Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications

Legal perspectives in EU projects

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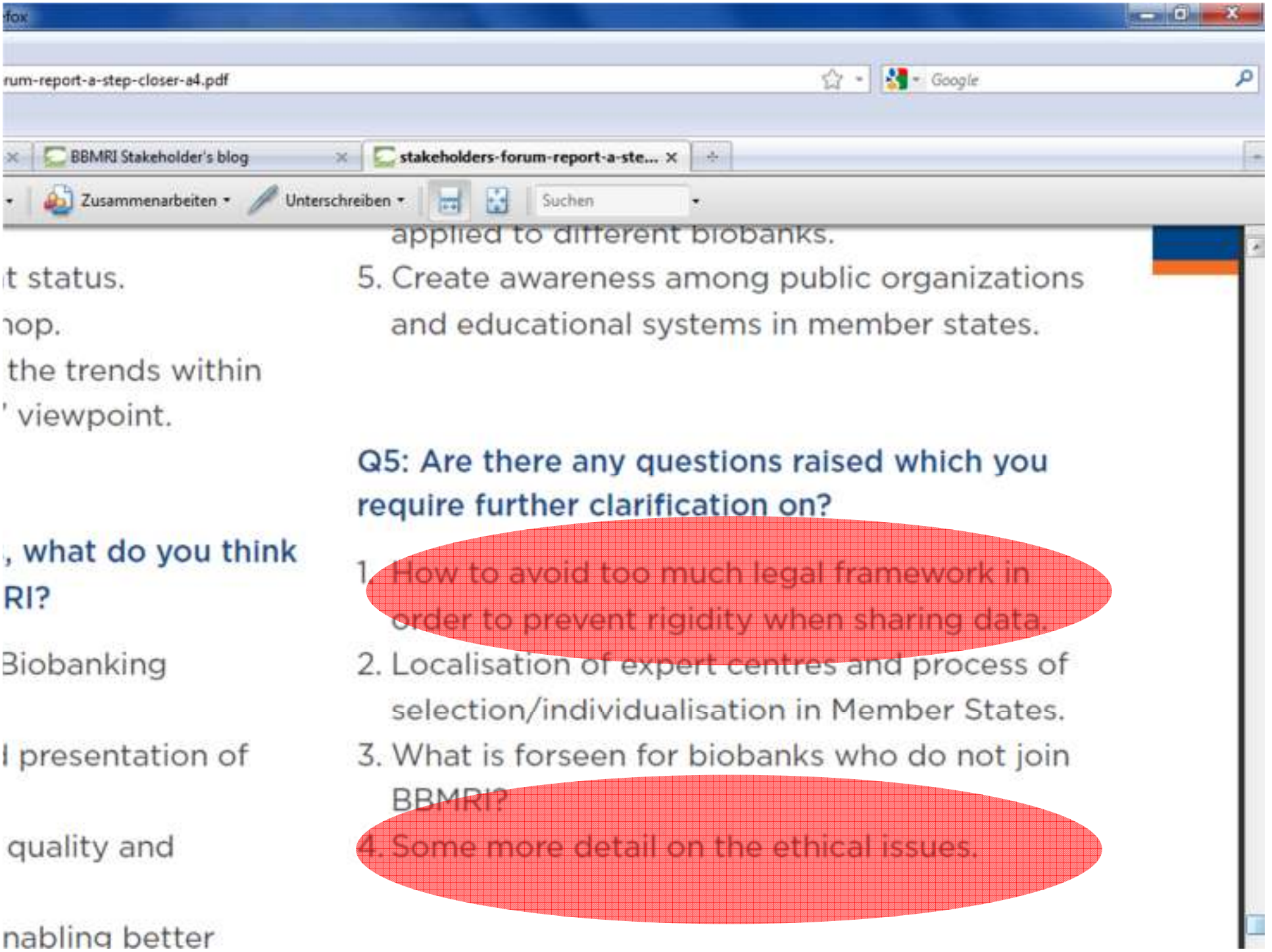
www.ponte-project.eu

- Why a lawyer?

A Confession

of Existing Drugs to other Indications


rum-report-a-step-closer-a4.pdf
Google
BBMRI Stakeholder's blog
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Zusammenarbeiten
Unterschreiben
Suchen
applied to different biobanks.
5. Create awareness among public organizations and educational systems in member states.
t status.
hop.
the trends within
' viewpoint.
Q5: Are there any questions raised which you require further clarification on?
, what do you think
RI?
1. How to avoid too much legal framework in order to prevent rigidity when sharing data.
Biobanking
2. Localisation of expert centres and process of selection/individualisation in Member States.
l presentation of
3. What is forseen for biobanks who do not join BBMRI?
quality and
4. Some more detail on the ethical issues.
nabling better

Background

- ACGT (Advancing Clinico Genomic Trials in Cancer)
  - EU-Research Project (Integrated Project – 6th Framework Programme)
  - Participants: 25 leading European institutions in the field of cancer research and IT (e.g. University of Oxford, FraunhoferG, Philips, etc.)
  - Aims
    - Development of new and better treatments for cancer by creating an innovative trans-European GRID-infrastructure
    - Europe-wide network of cancer research databases
  - www.eu-acgt.org

Use of EHR data in PONTE

- During life-time of project, data deriving from EHRs used by partners within PONTE in order to design and validate the platform (“Validation Phase”)
- Here data fully anonymous:
  - All personal identifiers removed
  - No link / key retained to original
  - ‘Simulation’ – extra safeguard involving changes to some of the original data values

Golden Rule

Processing of personal data is only allowed if:

- it is permitted by law or
- the data subject has consented to it

Personal data?

Data protection regarding human research

Art. 2 Dir. 95/46/EC

'Personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); **an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number** or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity

Data protection regarding human genetic research

Recital 26 Dir. 95/46/EC

Whereas the **principles of protection** must **apply** to any information concerning an identified or identifiable person; whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used **either by the controller or by any other person** to identify the said person; whereas the principles of protection shall **not apply** to data **rendered anonymous** in such a way that the data subject is no longer identifiable; …

Pseudonymous = de-facto anonymous?

- Anonymous, if the effort for identification is disproportionate with respect to the effort of time, money and manpower
- De facto anonymous data = anonymous data

→ Relevant factor: effort for identification

Golden Rule

Processing of personal data is only allowed if:

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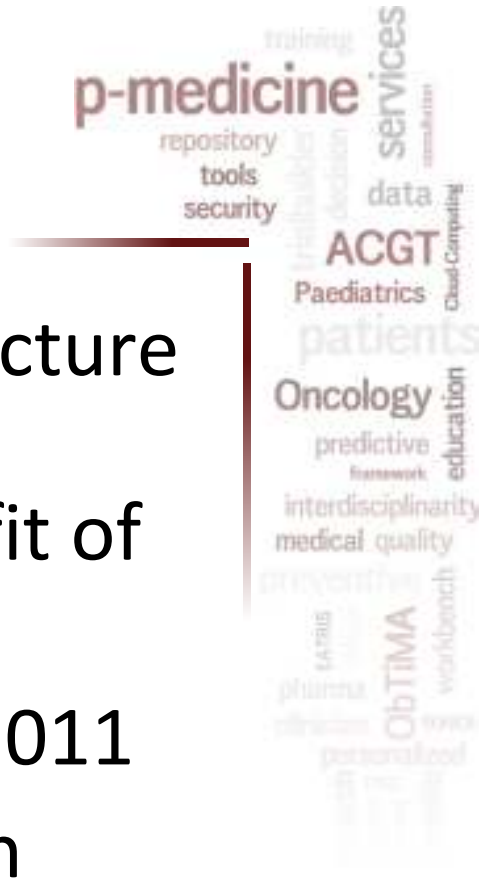
p-medicine

From data sharing and integration via VPH models to personalized medicine

Description



- **Aim**: Develop new tools, IT infrastructure and VPH models to accelerate personalized medicine for the benefit of the patient
- **Duration**: 4-year, start in February 2011
- **Funding**: European Community's 7th Framework Programme (co-funded)
- **Consortium**: 19 partners from 9 European countries and Japan

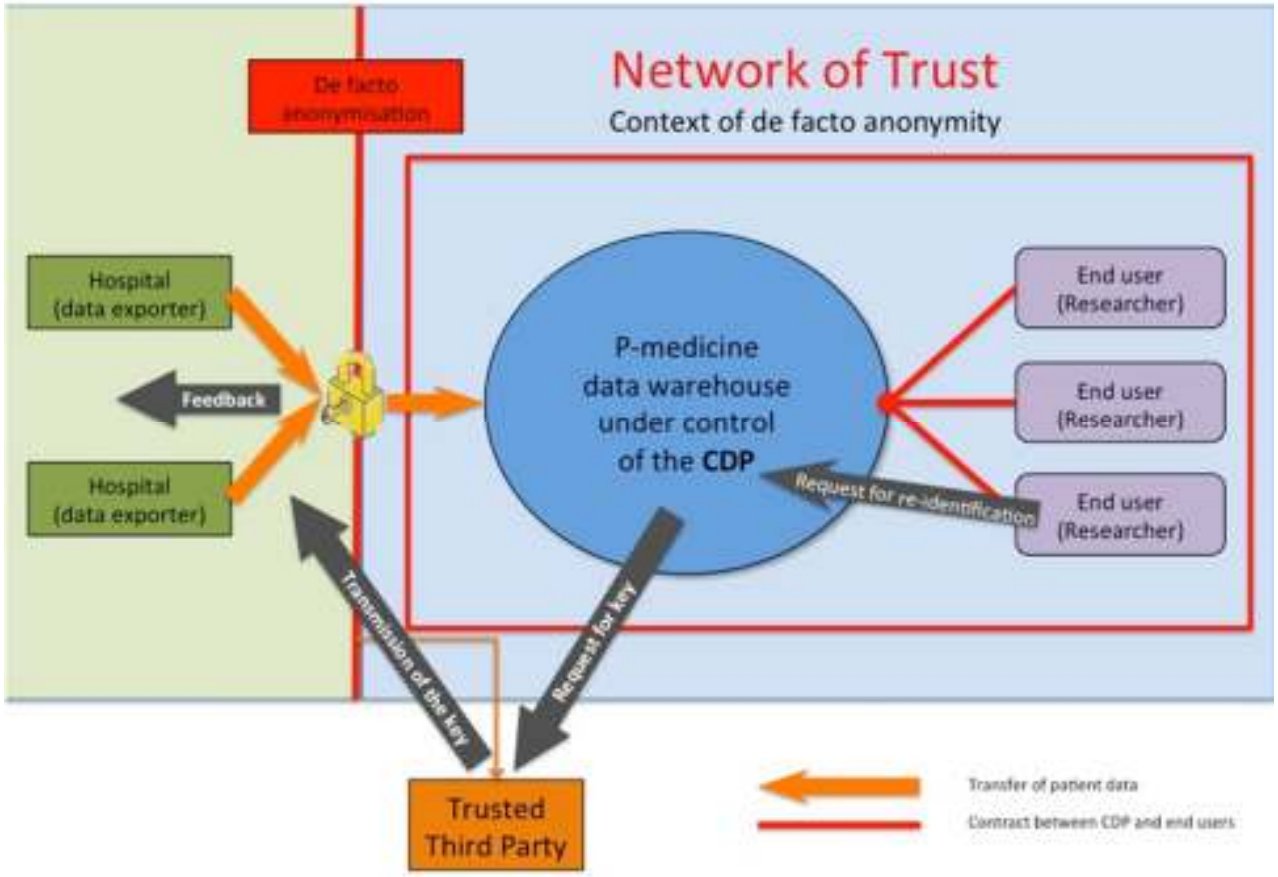
Our role in p-medicine

- WP5-Leader: Legal, ethical and security framework
  - New challenges
    - Patient Identity Management System
    - Access to biobanks
    - Patient empowernment
    - Data warehouse
    - Use of the tools in international Good Clinical Practice trials
- Legal helpdesk for the whole project

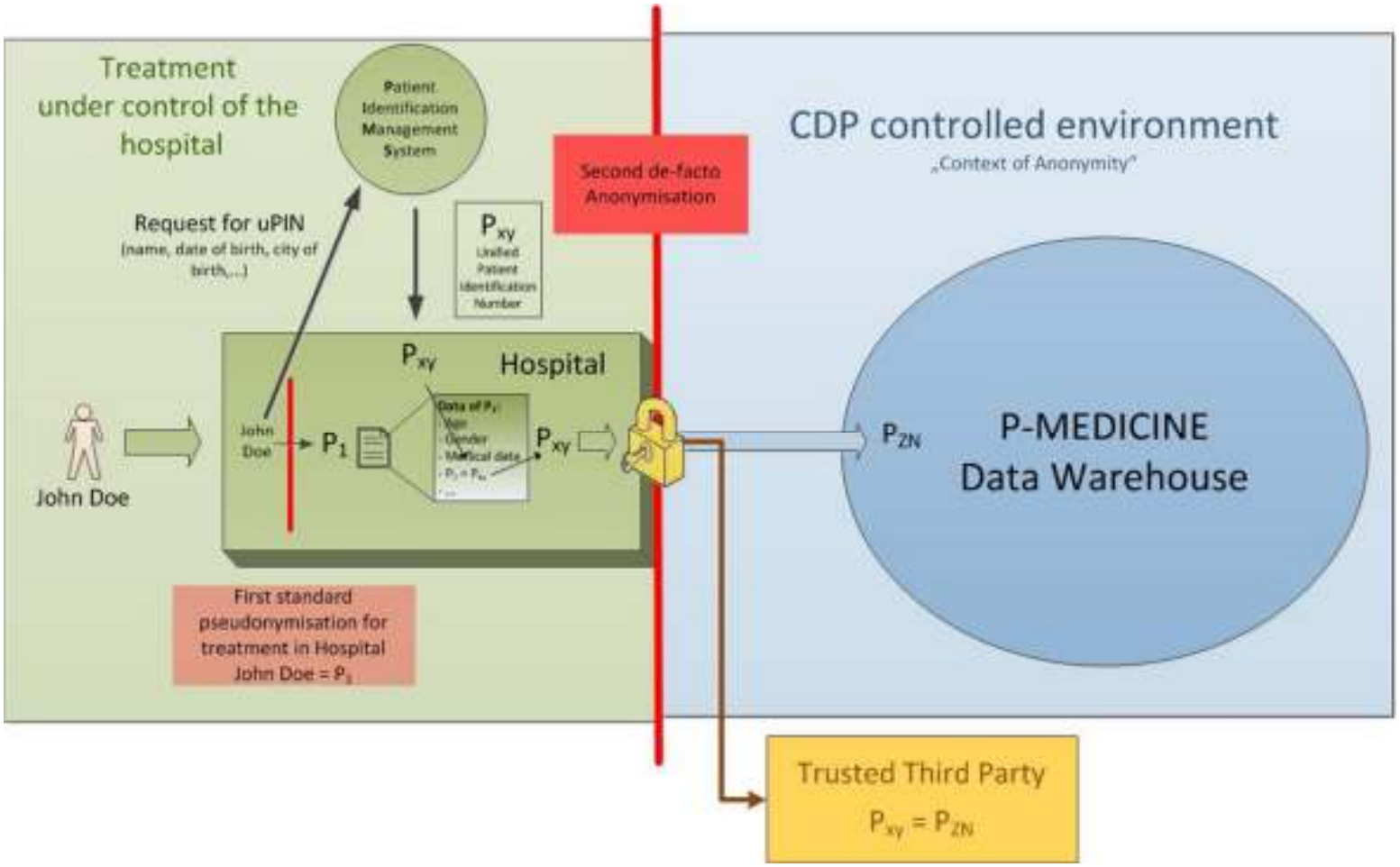
WP5 Description

- Setting up of the **data protection and data security framework** (D 5.1) (due M12)
- Report on legal and ethical issues **regarding data warehouse, data mining, IP issues** (D 5.2) (due M18)
- Report on legal and ethical issues **regarding access to biobanks** (D 5.3) (due M24)
- Report on legal and ethical issues regarding **patient empowerment** (D 5.4) (due M48)
- Report on legal and ethical issues for p-medicine **tools used for internat. GCP trials** (D 5.5) (due M18)

Data Protection Framework



Patient Identity Management System



CONTRACT

CONSENT IN A TRIAL & CARE ENVIRONMENT

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CONSENT IN A TRIAL & CARE ENVIRONMENT

CONTRACT

CONSENT IN A TRIAL & CARE ENVIRONMENT

- **Project full title:** Consent in Trial and Care Environment
- **Duration**: 2 years, X 2010 - IX 2012
- **Funding:** 499 235 Euro from European Community's 7th Framework Programme, as a support action
- **Consortium**: 5 partners

CONTRACT
CONSENT IN A TRIAL & CARE ENVIRONMENT

Overall objectives

- **CONTRACT** seeks to understand the way the European Data Protection Directive and the Clinical Trials Directive have had and continue to have an impact on the success of translational research. The project will focus on informed consent as a fundamental precondition for the legal processing of personal data and for carrying out a legally admissible trial.

CONTRACT
CONSENT IN A TRIAL & CARE ENVIRONMENT

Informed consent

- Informed consent is a necessity for translational research
  - as a legal requirement
  - only active participation of patients is the mean of success
  - as an ethical requirement
- Obtaining INFORMED consent raises difficulties because of the complexity of the matters
- (At least) three different forms of informed consent are relevant for translational research:
  - Consent to treatment
  - Consent to research
  - Consent for processing the personal data
- The former are not consistent with each other, in addition there is no common understanding of informed consent in the scholar world

Informed consent – role of European Union

- European Union legislation has direct influence on the informed consent
- Two of the three mentioned consents are legislated via European Directives

Consent to treatment	Consent for research	Consent for processing the data
• Defined under national legislation • No common understanding	• Defined in Clinical Trials Directive 2001/20/EC • Art. 2 (j)	• Defined in Data Protection Directive 95/46/EC • Art. 2 (h)

Approach

Creating the widest possible picture of Informed Consent

- Holistic [connecting legal, IT and clinical expertise]
- Stakeholders-oriented [directed into both receiving input and creating output for the partner projects]
- Combining partner projects' input with the legislation analysis

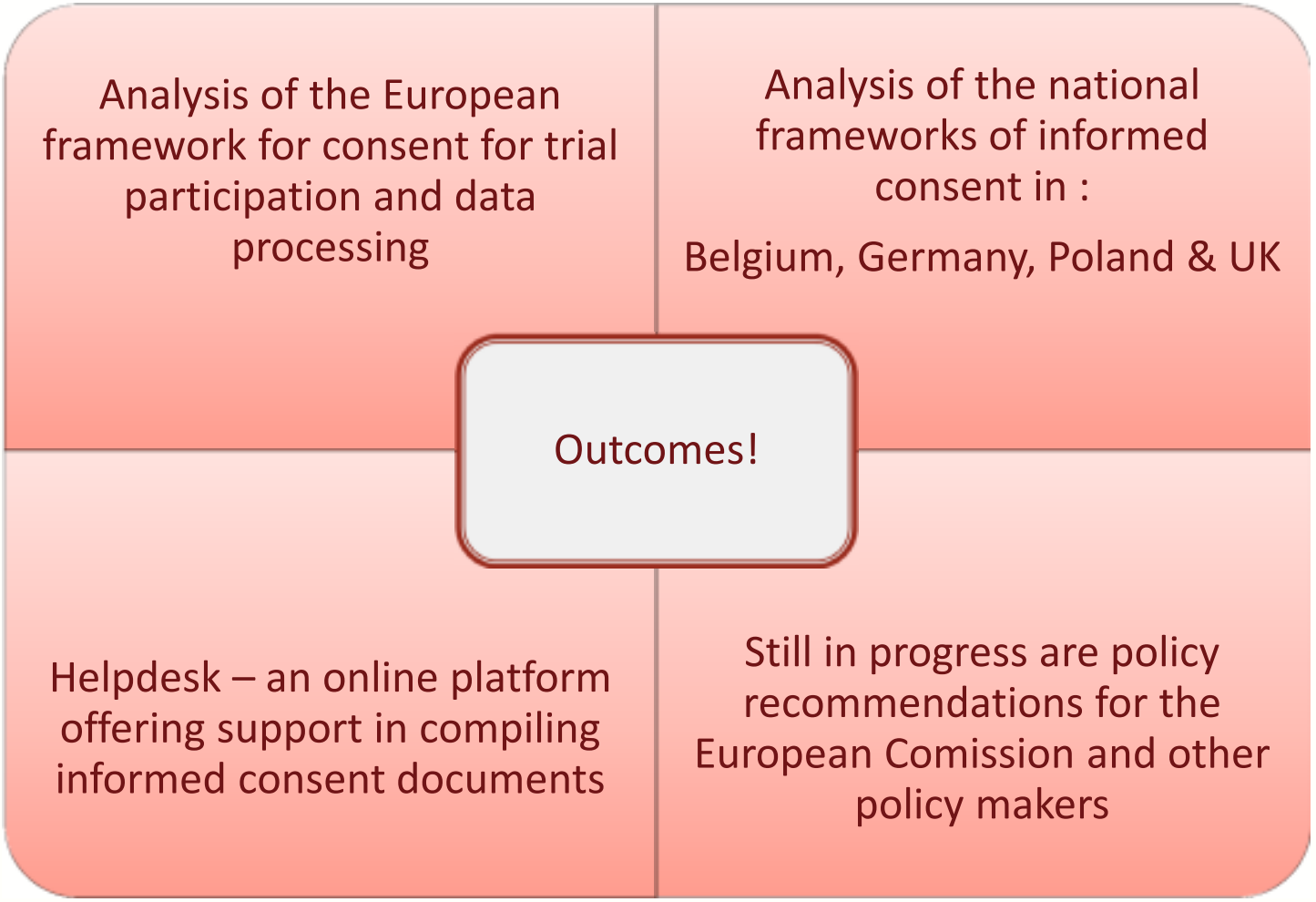
CONSENT IN A TRIAL & CARE ENVIRONMENT

Our role in CONTRACT

- Project coordination
  - Responsible for the project as a whole and overall managment
- Coordination of WP3 – Status in Europe – Good practices cases

  Analysing where the differences in handling informed consent derive from.
  - Legal settings
  - Ethical background
  - IT-infrastructure
  - Organisation

Main outcomes so far



www.linked2safety-project.eu

- **Project full title:** A Next-Generation, Secure Linked Data Medical Information Space For Semantically-Interconnecting Electronic Health Records and Clinical Trials Systems Advancing Patients Safety In Clinical Research
- **Duration**: 3 years, X 2011 - IX 2014
- **Funding:** 4, 57 Mio Euro from European Community's 7th Framework Programme
- **Consortium**: 9 partners

What is the whole project about?

L2S is developing next-generation IT infrastructure that will provide the pharmaceutical companies and healthcare professionals the efficient access at pan-European level to and the effective utilization of the increasing wealth of medical information contained in the EHRs and thus accelerate medical research, improve the quality of healthcare and enhance patient's safety.

Our role in Linked2Safety

- To review and analyze legislation with regard to patient's personal data ownership, protection, security, privacy and anonymity,

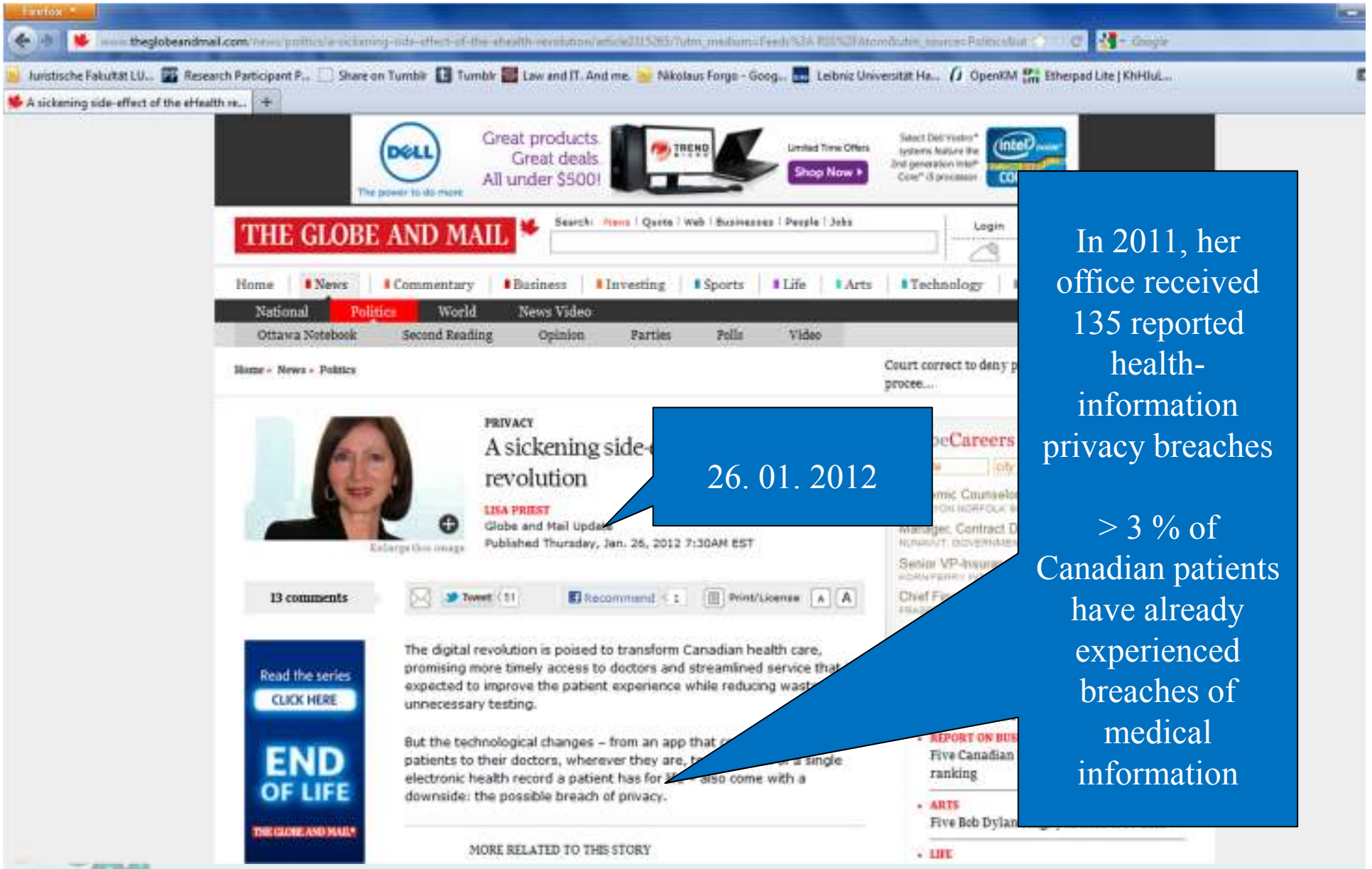
- Define legal, ethical and security requirements and guidelines concerning the design and development of software components,

- Reassure compliance with EU legislation.

What are the main challenges/issues ?

Develop the infrastructure that is effective, but is secure in respecting patients anonymity and privacy.

- Why a lawyer?



Ponte

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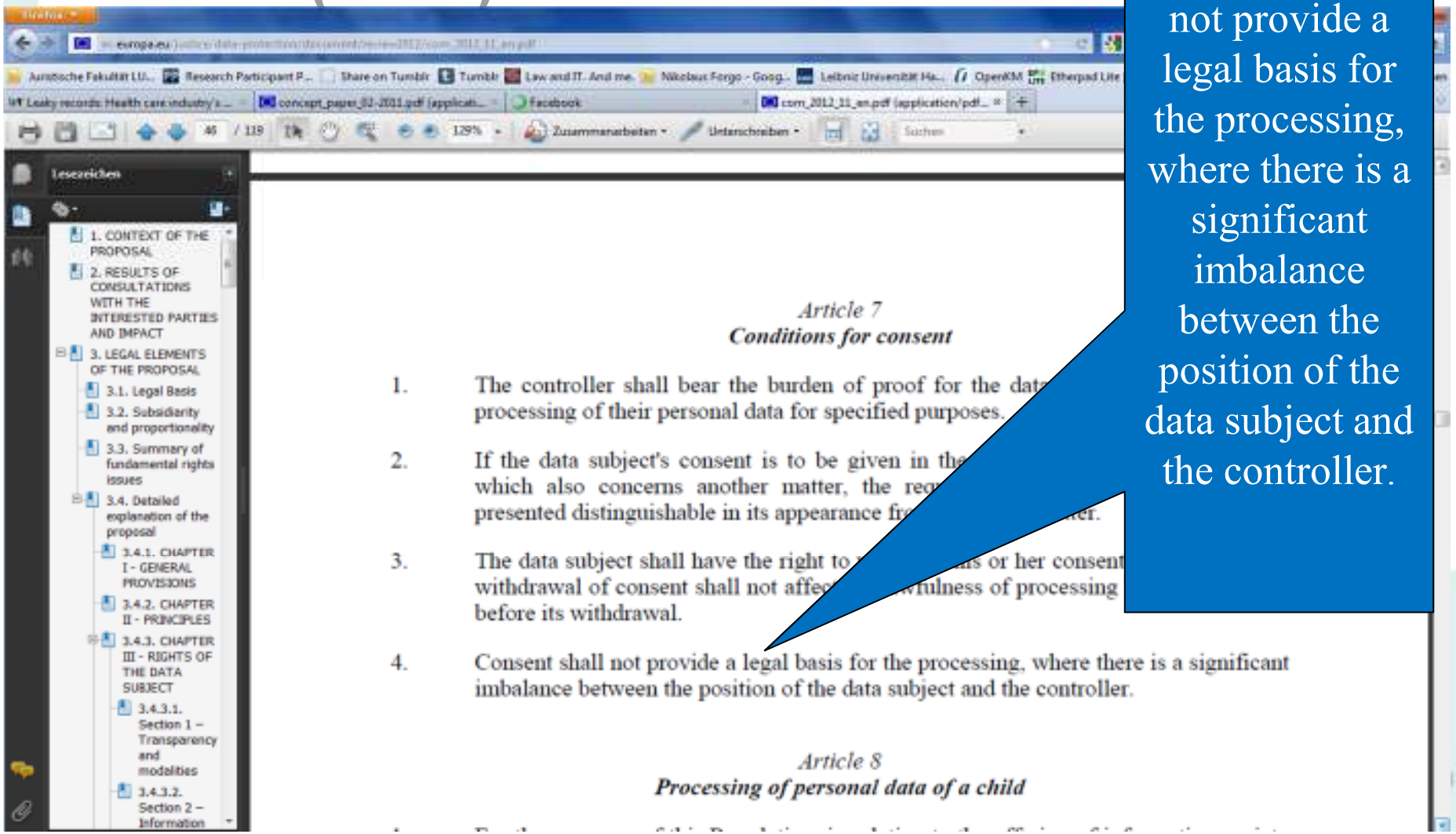
Theory …

83.9 % of patients agreed that, if the chief executive and senior management were made aware of risks but failed to act – and there is a serious breach – they should be fined or lose their jobs.

COM(2012) 11 final



Thank you!

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