

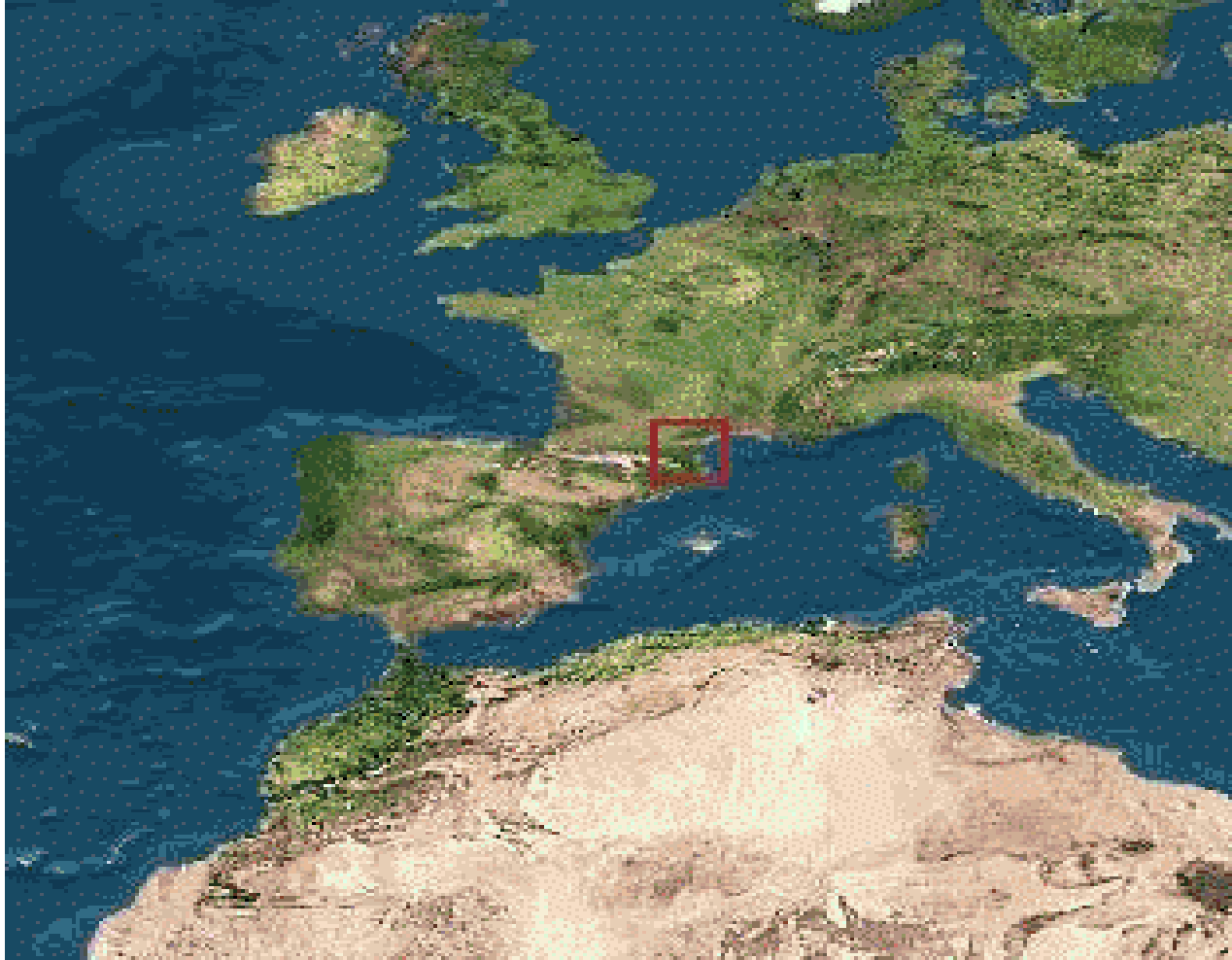
# **eHRs and the European Union – current legislation and future directions.**

Dr Richard Fitton

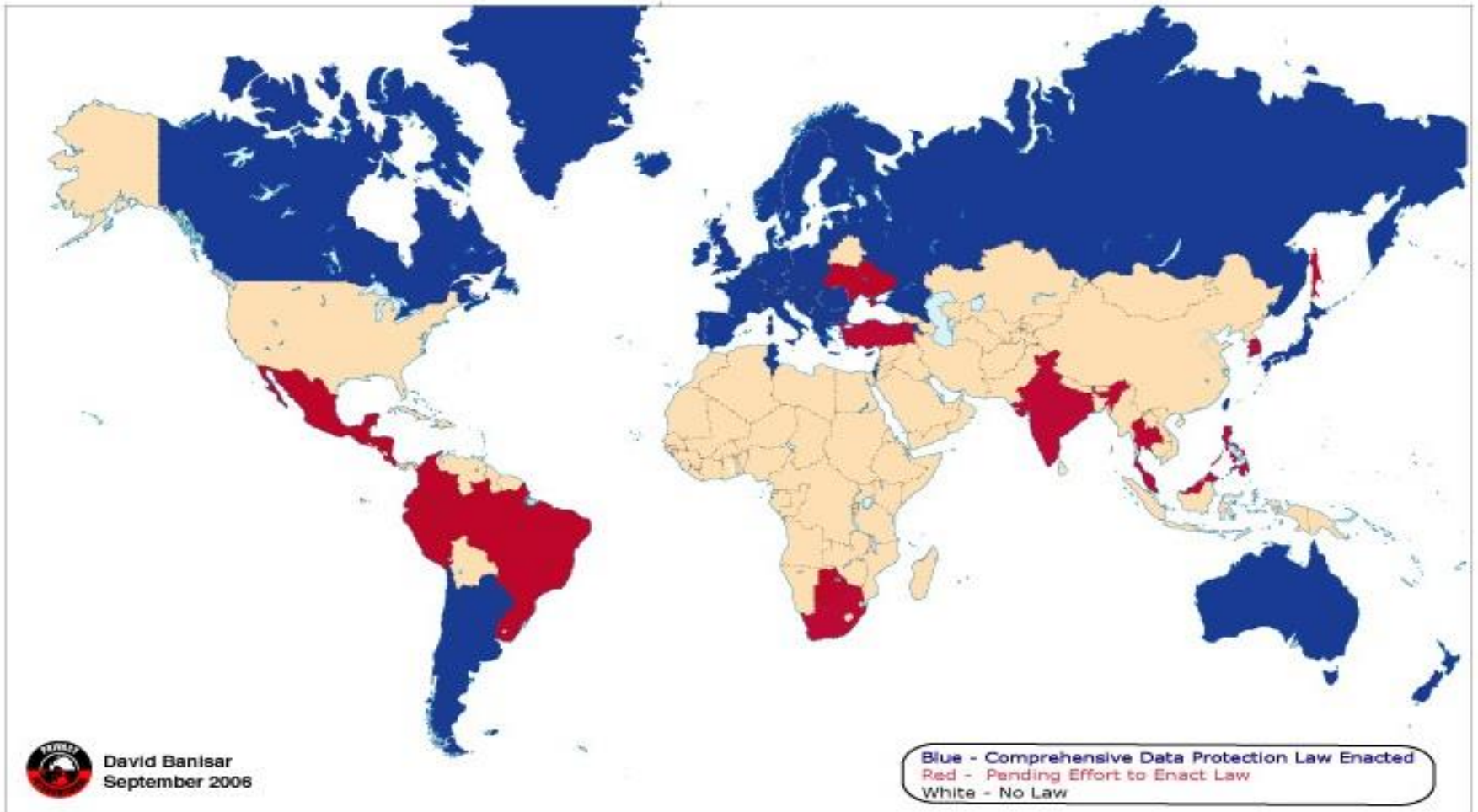
# Points to address

- The past, present and future data protection data legislation in the UK and Europe
- The European Declaration on Human Rights.
- The increasing role of the data subject.

# E-intelligence overcomes national boundaries



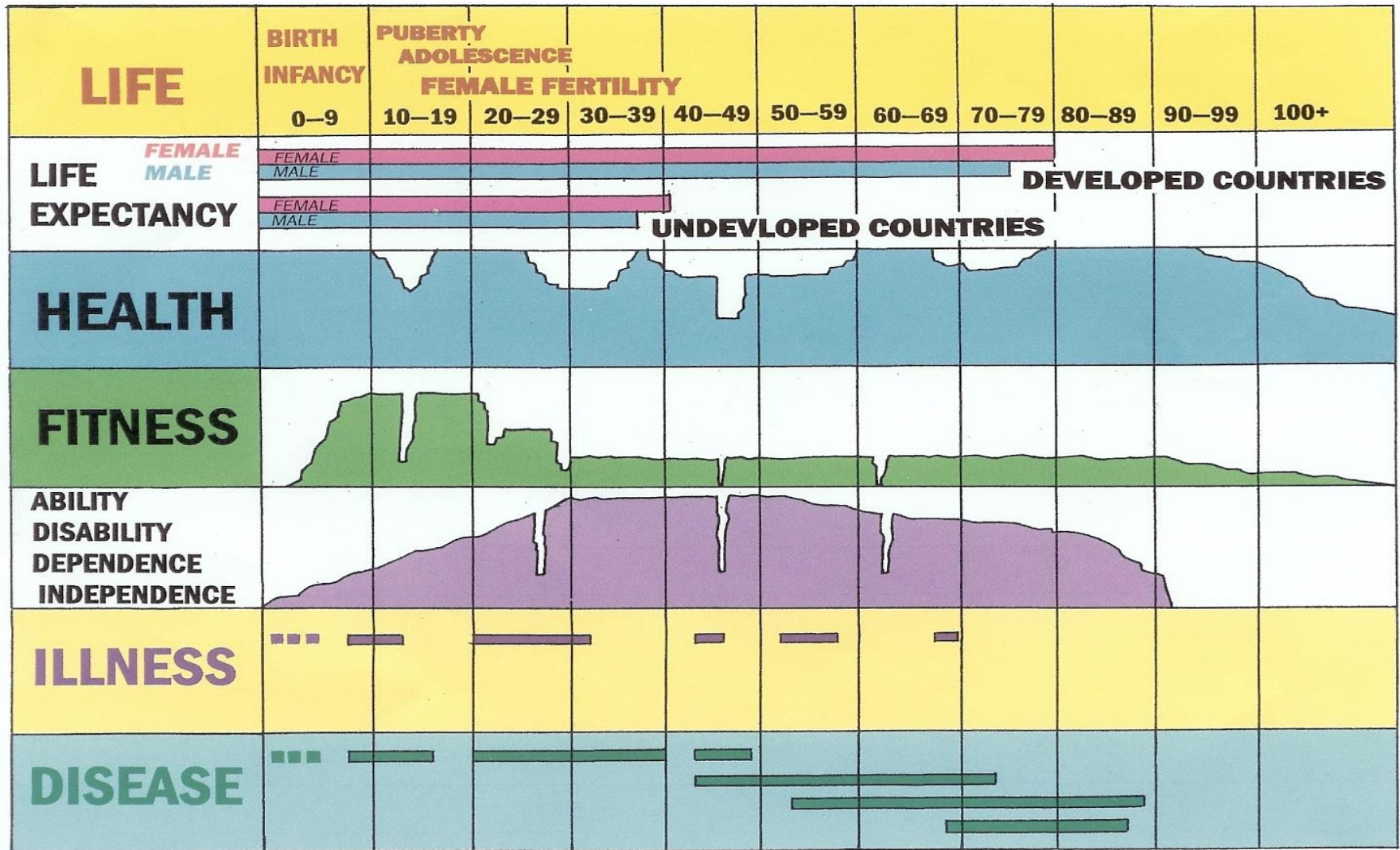
# Data protection enactment around the world



Current

The European Data Protection Directive 95/46/

# Life, health, independence, disease



# Member States of the European Union



(27 countries – 28 [Croatia] in July 2013)

# PRISME Forum SIG 22/05/2012

EUROPEAN COMMISSION

Brussels, XXX

COM(2012) 11/4 draft

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL**

**on the protection of individuals with regard to the  
processing of personal data and on**

**the free movement of such data (General Data  
Protection Regulation)**

(Text with EEA relevance)

{SEC(2012) 72}

{SEC(2012) 73}

# UNIVERSAL DECLARATION OF HUMAN RIGHTS

- **Article 3.**

- Everyone has the right to life, liberty and security of person.

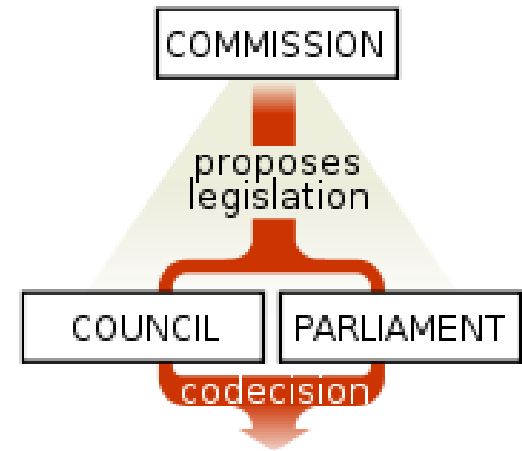
- **Article 12.**

- No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation.



# European Commission

- The **European Commission** is the executive body of the European Union. The body is responsible for proposing legislation, implementing decisions, upholding the Union's Treaty and the general day-to-day running of the Union.



# 3. LEGAL ELEMENTS OF THE PROPOSAL

## 3.1. Legal Basis

This proposal is based on Article 16 TFEU<sup>1</sup>, which is the new legal basis for the adoption of data protection rules introduced by the Lisbon Treaty.

<sup>1</sup> Treaty on the Functioning of the European Union

# European Commission

## legislative terms

**Regulation** – has a general scope, is obligatory in all its elements and is directly applicable to all member states of the European Union and constitutes the most powerful form of EU law.

**Directives** – are only applicable in the member states when the objectives they contained have been transposed into national law.

# EUROPEAN COMMISSION

“a proposal for a **Regulation** of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data”  
(27 countries – 28 in July 2012)

# EUROPEAN COMMISSION

“a proposal for a **Directive** ....with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences ...and the free movement of such data.”

# Data Sharing Review Report

# Data Sharing Review

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Richard Thomas and Mark Walport

Richard Thomas, UK Information Commissioner, 2002-2009

Sir Mark Walport, Director and Chief Executive of the Wellcome Trust

<http://amberhawk.typepad.com/files/thomas-walport-datasharingreview2008.pdf>

# Data Sharing Review Richard Thomas Mark Walport

- 4.11 In summary, the poor level of public trust and confidence in the sharing of personal information provides a critical backdrop to this review .... and highlights the need for substantial improvements in the ways that organisations handle personal information.

# Data Sharing Review

Richard Thomas Mark Walport

- *‘The treatment of individual patients relies on data collected from others.*
- *“... use evidence from other people’s data to treat me, but don’t use my data to help them”.’*



# Current Information Strongholds

Patients

Clinicians

ICT

PCOs  
NICEs  
NSFs  
Trust'

Evidence  
Based Medicine  
Science  
Research  
Development

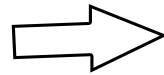
ICT  
Translation  
Home Access  
Visual/Auditory  
Learning Handicap  
Access

# Engaging with data/research subjects

- “Interdependence is a higher value than independence”
- Be proactive
- Begin with the end in mind
- Put first things first
- Think win/win
- Seek first to understand, then to be understood
- Synergise
- Balanced self renewal

# Patients and information are the most under-utilised resources in health service provision

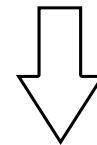
Patient Access  
to Record



Patient  
Contribution to  
Record



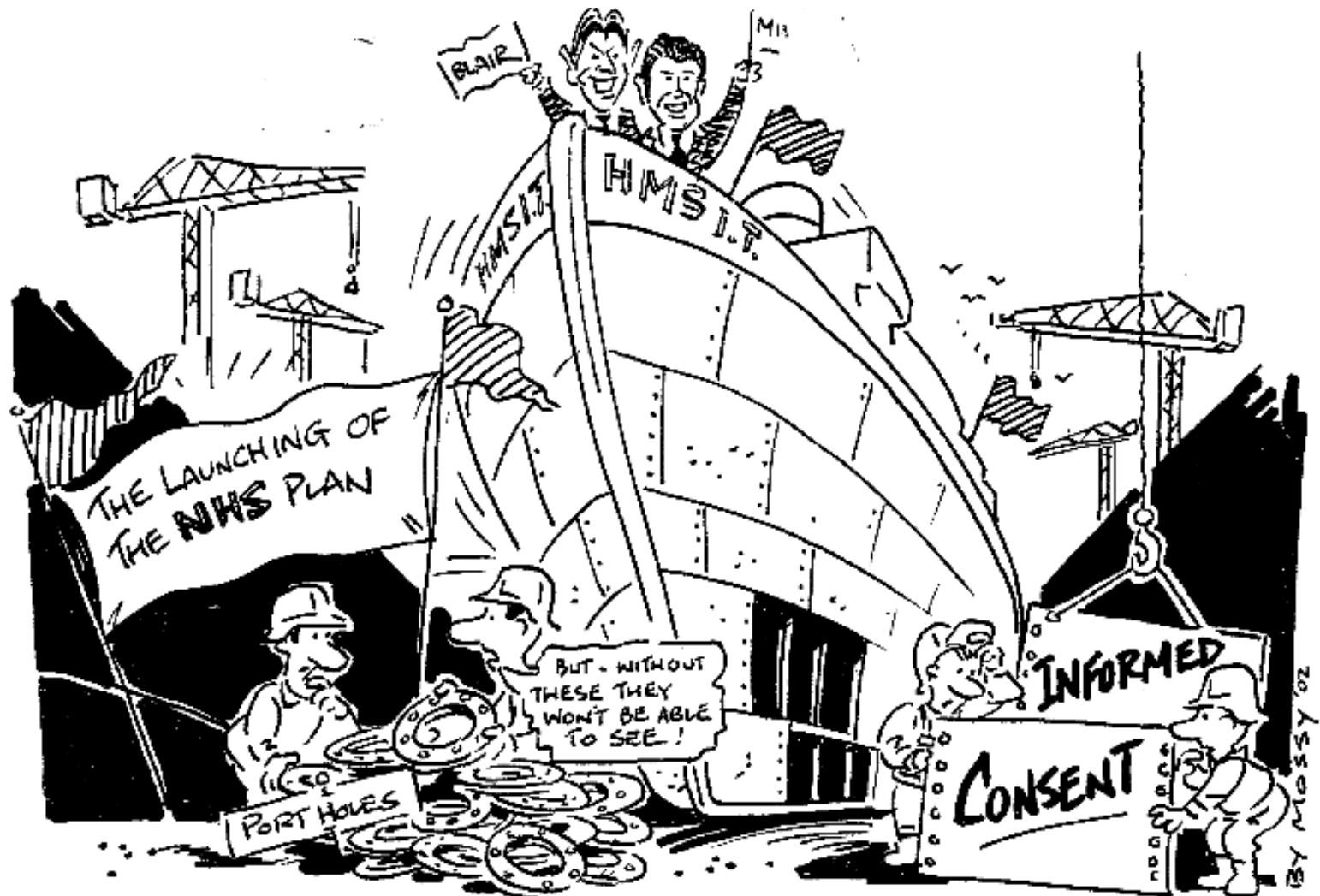
Patient  
Autonomy



Patient  
Partnership



# Lessons learned:



# DPA<sup>1</sup> Principles for the data subject

1. Personal data shall be processed fairly and lawfully
2. Personal data shall be obtained only for one or more specified and lawful purposes
3. Personal data shall be adequate, relevant and not excessive
4. Personal data shall be accurate and, where necessary, kept up to date.

<sup>1</sup>The UK Data Protection Act 1998

# DPA Principles

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary
6. Personal data shall be processed in accordance with the rights of data subjects
7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing and ... loss or destruction or damage
8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless ...

# European Draft proposals reflect these

**Article 5** sets out the principles relating to personal data processing...in particular:

- the transparency principle,
- the clarification of the data minimisation principle and
- responsibility and liability of the controller.

# European Draft proposal

**Article 11** introduces the obligation on controllers to provide transparent and easily accessible and understandable information,



# European Draft proposal

**Article 12** obliges the controller to provide procedures and mechanism for exercising the data subject's rights

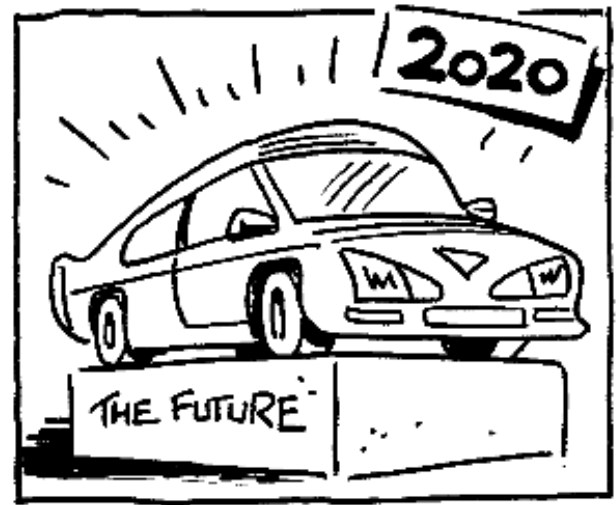
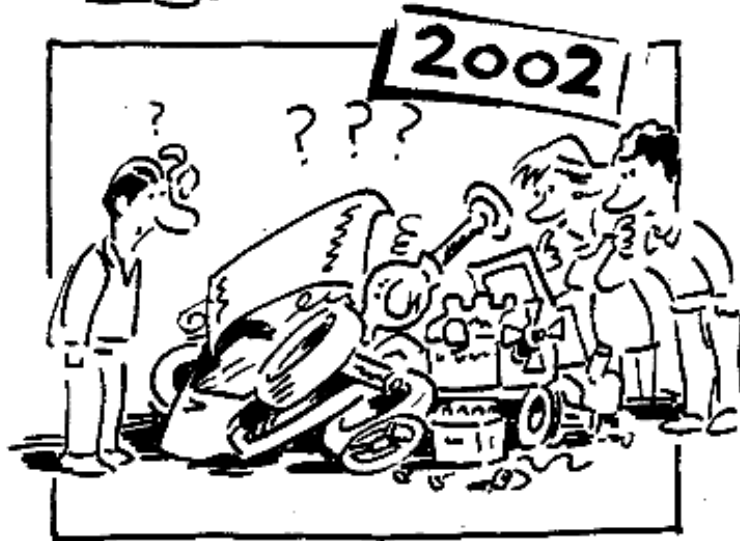
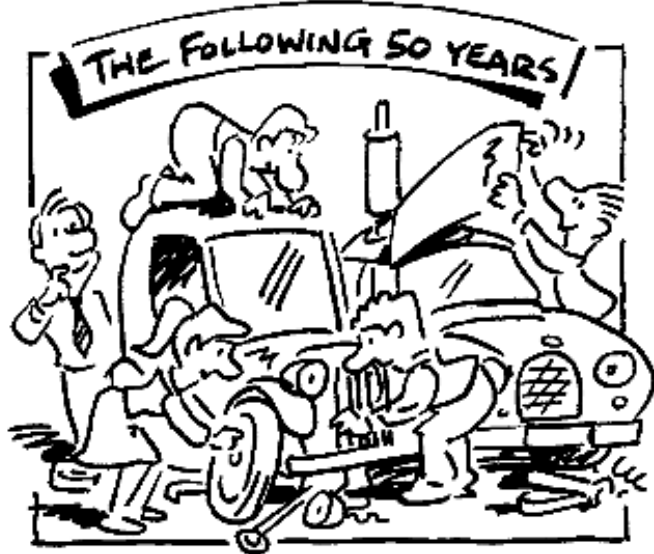
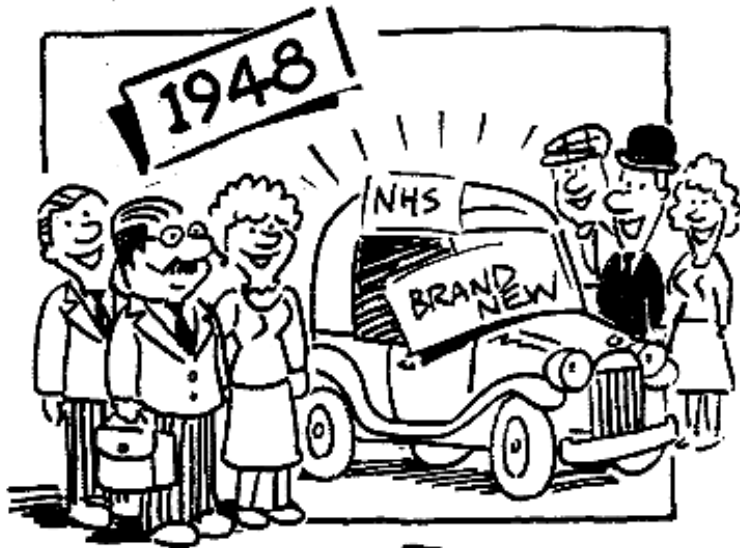
**Article 14** further specifies the controller's information obligations towards the data subject,

**Article 15** provides the data subject's right of access to their personal data,

# European Draft proposal

- **Article 17** provides the data subject's right to be forgotten and to erasure. ....
- **Article 18** introduces the data subject's right to data portability, i.e. to transfer data from one electronic processing system to and into another

# Lessons learned:



BY MOSSY

# Conclusion

The UK Biobank

(<http://www.ukbiobank.ac.uk/>)

provides a classic exemplar of how patient data should be collected and managed.