EUROPEAN CANCER PATIENT COALITION

The importance of Biobanking in Cancer-patient's perspective

Peter Riegman

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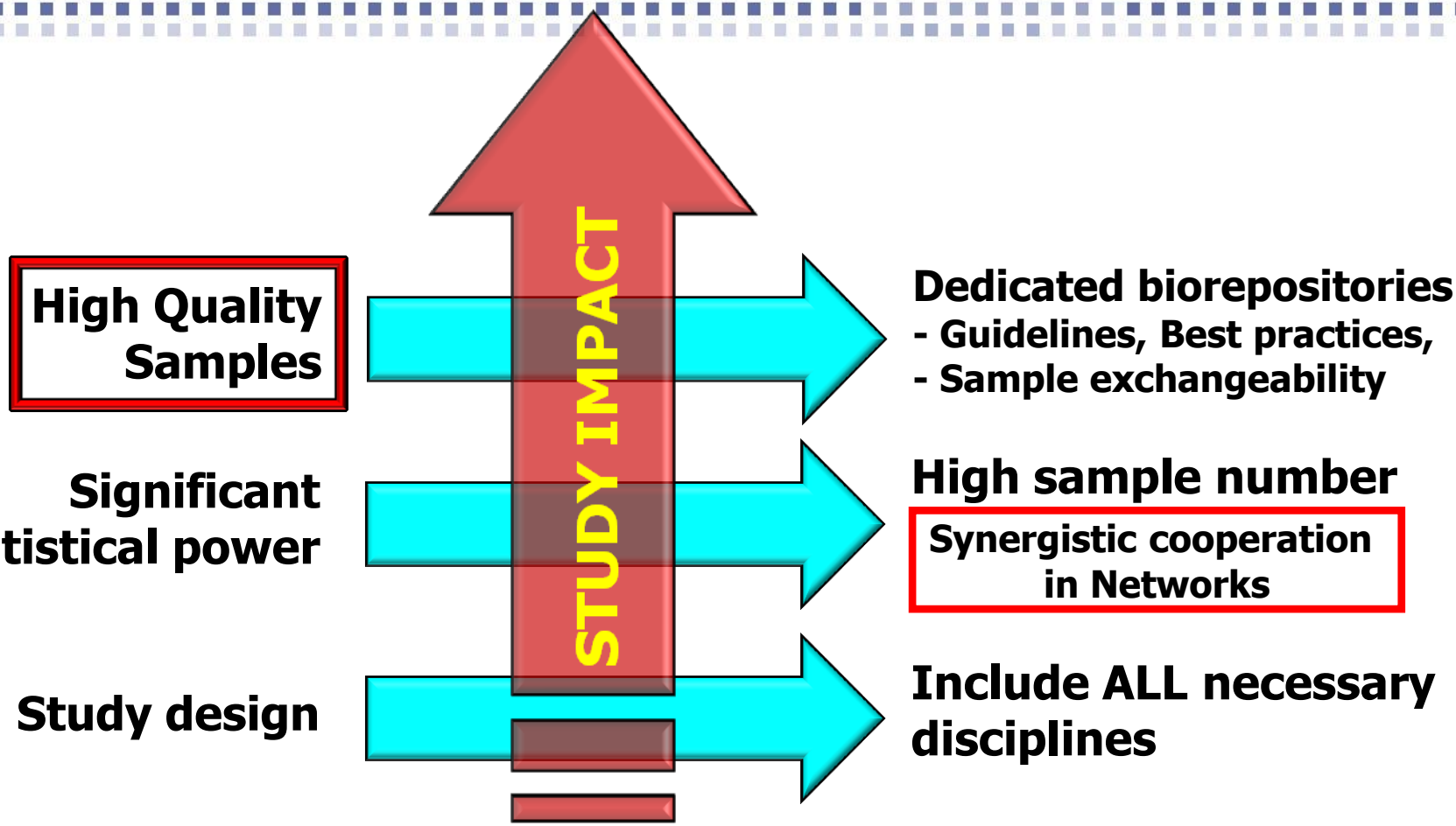
Innovation of Patient Care



Medical Translational Research

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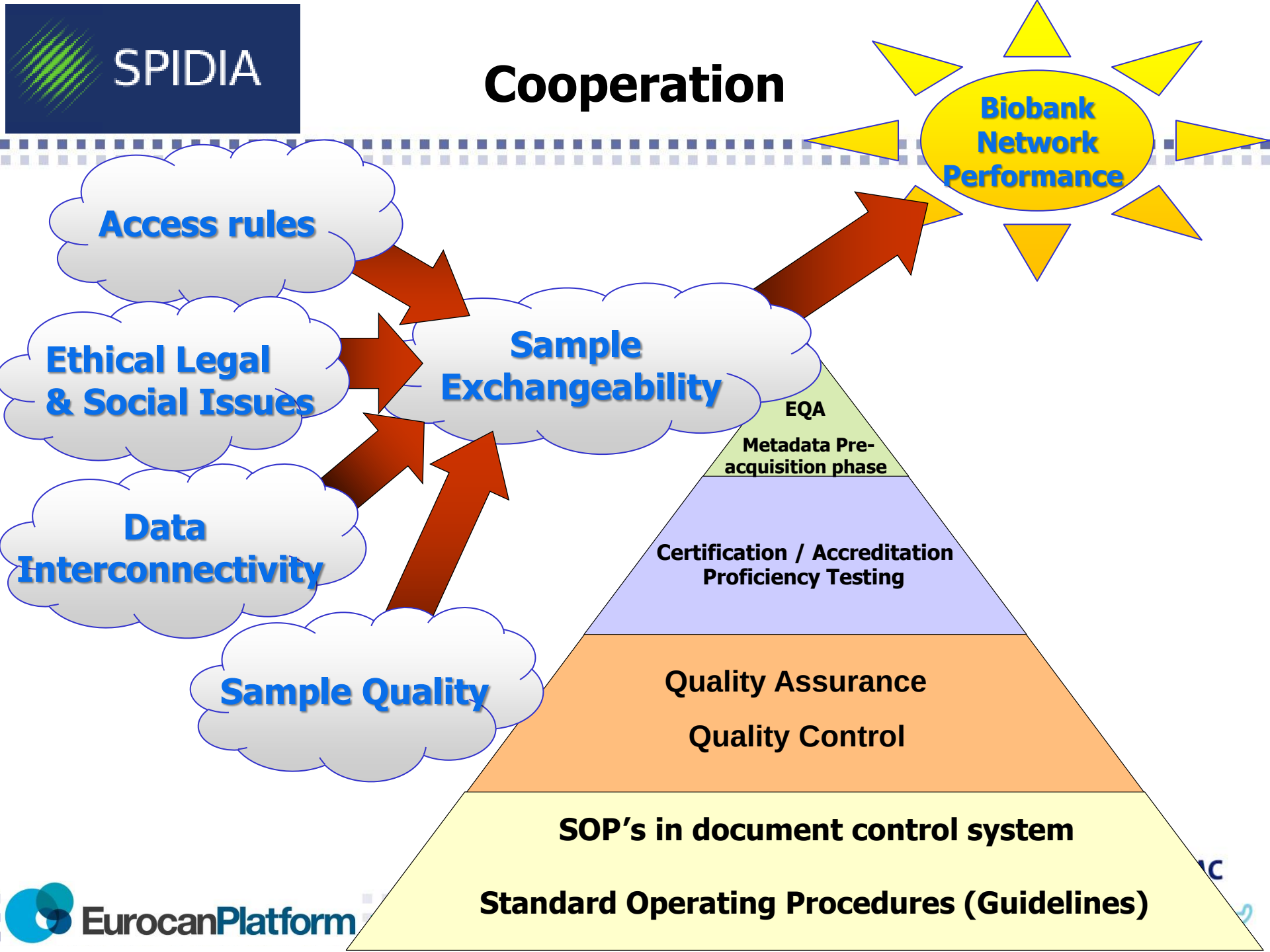
SPIDIA

Cooperation



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What is stored in biobanks

- Blood
- Tissue (surgical specimen)
- Cerebrospinal fluid
- Urine
- Stool
- Hair
- Nails
- Etc etc.

Determine:

- DNA sequence
- RNA content / expression
- Protein content / expression

> 40.000 data points per sample -> look for characteristics

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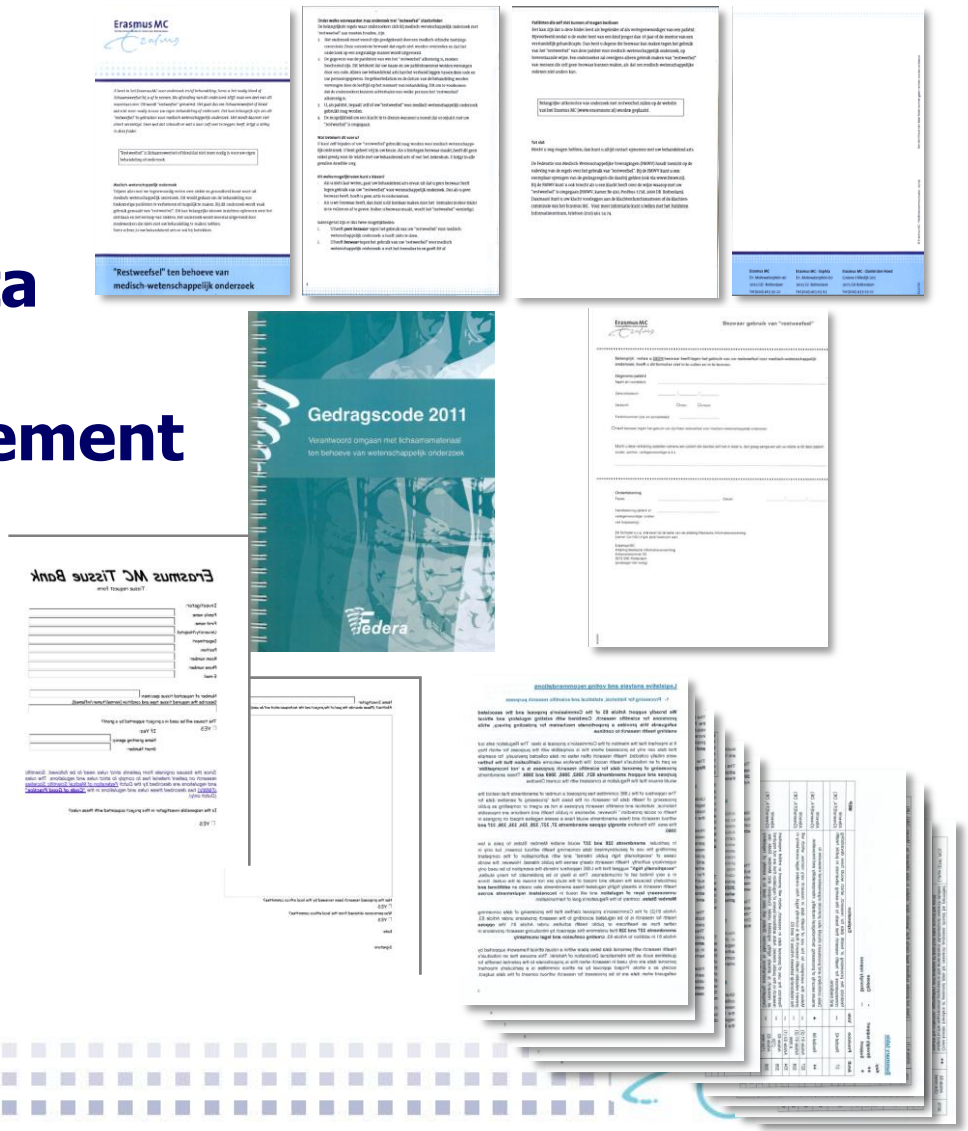
Benefits of Biobanks

Medical Research:

- Identify risk / susceptibility
- Diagnostic biomarkers
- Responders / Non-responders
- Patients with adverse effects
- Understanding disease development:
  - Identify new drug targets
  - Delay progression

Ethical / Regulatory Concerns

- Informed Consent
- Patient information
- Patient Quality of Life
- Privacy – Coding of data
- ME(T)C / IRB approval
- Material Transfer Agreement
- Return of Materials
- Feedback of Results
- Incidental findings
- Sample tracking



ELSI: Ethics - Transparency

Innovation of Patient Care

(Affordable) Translational Research

Low operational costs

Strict, but clear and useful rules

Collecting samples and medical research should be accepted as part of normal medical care
As normal procedure to improve medical care

Trust

Different risks -> Different rules

Ex vivo OBSEVATIONAL

- Residual Material — **Secondary use**

Opt-out; Privacy; ECL

- Extra Material — **Study**

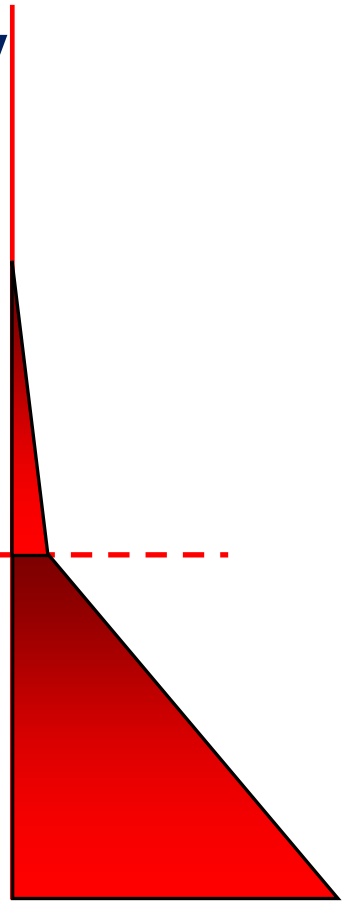
Informed Consent; METC; Privacy

In vivo INTERVENTION

- Trial

Trial related Material

Informed Consent; METC; Information; Privacy



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General Data Protection Regulation

Biobanking difficulties directly caused by defenitions:

- **Explicit consent** -> informed consent THROUGH ACTION
  -> OPT-OUT no longer allowed
- **FOR SPECIFIC AIMS** -> BROAD CONSENT no longer allowed
- **Pseudomised data** new defenition -> NO CODED DATA
- **Data subject** may not be **singled out**
  (Tracability – ID or discrimination)

Article 81 and 83 No agreement yet
Political influence

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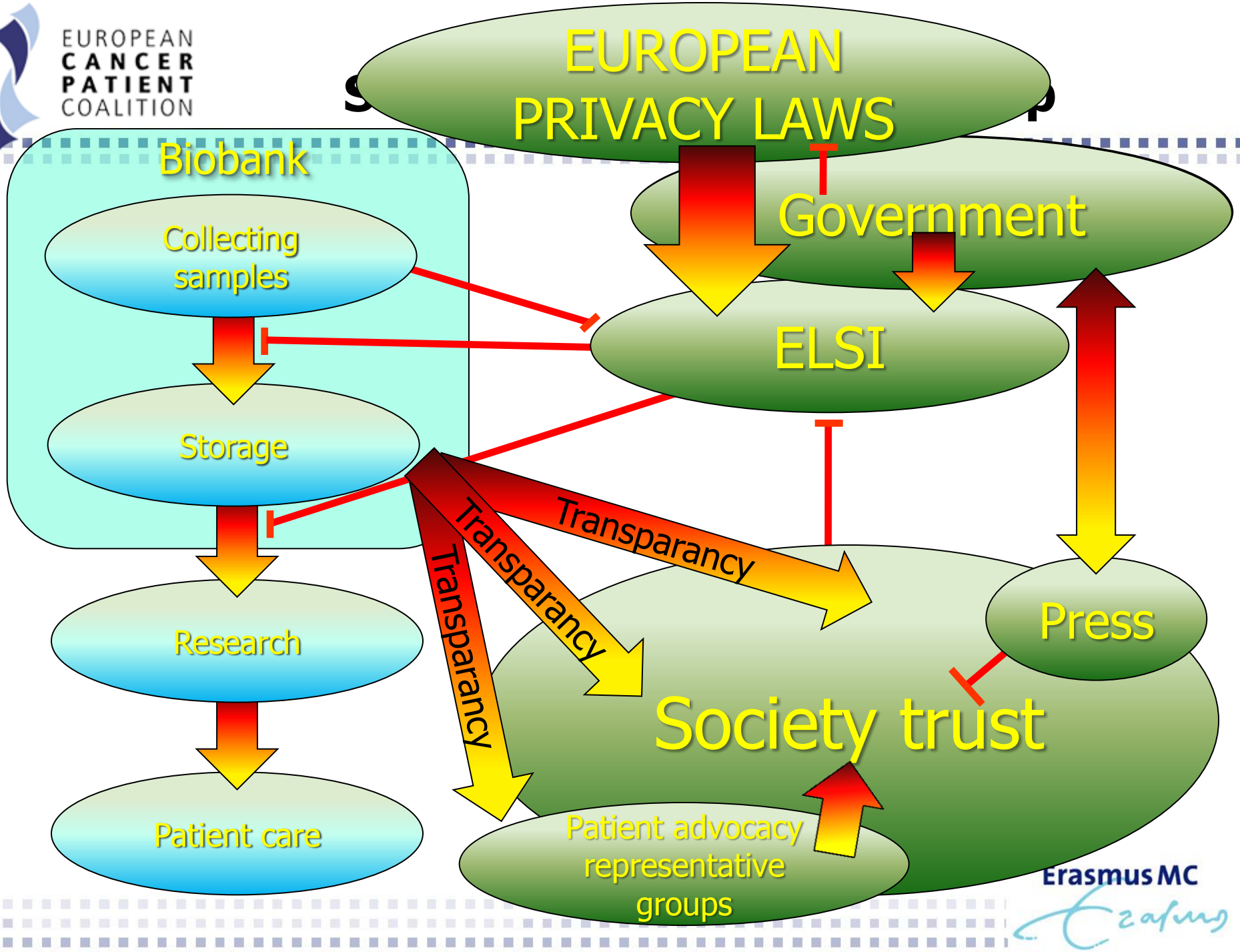

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NOTHING ABOUT US, WITHOUT US!

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Biobanking: FAQs

This document was written by medical researchers and approved by ECPC in the context of the EurocanPlatform Project: WP10.

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