

Symposium

Ethical, Legal, and Societal Aspects in View of Recent EU Legislation

Programme

22 – 23 October 2025

Bilbao, Spain

Wednesday, 22. October 2025

13:00 – 14:00 **Light Lunch & Registration**

14:00 – 14:15 **Welcoming Remarks & Setting the Scene**

Alberto Emparanza (Dean of the Faculty of Law at the University of the Basque Country UPV/EHU)

Teresa Escámez (Scientific Director of the Spanish National Node at BBMRI-ERIC)

Pilar Nicolás (Coordinator of the ELSI Group at the Spanish National Node BBMRI-ERIC - Permanent researcher at the University of the Basque Country UPV/EHU)

Jens Habermann (Director General, BBMRI-ERIC)

14:15 – 14:45 **BBMRI-ERIC's 10-year Roadmap: Biobanking for a Healthier World and ELSI Perspectives**

Jens Habermann (Director General, BBMRI-ERIC)

14:45 – 16:15 **SESSION 1: The European Health Data Space (EHDS). General Overview**

Chair: **Pilar Nicolás** (Coordinator of the ELSI Group at the Spanish National Node BBMRI-ERIC - Permanent researcher at the University of the Basque Country UPV/EHU)

Keynote Speaker: The European Health Data Space: From Vision to Reality, **Mélodie Bernaux** (COM-DG SANTE-EHDS)

Sustainability by Design and the European Health Data Space, **Ciara Staunton** (Ciara Staunton Consulting)

From Biospecimens to Bytes: Aligning GDPR, Tissue Laws, and the European Health Data Space for Seamless Health Research, **Mireille Sant and Kim Tabone** (University of Malta)

Emerging Biobank Governance in Moldova: Aligning with EHDS Principles, **Elena Romancenco** (State University of Medicine and Pharmacy in Moldova)

Panel Discussion

16:15 – 16:45 **Coffee Break**

16:45 – 17:00 **Group Picture**

17:00 – 18:30 **SESSION 2: Bringing the Community Together: Physicians, Researchers & Infrastructures**

Chair: **Dorota Krekora-Zajac** (BBMRI.pl, University of Warsaw)

Keynote: **Patient Advocacy Impact on Regulation, Infrastructure and Access to HTAR and EHDS in EU and in Sweden, Margareta Haag** (Swedish Network Against Cancer)

RENACER: Physicians, Researchers and Patients Towards Brain Metastases Treatment, **Carmen Ortega-Sabater** (CNIO)

What Motivates or Discourages Young Adults from Participating in Longitudinal Cohort Studies? **Isabelle Budin Ljøsne** (Norwegian Institute of Public Health)

From Data to Dialogue: How Donor Insights Shape Collaborative Biobank Strategies, **Adelina Ovcharenko** (MIDGAM)

New Strategy in Broad Consent-based Biobanking with Minors: Re-Information Instead of Re-Consent when Children Attain Full Age, **Roland Jahns** (ibdw)

Panel Discussion

Thursday, 23. October 2025

08:00 – 09:00 **Registration**

9:00 – 10:30 **SESSION 3: Citizen Participation, Transparency & Science**

Chair: **Mónica Cano Abadía** (BBMRI-ERIC)

Keynote Speaker: **Building patients' trust in the context of EHDS, Veronica Popa** (EURORDIS)

Building Trust & Collaboration in “Cancer” Mission: Citizen Participation, Technology, and Scientific Integrity, **Pilar Caro** (CNIO)

From Feedback to Follow-Up: How Participants Shaped the Cantabria Cohort Questionnaires, **Adelaida María Celaya Puértolas** (IDIVAL)

Facilitating Transparency in Biomedical Initiatives through Creative Practices, **Jusaku Minari** (Kyoto University)

Who Gets to Speak? Who Gets Heard? Navigating Power Imbalances, Representativeness and Practical Feasibility of Citizen Engagement in a National Health Data Infrastructure, **Miriam Beusink** (Health-RI)

Panel Discussion

10:30 – 11:00 **Coffee Break**

11:00 – 12:30

SESSION 4: Data Subjects' Rights

Chair: **Signe Mežinska** (University of Latvia, BBMRI.lv)

Keynote Speaker: Rights of data subjects in emerging data spaces, **Fruzsina Molnár-Gábor** (Heidelberg University)

Incidental Findings under the European Health Data Space (EHDS) Regulation, **Catarina de Almeida** (University of Vienna)

Incidental findings beyond the EHDS. Challenges for the Member States and lessons from genomics, **Guillermo Lazcoz** (UPV/EHU)

Current Consent Forms and EHDS. Challenges for Polish Biobanks, **Dorota Krekora-Zajac** (BBMRI.pl, University of Warsaw)

How to Elucidate Consent-Free Research Use of Medical Data – the Concept of Health Data Literacy as a Pioneer for the Opt-Out Regulation, **Gesine Richter** (University of Kiel)

Panel Discussion

12:30 – 14:00

SESSION 5: The Role of Biobanks in the EHDS Governances

Chair: **Erdina Ene** (BBMRI-ERIC)

Keynote Speaker: The potential roles of the biobanks in the European Health Data Space Ecosystem, **Roberto Bilbao** (Scientific director of the Basque Biobank of the Foundation for Innovation and Research in Health, member of the ISCIII Biobanks and Biomodels Platform)

The Impact of Regulation on the European Health Data Space (EHDS) on Secondary Use of Data from Biobanks, **Radek Halouzka and Jan Kurán** (Masaryk Memorial Cancer Institute)

Data Sharing in Pediatric Research Within the EHDS, **Jakub Pawlikowski** (Medical University of Lublin) and **Joanna Pawlikowska** (University of Białystok)

Not just BBMRI digital standard consent for biobanking: ELSI digital tools and environments as a vector for self-determination and participation, **Sara Casati** (BBMRI.it, National Council for Research)

Global Biobank Transfers: Rights of Biological Material Owners and Ethical Challenges from South to North, **Diana Bernal** (Consejo Nacional de Bioética - Universidad del Rosario)

Panel Discussion

14:00 – 15:00

Light Lunch

15:00 – 16:30

SESSION 6: Presentations by Early-Career Researchers

Chair: **Marialuisa Lavitrano** (UNIMIB, BBMRI-ERIC.it)

Promoting the Use of Biobanks as Trusted Platforms for Data Sharing for Research Purposes in the European Health Data Space, **Laura Centeno Casado** (CSIC)

Bioethica Reflection, Post-mortem fertilisation in the Iberian context in the 21st century, **João Proença Xavier** (University of Salamanca / University of Coimbra)

Ethical and legal implications on the secondary use of personal electronic health data for scientific research purposes in the nascent EHDS framework, **Mikel Recuero** (University of the Basque Country)

Ethical Dimensions of Artificial Intelligence in Cancer Care, **Loay Al-Dager** (Al-Azhar University)

Poster Presentations:

European Health Data Space, right to opt-out and the Electronic Health Record 2.0: a possible solution to the Italian ethical and legal context. Pilot proposal to Lepida S.c.p.a for the introduction of a dynamic digital consent in the HER, **Margherita Carpani** (University of Bologna)

Building Biobank-Centered Collaboration in Rare and Undiagnosed Diseases under ELSI Principles, **Beste Özkalay** (Izmir Biomedicine and Genome Center)

Podium Discussion

16:30 – 18:00

SESSION 7: ELSI Aspects of Artificial Intelligence in Biobanking

Chair: **Francesca Tassinari**, **University of the Basque Country (UPV/EHU)**

Keynote Speaker: **AI and biobanks: exploring the ELSI**, **Iñigo de Miguel Beriain** (Distinguished researcher UPV/EHU, member of the Spanish Bioethic Committee)

Citizen Science in Biobanking: Experiences and Emerging Opportunities, **Signe Mežinska** (University of Latvia, BBMRI.LV)

Trustworthy Medical AI: An Embedded Ethics Perspective, **Mónica Cano Abadía** (BBMRI-ERIC)

Tough Questions for Ethical Data Governance: Monetising Data Altruism for the Public Interest, **Sara Degli Esposti** (CSIC)

Social Acceptance of Artificial Intelligence in Biobanking, **Élodie Caboux** (IARC/WHO)

Panel Discussion

18:00 – 18:15 **Closing Remarks**

Organisers

BBMRI-ERIC

University of the Basque Country (UPV/EHU)

University of Milano-Bicocca (UNIMIB)

Platform ISCI| Biomodels and Biobanks

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Venue

Bizkaia Aretoa - UPV/EHU

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