



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



## Legal perspectives in EU projects

Prof. Dr. Nikolaus Forgó  
Leibniz University Hannover  
nikolaus.forgo@iri.uni-  
hannover.de

[www.ponte-project.eu](http://www.ponte-project.eu)



- Why a lawyer?



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# A Confession



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applied to different biobanks.

it status.

rop.

the trends within

' viewpoint.

5. Create awareness among public organizations and educational systems in member states.

**Q5: Are there any questions raised which you require further clarification on?**

, what do you think  
RI?

Biobanking

I presentation of

quality and

nablina better

1. How to avoid too much legal framework in order to prevent rigidity when sharing data.
2. Localisation of expert centres and process of selection/individualisation in Member States.
3. What is foreseen for biobanks who do not join BBMRI?
4. Some more detail on the ethical issues.



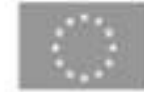
# Background

- 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](http://www.eu-acgt.org)



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## 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



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# Golden Rule

Processing of **personal data** is only allowed if:

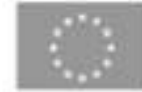
- it is **permitted by law** or
- the data subject has **consented to it**



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Personal data?



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# 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



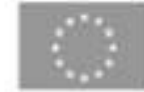
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## Recital 26 Dir. 95/46/EC

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





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# p-medicine

From data sharing and integration via VPH models to personalized medicine



# Our role in p-medicine

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

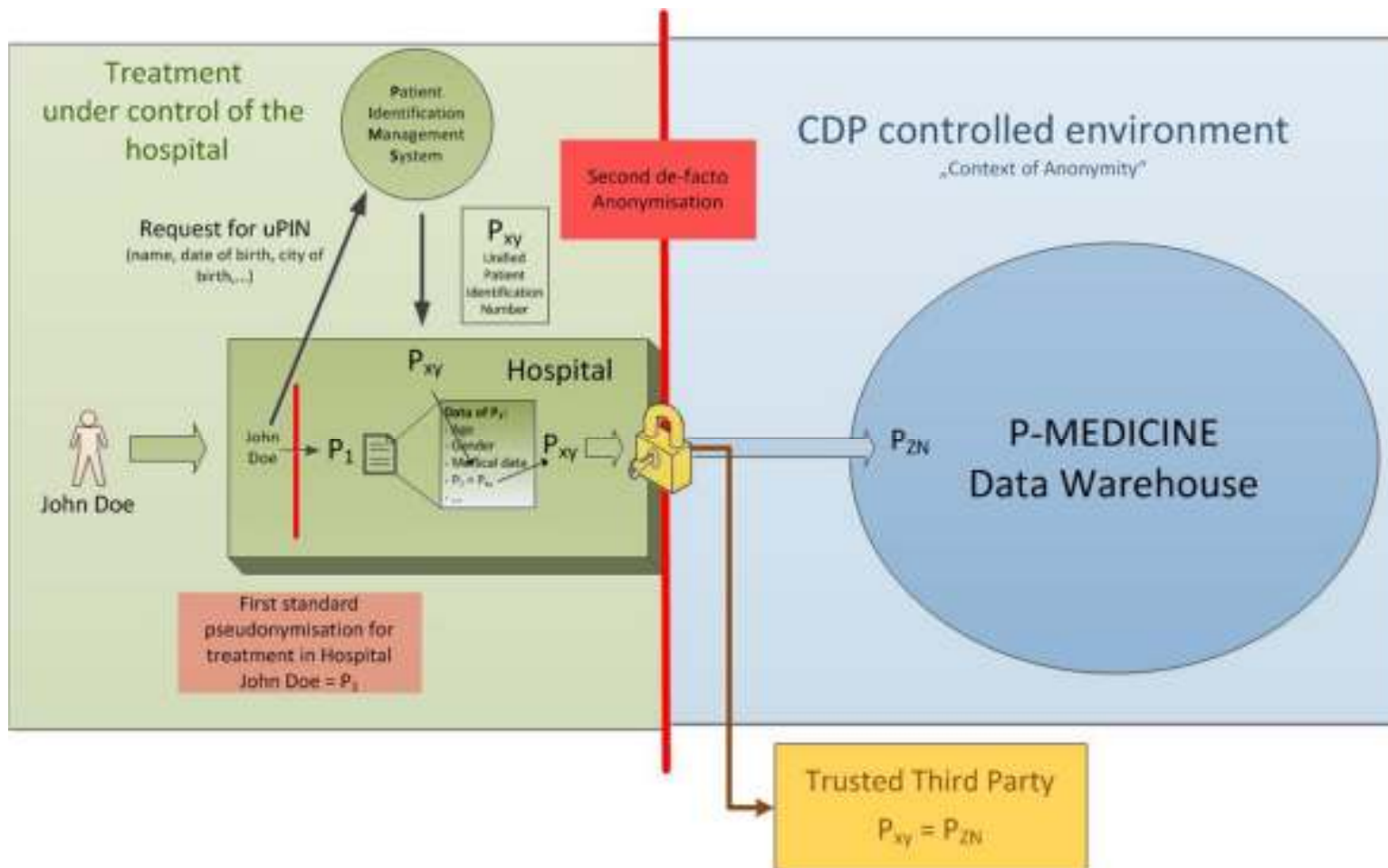








# Patient Identity Management System



# CONTRACT

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 7<sup>th</sup> Framework Programme, as a support action
- **Consortium:** 5 partners

# 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.

# 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

- Defined under national legislation
- No common understanding

### Consent for research

- Defined in Clinical Trials Directive 2001/20/EC
- Art. 2 (j)

### Consent for processing the data

- Defined in Data Protection Directive 95/46/EC
- Art. 2 (h)



# Approach

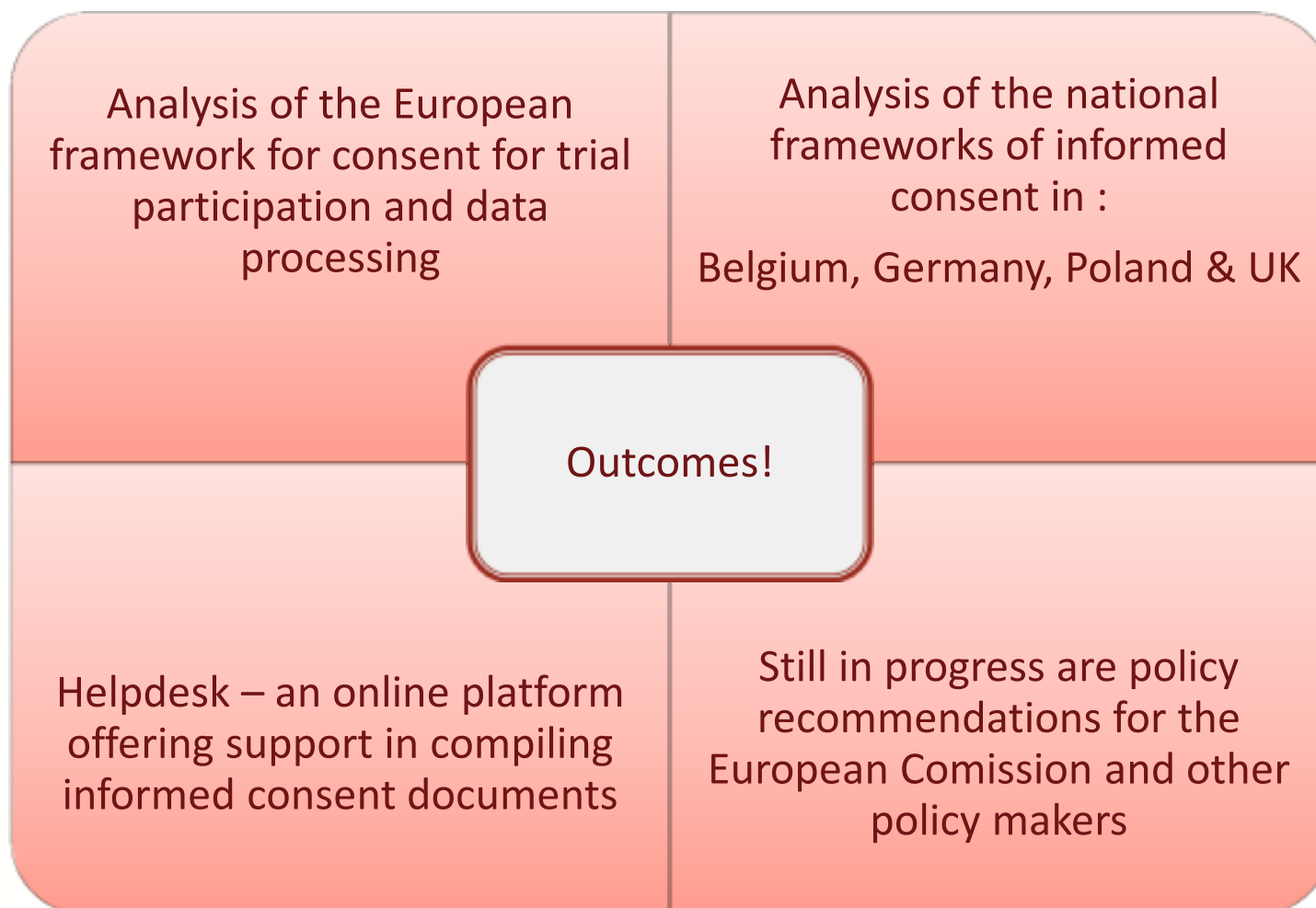
Creating the widest possible picture of  
Informed Consent

- 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

# Our role in CONTRACT

- Project coordination
  - Responsible for the project as a whole and overall management
- 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](http://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 7<sup>th</sup> 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?



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A sickening side-effect of the eHealth re...

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Court correct to deny p...  
procee...

PRIVACY  
A sickening side-effect of the eHealth revolution

LISA PRIEST  
Globe and Mail Update  
Published Thursday, Jan. 26, 2012 7:30AM EST

26. 01. 2012

13 comments

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The digital revolution is poised to transform Canadian health care, promising more timely access to doctors and streamlined service that is expected to improve the patient experience while reducing waste and unnecessary testing.

But the technological changes – from an app that connects patients to their doctors, wherever they are, to a single electronic health record a patient has for life – also come with a downside: the possible breach of privacy.

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In 2011, her office received 135 reported health-information privacy breaches

> 3 % of Canadian patients have already experienced breaches of medical information



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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.



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# COM(2012) 11 final

Consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller.

The screenshot shows a PDF document titled 'COM(2012) 11 final' in a browser window. The document is a proposal for a regulation on data protection. The left sidebar shows a table of contents with sections like '1. CONTEXT OF THE PROPOSAL', '2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT', and '3. LEGAL ELEMENTS OF THE PROPOSAL'. The main content area displays Article 7, 'Conditions for consent', which lists four points. The fourth point is highlighted by a blue callout box. Below Article 7, the start of Article 8, 'Processing of personal data of a child', is visible.

*Article 7*  
**Conditions for consent**

1. The controller shall bear the burden of proof for the data subject's consent to the processing of their personal data for specified purposes.
2. If the data subject's consent is to be given in the context of a written agreement which also concerns another matter, the request for consent must be presented distinguishable in its appearance from the other matters.
3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.
4. Consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller.

*Article 8*  
**Processing of personal data of a child**



Thank you!  
nikolaus.forgo@iri.uni-hannover.de



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