



WP6 – Ethics & Legal Framework

**WP Lead – Ine Van Hoyweghen
KU Leuven, Life Sciences & Society Lab**

**General Assembly meeting 16.11.2023
Luca Marelli & Elisa Lievevrouw**



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



WP6 – Work plan 2023

- Ethics Advisory Board scheduled **before Christmas 2023**
- Preparation of an Ethics Report for this meeting
- If anyone from the consortium would like to join this meeting, please contact Luca Marelli



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

WP6 – Work plan 2024



Year	N°	Deliverable/Milestone	Activity
2024	D6.9	Ethical Monitoring (3)	Submission internal report (31/03/24)
2024	D6.10	H - Requirement No. 3	Submission internal report (30/09/24)
2024	D6.11	Policy White Paper	<ul style="list-style-type: none">• Document analysis of regulatory landscape for mental health apps• Expert conversations with IMMERSE members on regulatory barriers for implementation mental health apps
2024	D6.12	Ethical Monitoring (4)	Submission internal report (31/03/25)



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

WP6 – Data Collection White Paper



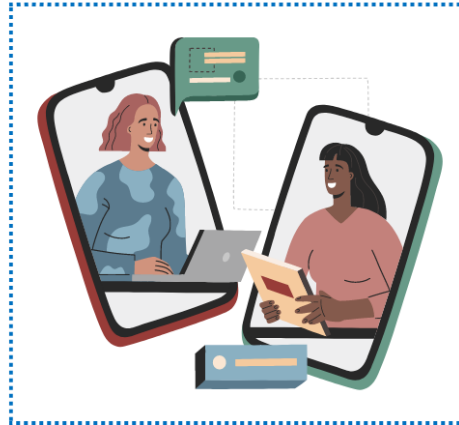
2023



1. Document Analysis

Overview of regulatory challenges and opportunities for mental health apps

2024



2. Expert conversations

Online conversations with IMMERSE members on regulatory barriers for implementation TherapyDesigner App

2024



3. Focus Groups

Focus groups with IMMERSE stakeholders on governance of mental health apps



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

WP6 – Data Collection White Paper



IMMERSE



1. Document Analysis

Mapping exercise

Mapping the relevant regulatory/industry and policy documents for digital health

Overview of challenges/opportunities

Understanding how they challenge DMMH research, and the expansion of DHT in general

Desk Review of existing ELSI literature

Accepted publication (2023) in Social Science & Medicine on “Weaving EU digital health policy into national healthcare practices. The making of a reimbursement standard for Digital Health Technologies in Belgium” by Elisa Lievevrouw, Luca Marelli, Ine Van Hoyweghen

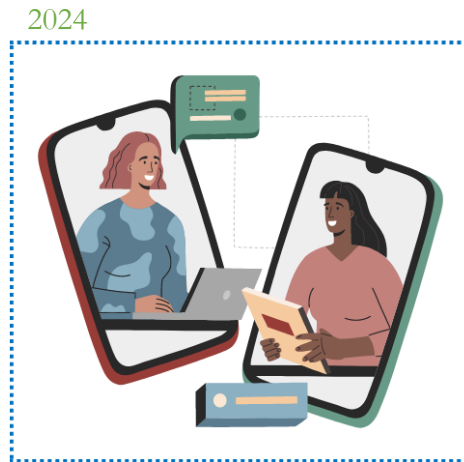


This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

WP6 – Data Collection White Paper



IMMERSE



2. Expert conversations

Expert interviews with IMMERSE partners to understand these regulatory challenges and opportunities *in practice*

Which regulatory challenges did you encounter in the development of the TherapyDesign app?

What are the regulatory barriers and opportunities for digital health?

Accepted Ethical Approval by Social and Societal Ethics Committee (SMEC) on Sept. 6, 2023

Start planning interviews

- Who? PI's, PhD/Postdoc researchers, Industry partners, across different countries
- When? January 2024, Online
- Recruitment? **Today** at Steering Committee, or email Elisa Lievevrouw



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

WP6 – Data Collection White Paper



2024



3. Focus Groups

Towards a white paper for DMMH research

Building from the document analysis and interviews, we aim to organize focus groups with members from IMMERSE and external stakeholders to discuss different ways forward to govern digital health technologies

Planned for **September** 2024



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