3RD INTERNATIONAL CONFERENCE: THE EUROPEAN HEALTH DATA SPACE

SECONDARY USE OF DATA AND DATA SUBJECT RIGHTS.

Secondary Use of Health Data in Biobanks: Protecting Subject Rights under the European Health Data Space

Insights from the Oncological Collection at the Medical University of Bialystok Biobank

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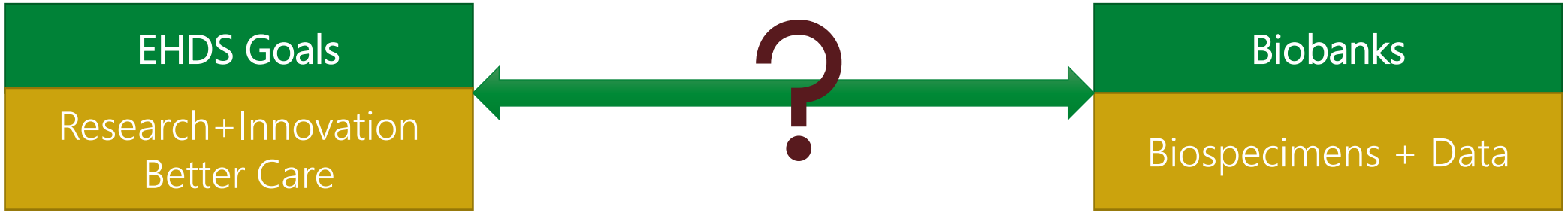
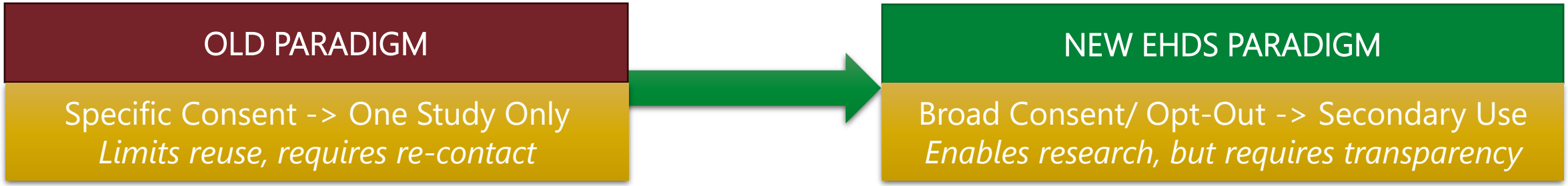
The EHDS Revolution & The Biobank Conundrum

- The **EHDS** creates a unified framework for accessing health data for secondary use (research, policy-making, innovation).
- **Biobanks** are not just data repositories; we are the **bridge** between the physical sample and the digital data. We hold the key to **longitudinal, clinically-annotated datasets**.



The Core Tension:
How do we unlock the immense potential of this data for science while upholding the **fundamental rights** of the subjects who provided it - rights now **redefined** by both **GDPR** and the upcoming **EHDS**?

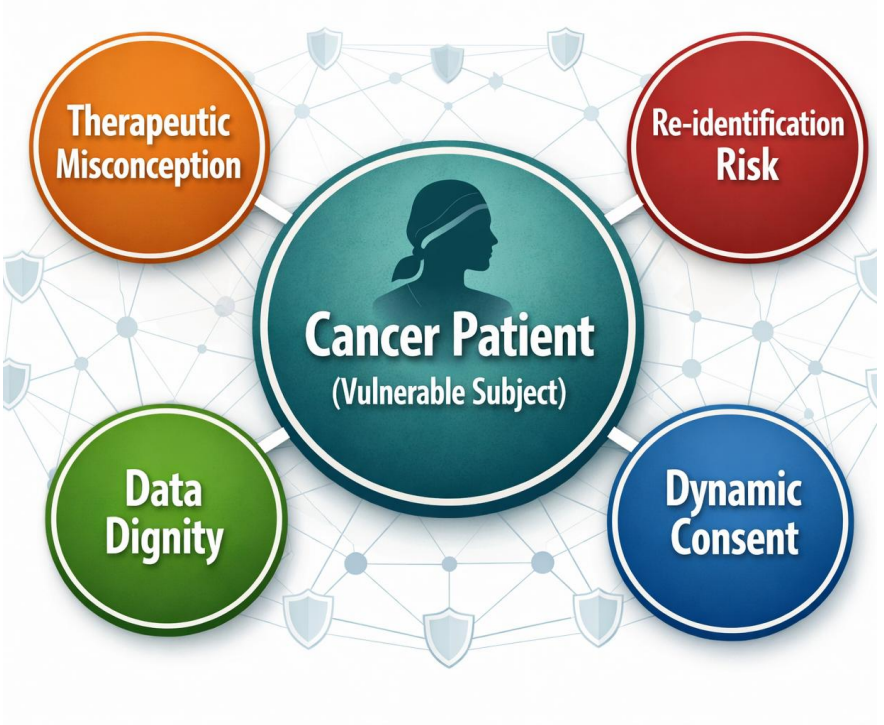
The Paradigm Shift in Consent



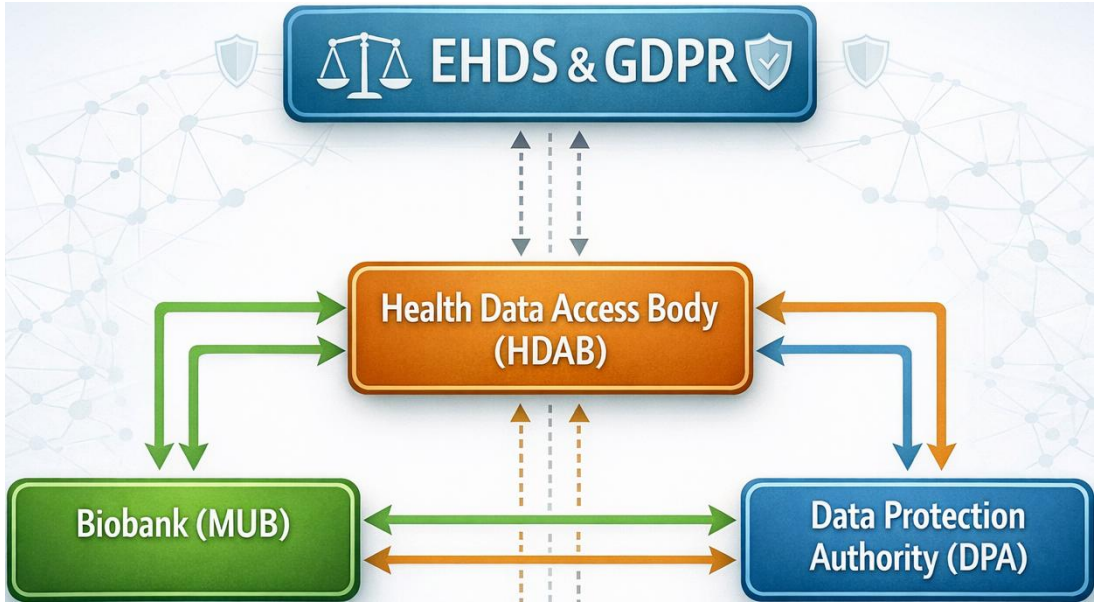
- **Moving beyond traditional models:** EHDS encourages models that allow for broader future use without seeking new consent for every project.
- **The MUB Biobank approach:** We are biobanking biological material and data for Oncological Collection using a **Broad Consent** model, fully compliant with GDPR Art. 9 and Recitals.
- **Key safeguards for Broad Consent:**
  - ✓ **Granularity:** Allowing participants to choose different levels of sharing,
  - ✓ **Transparency:** Clear information on governance, types of future research, and commercialization potential,
  - ✓ **Right to withdraw:** An easily accessible, functional mechanism for participants to withdraw their data and samples at any time.

Protecting the Vulnerable Subject – Oncological Patients

- **Vulnerability:** Cancer patients are often in a state of dependency on their clinicians. We must guard against „therapeutic misconception": the belief that consenting to research will directly impact their care.
- **Re-identification risk:** Combining genomic data from tumors with clinical registries across borders increases the risk of re-identification, even in anonymized datasets.
- **Safeguards at MUB Biobank:**
  - ✓ **Strict separation:** Clear separation of the clinical care team from the biobanking and data access team during the consent process.
  - ✓ **Data security:** Pseudonymization and encryption, with pseudonymized data access strictly limited to approved researchers.
  - ✓ **Empowerment:** Using tools like „multi-level consent" to keep participants informed and to reinforce their control.

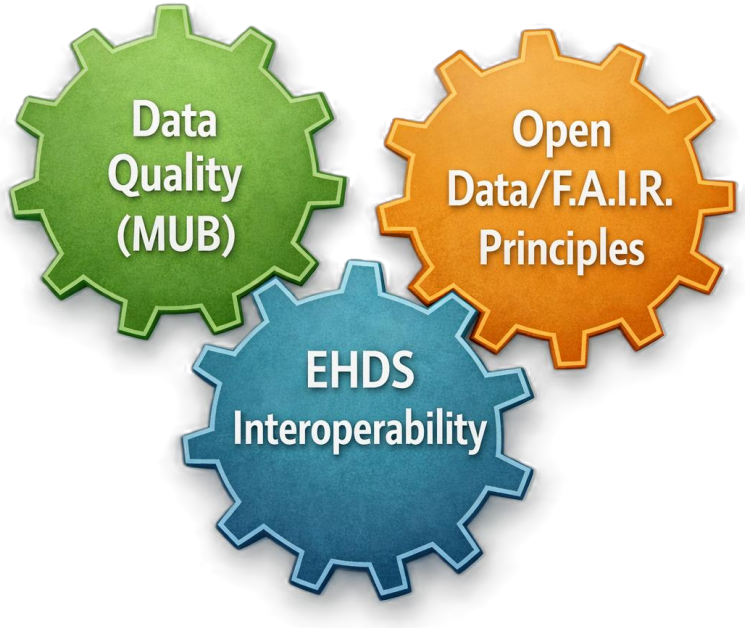


Governance: The New Ecosystem of Oversight



- **New Roles:** EHDS introduces Health Data Access Bodies (HDABs) as the single point of entry for data requests.
- **MUB's Role:** The Biobank acts as a **Data Holder**. We do not make access decisions alone.
    1. A researcher applies to the HDAB.
    2. The HDAB, in coordination with the Biobank and relevant ethics committees, evaluates the purpose, legal basis, and alignment with consent.
    3. Only upon approval is data made available in a secure environment.
- **Accountability:** This decentralized model distributes responsibility, preventing a single point of failure and ensuring checks and balances.

Interoperability, Quality, and the Open Data Directive



- **Quality is the foundation:** For secondary use to be valid, data must be of high quality. We recommend adhering to the BBMRI-ERIC and ISBER quality guidelines.
- **Interoperability:** EHDS mandates common formats, like Fast Healthcare Interoperability Resources (FHIR) for electronic health care data.
- **Interface with Open Data Directive:** Where possible, non-personal, aggregated data derived from the Biobank can be made openly available to maximize transparency and innovation, while strictly protecting patient privacy.

Challenges and Open Questions

- **Liability allocation:** In this new ecosystem, if a data breach occurs via researcher accessing data through the HDAB, where does liability lie?
  - ➢With the HDAB? The Biobank? The researcher's institution?
- **Professional secrecy:** How do we reconcile the EHDS push for openness with the strict professional secrecy obligations of medical doctors in countries like Poland?
- **Funding sustainability:** Implementing these complex technical and governance solutions requires significant, sustained investment.
  Where will the funding for Biobanks as data infrastructures come from?

Conclusions & Recommendations

- **Biobanks are essential:** They are more than repositories; they are active, responsible **intermediaries** in the EHDS data economy.
- **Rights are paramount:** The shift to **broad consent** and **secondary use** must be matched with robust safeguards, especially for vulnerable populations like cancer patients. **Transparency** and the **right to withdraw** are non-negotiable.
- **Governance is key:** The distributed model involving HDABs, DPAs, and Biobanks is the right path, but it requires intense **coordination** and **clarity** on roles.
- **Recommendations:**
  - ✓**For biobanks:** Invest in dynamic consent platforms and FAIR data practices.
  - ✓**For policymakers:** Clarify liability frameworks and provide sustainable funding for data infrastructure.

Thank you for your kind attention

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