NeuroCOV Workshop

The European Health Data Space: Forecasting Technoscientific, Ethical and Social Challenges in Implementation

Langenbeck Virchow Haus,
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The Regulation on the **European Health Data Space (EHDS)** is bound to have a transformative impact on the health domain in Europe, (re)shaping healthcare delivery, and research and innovation activities across the EU. Driven by a vision of harmonising regulatory and technical standards, the EHDS is intended to increase citizens' control on (trans-border access to) **electronic health records**, while fostering **health data sharing practices** across the continent. Yet, major challenges loom large on the EHDS' horizon, as also evidenced by the "(major) revisions" recommended by the EU Parliament and the Council to the Commission's Proposal, as part of the ordinary legislative procedure leading to the EHDS' approval and implementation.

This workshop - convened under the aegis of the Horizon Europe-funded NeuroCOV project - aims to gather **key players** in European health policy, research, and care, to set the agenda for sustained **public scrutiny** of the proposed Regulation, geared to analyse the impact and anticipate challenges from the implementation of the EHDS. The workshop will take its cue from an overview of the policy process and 'Trilogue' negotiations following the Commission's Proposal in 2022, with the aim to trace the key issues at stake in the policy debates. Next, it will articulate perspectives from key stakeholders in the health domain, anticipating opportunities and challenges in aligning current health research and care practices to EHDS standards and regulatory requirements. Thirdly, we will outline and discuss normative models – from governance to consent – that could sustain the socially robust implementation of the EHDS.

The collective reflection will be driven by an underlying question – all the more relevant in light of the upcoming European elections: **what part can our 'thought collective' play in bringing to the fore the profoundly socio-political stakes underlying the envisaged creation of a "European" health data "space"?**

WORKSHOP PROGRAMME

Time	Session
10:00 - 10:30	**Arrival and welcome**
10:30 - 10:45	**Introduction to the worksop** Joachim Schultze, DZNE, Giuseppe Testa, Human Technopole, Luca Marelli, University of Milan
10:45 - 11:30	**Turning the EHDS into law: driving visions and key challenges in the EHDS policy process** Mélodie Bernaux, European Commission Katarína Kutajová, EU Parliament
11:30 - 12:45	**Challenges and opportunities in implementing the EHDS: perspectives from health stakeholders** Joachim Schultze, DZNE Giuseppe Testa, Human Technopole Andrea Ganna, University of Helsinki Emanuele Villa, Human Technopole
12:45 - 13:45	**Lunch break**
13:45 - 15:00	**The governance of the EHDS and the role of Health Data Access Bodies** Camille Cloitre, Health Data Hub Peija Haaramo, FINDATA Alexander Degelsegger-Márquez, Austrian National Public Health Institute Katharina Schneider, BfArM
15:00 - 16:00	**Ethical and social challenges: beyond the 'notice-and-consent' model** Barbara Prainsack, University of Vienna Mahsa Shabani, University of Amsterdam Irene Schluender, TMF Berlin
16:00 - 16:30	**Coffee break**
16:30 - 17:30	**Enacting the EHDS: A roadmap towards socially robust implementation** Moderation: Luca Marelli, University of Milan, Ine Van Hoyweghen, KU Leuven