

WP6 Ethical and Legal Framework

WP co-leads: Ine Van Hoyweghen, Luca Marelli

Main beneficiary: KU Leuven

Other beneficiaries: CIMH, UEDIN, UK BA, UPJS

EC Evaluation, 19.6.2024



This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

WP6 - Staff



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WP6 – Overview, objectives, and aims



- **Objective 1 / Task 6.1 Ethics and data protection compliance**
 - **Support** for ethics approvals
 - Provision of ethical and legal **guidance**
 - **Monitoring** of ethics compliance during the whole project lifecycle
- **Objective 2 / Task 6.2 Harmonization of data management procedures**
 - Ethics-compliant, harmonized **data governance framework** (primary and secondary data uses)
- **Objective 3 / Task 6.3 Ethical, legal and policy analysis**
 - **Analysis** of EU / national policy (focus: regulatory requirements / data governance)
 - Governance **white paper**



WP6 – Deliverables & Milestones



| Milestone / deliverable | Title | Original deadline | Status |
|-------------------------|--|-------------------|--------|
| D6.1 | Ethics compliance | 9 | ✓ |
| D6.2 | Data protection compliance /1 | 3 | ✓ |
| D6.3 | Data protection compliance /2 | 3 | ✓ |
| D6.4 | Risk assessment | 3 | ✓ |
| D6.5 | Appointment of Ethics Advisory Board | 3 | ✓ |
| D6.6 | Copies of import/export authorisations | 6 | ✓ |
| M3 | Establishing a data governance framework | 6 | ✓ |



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WP6 – Deliverables & Milestones



| Milestone / deliverable | Title | Original deadline | Status |
|-------------------------|--|-------------------|--------|
| D6.7 | Ethical monitoring (1) | 12 | ✓ |
| M6 | First analysis of regulatory requirements, feeding insights back into the project | 12 | ✓ |
| D6.8 | Ethical monitoring (2) | 24 | ✓ |
| M13 | Second analysis of regulatory requirements, feeding insights back into the project | 24 | ✓ |
| D6.9 | Ethical monitoring (3) | 36 | ✓ |
| M19 | Third analysis of regulatory requirements, feeding insights back into the project | 36 | ✓ |
| D6.10 | Report on the status of posting results in the study registry(s) | 42 | Active |
| D6.11 | Policy white paper | 45 | Active |
| D6.12 | Ethical monitoring (4) | 48 | Active |



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WP6 – Overview, objectives, and aims



1. Ethics compliance

- **Harmonized consent template** (focus on data protection clauses) (input from **WP5** and **WP7**)
- **Harmonization of study protocols**
 - **Phase I:** - Study protocol and amendments obtained ethics approvals
 - **Phase II:** - Study protocol and amendments obtained ethics approvals
 - Compliance with regulatory requirements (**WP7, WP2**)
- Appointment of independent **Ethics Advisory Board**
 - Periodically consulted on key ethically-sensitive aspects of the project (including patient recruitment, issues around consent, risk assessment, data governance framework)
 - Feedback received and implemented
 - Next meeting planned in second half of 2024
- Ongoing: **ethics monitoring**



WP6 – Overview, objectives, and aims



2. Data protection compliance

- Inventory of **national data protection legislations**
 - Further conditions (health data) pursuant art. 9(4) GDPR
 - Adequacy decision for data transfers with UK (28.6.2021)
- Appointment of **DPOs**
- **Technical and organizational measures** to safeguard data subjects (art. 89(1) GDPR)
 - Inputs for **DMP (WP3)**
 - Data Governance Framework (**DGF**)
- **Legal agreements** enabling data transfers within consortium
 - Joint Controllers Agreement (JCA) ✓
 - Data Processing Agreement (DPA) Phase I ✓
 - Data Processing Agreements Phase II ✓
 - Contracts with investigation sites (**WP7**) ✓



WP6 – Overview, objectives, and aims



3. Harmonization of data governance: Data Governance Framework (DGF)

- Living document, providing a documented basis for making **data access and data transfers decisions** (primary and secondary uses)
- Voted by the SC and **incorporated in the CA** (14.8.2022)
- Establishment of a **Data Governance Board (DGB)** tasked with overseeing and approving all data flows within and outside the IMMERSE consortium (data governance throughout full life cycle of personal data)
- DGF defines DGB's composition and voting prerogatives, Standard Operating Procedures
- Terms of Reference for **Data Access Review procedure**:
 - Primary processing: **IMMERSE Abstract Submission System – 'DROPS' (WP8)**
 - Secondary processing: **Controlled Access Model**
- Criteria for Assessing Data Access Applications



WP6 – Overview, objectives, and aims



4. Policy analysis

- Analysis of **regulatory landscape for mHealth apps**
- Analysis of prospective impact of the **Regulation on the European Health Data Space (EHDS)**

→ **White paper**



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WP6 – Overview, objectives, and aims

4.1 Analysis of regulatory landscape for mHealth apps

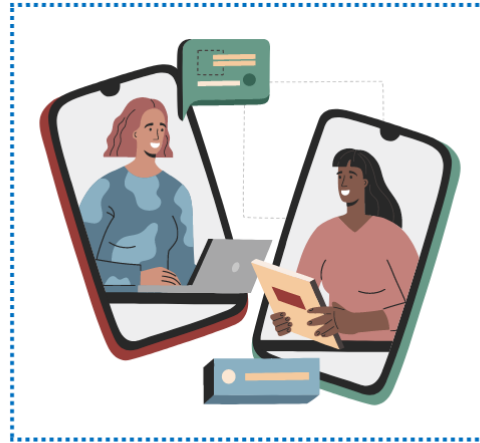
2023/2024



1. Document Analysis

- Mapping relevant **regulatory/industry and policy documents** for digital health
- Overview of **regulatory challenges and opportunities** for mental health apps

Summer 2024



2. Expert conversations

- **Expert conversations with IMMERSE partners** on regulatory barriers for implementation DMMH

1. **Publication:** Lievevrouw, E., Marelli, L., & Van Hoyweghen, I. (2024). Weaving EU digital health policy into national healthcare practices. The making of a reimbursement standard for digital health technologies in Belgium. *Social Science & Medicine*, 346, 116620.
2. **Opinion Piece with members of several WPs in *Politico.eu*** on regulatory challenges raised by MDR
3. **Ethics Approval** by Social and Societal Ethics Committee (SMEC) at KU Leuven, Sept. 6, 2023

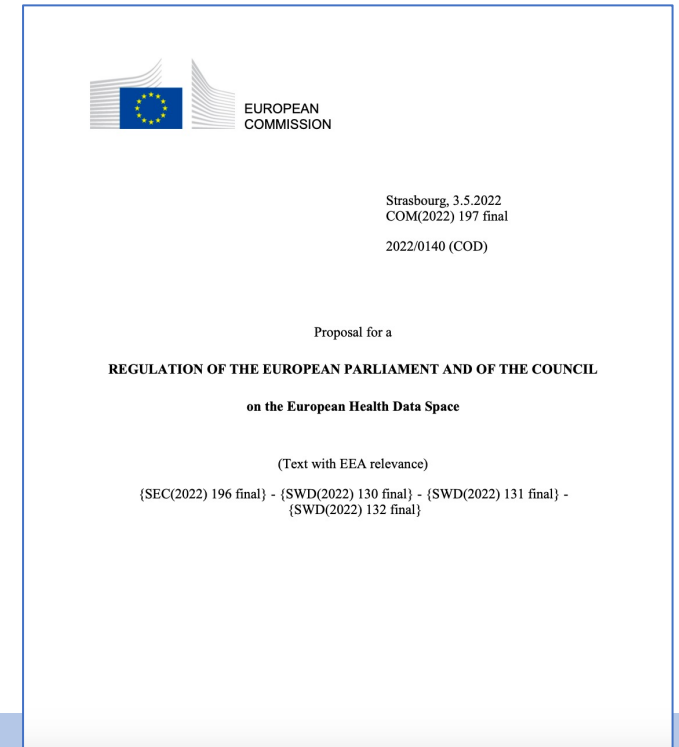


WP6 – Overview, objectives, and aims



4.2 Analysis of prospective impact of the Regulation on the European Health Data Space (EHDS)

- EHDS is the **first domain-specific common European data space** (European Data Strategy, 2020), it is intended to address health-specific challenges to health data access and sharing
- Two main stated objectives: (i) Facilitate **primary use** of health data (EHR) by patients across the EU; (ii) Enhance **secondary data** uses by researchers, innovators, policymakers
- Direct relevance for the **IMMERSE consortium** («data holder») and for the broader field of **digital health**



WP6 – Overview, objectives, and aims



4.2 Analysis of prospective impact of the Regulation on the European Health Data Space (EHDS)

KU LEUVEN **erc** **iHub** **BSTS**

Towards the European Health Data Space: An Interdisciplinary Expert Roundtable
Leuven, October 25th, 2022
KU Leuven, Leercentrum AGORA, OZA01 - Galapagos, Edward Van Evenstraat 4, 3000 Leuven

Co-convenors
Luca Marelli, Life Sciences & Society Lab, KU Leuven
Marthe Stevens, Interdisciplinary Hub for Digitalization and Society, Radboud University
Ine Van Hoyweghen, Life Sciences & Society Lab, KU Leuven
Tamar Sharon, Interdisciplinary Hub for Digitalization and Society, Radboud University

Rationale
The digitalization and integration of European health systems have increasingly acquired priority status in the policy agenda of the European Union. Recent years have witnessed the launch of major health policy, data governance, and regulatory initiatives, culminating in the recent Proposal by the European Commission for a Regulation on the European Health Data Space (EHDS) (European Commission, 2022). The latter is intended to address challenges to health data access and sharing, which in turn is perceived as a fundamental pre-requisite for the completion of a European Health Union built on greater coordination among national health systems.

The Commission's Proposal is poised to pave the way for establishing the legal framework underpinning the implementation of the EHDS, and was heralded as a crucial step towards "unlock[ing] the full potential of health data" (European Commission, n.d.). Yet, major challenges loom large on the EHDS horizon – which call for heightened interdisciplinary scrutiny on the part of scholars and practitioners. Moving from the above, in this expert roundtable we intend to discuss the challenges, pitfalls, and potential criticalities underlying the proposed realization of the EHDS, while also pointing to viable alternatives and possible solutions to the issues identified. Gathering a panel of experts from a variety of backgrounds – from law to ethics, from philosophy and the social sciences to biomedicine – we aim to scrutinize the manifold challenges awaiting the realization of the EHDS, so as to bring collective insights to bear onto policy discussion and formulation.

Confirmed speakers
Panel 1: Irene Schlünder (TMF Berlin), Tom Southerington (FINBB), Sara Roda (CPME), Dorota Krekora Zając (University of Warsaw), Ilaria Colussi (BBMRI)
Panel 2: Mihaela Matei (ECRINI), Mahsa Shabani (Ghent University), Klaus Hoeyer (University of Copenhagen), Alexander Degelsegger Márquez (Austrian National Public Health Institute) and Barbara Prainsack (University of Vienna)
Panel 3: Selim El-Sayed and Barbara Prainsack (University of Vienna); Robin van Kessel (Maastricht University); Martin Boeckhout (MLC Foundation); Marthe Stevens, Tamar Sharon (Radboud University), Luca Marelli, and Ine Van Hoyweghen (KU Leuven)

Organization support team
Elisa Leila Elhadj (KU Leuven), Steven Kraaijeveld (Radboud University), Vittoria Porta (European Institute of Oncology Milan & University of Oxford)

Health policy 135 (2023) 104861

Contents lists available at ScienceDirect

Health policy

journal homepage: www.elsevier.com/locate/healthpol

ELSEVIER

Policy Comment

The European health data space: Too big to succeed?

Luca Marelli^{a,b,1,*}, Marthe Stevens^{c,1}, Tamar Sharon^{c,1}, Ine Van Hoyweghen^{b,1}, Martin Boeckhout^{d,2}, Ilaria Colussi^{e,2}, Alexander Degelsegger-Márquez^{f,2}, Selim El-Sayed^{g,2}, Klaus Hoeyer^{h,2}, Robin van Kessel^{i,j,2}, Dorota Krekora Zając^{k,2}, Mihaela Matei^{l,2}, Sara Roda^{m,n,2}, Barbara Prainsack^{g,2}, Irene Schlünder^{o,2}, Mahsa Shabani^{p,q,2}, Tom Southerington^{r,s,2}

Check for updates

Publication: Marelli, L., Stevens, M., Sharon, T., Van Hoyweghen, I., Boeckhout, M., Colussi, I., ... & Southerington, T. (2023). The European health data space: Too big to succeed?. *Health policy*, 135, 104861.

News
European Parliament

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Press room / EU Health Data Space: more efficient treatments and life-saving research

EU Health Data Space: more efficient treatments and life-saving research

Press Releases **PLENARY SESSION** ENVI LIBE 24-04-2024 - 12:55

- Citizens will have access across the EU to an electronic health record containing prescriptions, imagery and lab tests
- Anonymised health data to be shared for research e.g. into rare diseases
- Strong privacy safeguards governing how and for what purpose sensitive data are shared

MEPs approved the creation of a European Health Data Space, improving citizens' access to their personal health data and boosting secure sharing in the public interest.

Expert workshop, Oct. 2022



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WP6 – Dissemination



Research papers:

Marelli, L., Stevens, M., Sharon, T., Van Hoyweghen, I., Boeckhout, M., Colussi, I., ... & Southerington, T. (2023). The European health data space: Too big to succeed?. *Health policy*, 135, 104861

Lieievrouw, E., Marelli, L., & Van Hoyweghen, I. (2024). Weaving EU digital health policy into national healthcare practices. The making of a reimbursement standard for digital health technologies in Belgium. *Social Science & Medicine*, 346, 116620.

Media outreach:

Opinion piece (*politico.eu*): «From Progress to Paralysis: bridging the translational gap in digital mental health care»

Conferences and workshops:

25 October 2022. International workshop: «Towards the European Health Data Space. An interdisciplinary expert roundtable». KU Leuven



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WP6 – Challenges, delays, and solutions



- **JCA & DPA**

Complexity in arriving at institutional agreement on **one single joint agreement** (rather than multiple ones), though this should streamline data processing operations down the road



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WP6 – Next steps



- Next EAB meeting planned for Fall 2024
- Ethical monitoring
- Analysis of EHDS Regulation (consolidated text approved by EU Parliament)
- Analysis of regulatory challenges for DMMH uptake



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