one of the main priorities in all countries.

This is obviously one of the main societal projects to encourage.

Health research is critical to secure the wellbeing of EU citizens ;
this has led these last 30 years :

- **to improve life expectancy,**
- **to increase survival after severe diseases (e.g. cancer*)**
- **to develop new pharmacological treatments (e.g. orphan drugs**)**
- …

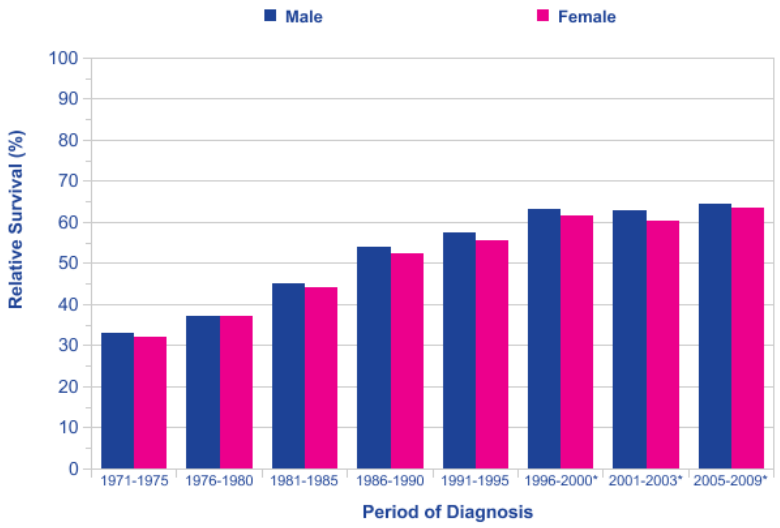
* Increased survival after severe diseases : Treatment of leukaemia :

Increase in survival rate between 1973 and 2007 : 32 → 64 %
It was possible thanks to medical research, new drug development, patient inrolment in Clinical Trials and their <u>medical data analysis.</u>

Leukaemia (C91-C95): 1971-2009

Age-Standardised One Year Relative Survival Rates, England and Wales 1971-1995, England 1996-2009

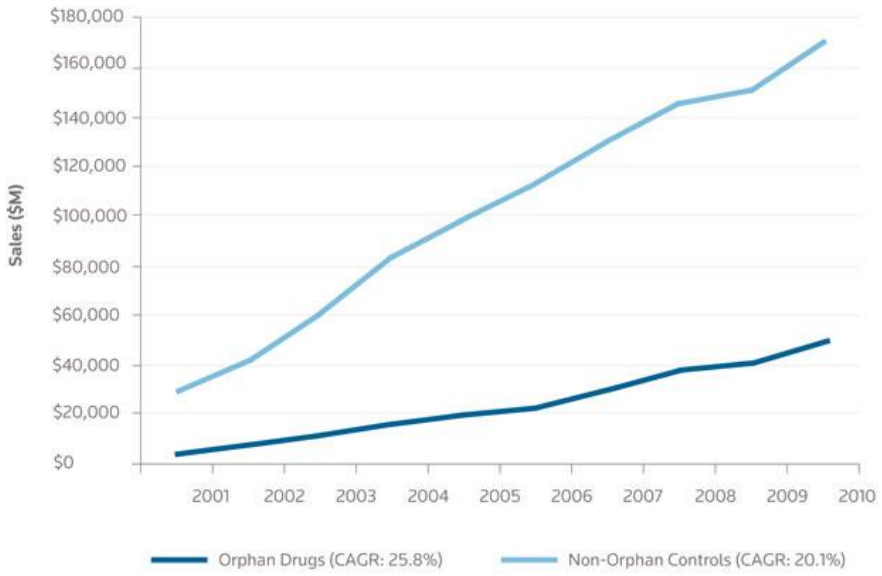
		Relative Survival (%)	
Country	Period of Diagnosis	Male	Female
England and Wales	1971-1975	33	32
	1976-1980	37	37
	1981-1985	45	44
	1986-1990	53,8	52,5
	1991-1995	57,4	55,5
England	1996-2000	63,2	61,6
	2001-2003	62,9	60,2
	2005-2009	64,5	63,5



Ref. cancerresarchuk.org

** Orphan Drugs in EU (EMA- London)

Increase in the number (and costs) of Orphan drugs



Source: Thomson Reuters Cortellis

7.000 rare diseases

(prevalence < 5/10.000)

5% of the population

30 million patients in EU

EU Regulation 141/2000-EMA

most are genetic diseases

→patients data analysis

…. these medical progresses were possible because patients' personal data were analysed (data collected and kept confidential).

In some cases, it is important and ethical to use personal data without specific explicit patient consent.

It is very important to have a legal framework in EU (such as Article 83) for health research, including personal data analysis with respect to the rights of individuals to privacy.

This is already guaranteed by EU Clinical Trial Directive (2004), by Laws and Ethics Committees mandatory advices in EU.

Ethics Committes have to analyse all research protocols.

(physicians, pharmacist(s), nurses, jurist(s), patients representative, …)

Values in Medical Ethics :

respect for autonomy, beneficience, non-maleficience, justice, respect for persons, patient protection, information, consent, …

Ethics Committees and patient protection.

Framework

Health research is already conducted within a robust framework in EU (Helsinki convention, Good Clinical Practice, Human rights, EU Directive on clinical trials, laws on patients rights, laws on private life protection,…).

Medical data are only accessible to authorized professionals with tracability and under medical confidentiality (data protection and tracability in the Hospitals).

Ethics committees have national interactions, organisation and agreement. Many have international agreement.

Role of Ethics Committees :

Evaluation of all the medical research protocols involving human beings;

The Ethics Committee has to evaluate :
the scientific justification and adequate preclinical experiments,
the objective of the research, the alternative methods that could be used
the anticipated benefit for the subject or other persons
the risks and inconviences,
the respect of physical and mental integrity of the subjects,
the right to withdraw from the study,
the investigator competence,
the patient's information and consent forms,
the right to respect for private life and the protection of personal data, correct data collection, access and treatment (codes, anonymisation…).
…

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Some comments from Ethics committees :

Evolution towards « Personalized medicine and treatment»

- → ***More targeted drugs (more efficacy, less side effects, lower costs)***
- → ***Based on (Bio-)Markers, indicators of patient subgroups, patient characteristics or sensitivity, which come from the personal data collected.***

Some comments from Ethics committees :

Investigators often use often registries or patient's lists to let them informed of research protocols or trials and improve recruitment.

It is important for health research to use personal data without specific explicit patient consent (e.g. to identify patients with rare disease, patients subgroups, patients with specific biomarkers…)

Some comments from Ethics committees :

Many data collected for medical research are pseudonymised -Key coded- data (with safeguards to protect individual rights to privacy), other are anonymized data.

The processing of pseudonymised data is crucial for research, it must be regulated in proportion to the risks of reidentification.

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FEAM is favourable to the new European Data Protection Regulation (DPR) but not to the conclusions of the LIBE committee rapporteur, which will compromise EU research in Health and Medicine sectors.

Many safegards already exist to guarantee

- a safe and secure use of patients data for medical research

- the rights and interests of individuals.

Patients data provide a vital resource for health research.

These data may be used with respect

- of the main values in medical ethics and

- of societal interest.

/JMM