

WP6. Ethical and legal framework

**Lead: Ine Van Hoyweghen
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General Assembly meeting, Bratislava 4-5 May 2023



WP6 – Deliverables, Milestones & activities in 2022 - 2023

Year	N°	Deliverable/Milestone	Activity
2022	D6.7	Ethical Monitoring (1)	Deliverable submitted and accepted (31/03/22)
2022	MS13	Second analysis of regulatory requirements (Focus: European Health Data Space)	<ul style="list-style-type: none"> • Interdisciplinary Expert Roundtable in Leuven, 25.10.2022 • Position paper (under review)
2023	D6.8	Ethical Monitoring (2)	Deliverable to be submitted

To do list:

- Collecting ethics & regulatory approvals Phase II
- Participation in WP7 meetings (amendments)
- Ethics approvals protocol tracker



WP6 – Interdisciplinary Roundtable

Leuven, 25.10.2022



Panel 1. Irene Schlünder (TMF Berlin), Tom Southerington (FINBB), Sara Roda (CPME), Dorota Krekora Zajac (University of Warsaw), Ilaria Colussi (BBMRI)

Panel 2. Mihaela Matei (ECRIN), 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. Seliem 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)



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

WP6 – Work plan 2023-2024



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	MS.19	Third analysis of regulatory requirements, feeding insights back into the project	<ul style="list-style-type: none"> • Draft paper on conflicting consent requirements for DMMH apps • Document analysis of regulatory landscape for DMMH apps • Expert conversations with IMMERSE partners on regulatory barriers for implementing DMMH
2024	D6.11	Policy White Paper	
2024	D6.12	Ethical Monitoring (4)	Submission internal report (31/03/25)



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WP6 – Proposed publication on conflicting consent requirements for minors

WHAT IS AT STAKE?

17+



Parental consent needed to download Therapy Designer app for minors under 17.



“Parental oversight recommended”



MDR
Informed consent of the minor’s «legally designated representative» needed

12+



No parental consent needed for research participation



Research Ethics Documents:
Minors generally recognized as vulnerable population (reduced autonomy), hence entitled to protection

Conflicting age requirements for the TherapyDesigner Application



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WP6 – Proposed publication on conflicting consent requirements for minors

WHAT IS AT STAKE?



Normative Analysis

What are the ethical implications of involving "consenting" minors in research without parents' consent?
Does minor's consent meet criteria of validity?
Are minors a vulnerable population to be protected?

Analysis of Governance Issues

How do distinct age thresholds for consent relate to different regulatory categorizations?
What does it say about the role of Big Tech in regulating new health technologies?
How to tackle harmonization issues across different scales of governance?

Are there other relevant elements that should be added to this discussion?



WP6 – Proposed publication on conflicting consent requirements for minors



Proposed Paper Outline

Introduction: The IMMERSE project and the issue at stake

Conceptual background: Overview of conflicting age requirements & distinct logics behind these competing requirements

The TherapyDesigner Case: How does this mismatch impact on the development of TherapyDesigner app?

Analysis of normative and governance issues

Discussion: how could these issues be tackled?

Suggested steps forward ...

1. First Working Group meeting: end of **May 2023**
2. Submission abstract to IMMERSE: end of **May 2023**
3. Submission first draft to journal: **September 2023**

Would you like to contribute?

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WP6 – Data Collection White Paper

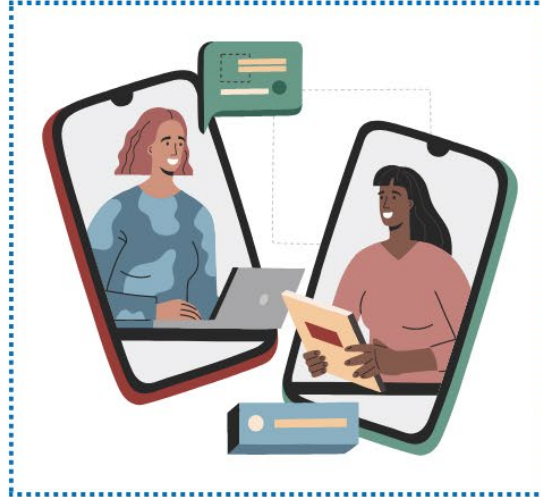
2023



1. Document Analysis

Overview of regulatory challenges and opportunities for mental health apps

2023



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



WP6 – Data Collection White Paper



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



WP6 – Data Collection White Paper



2. Expert conversations

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

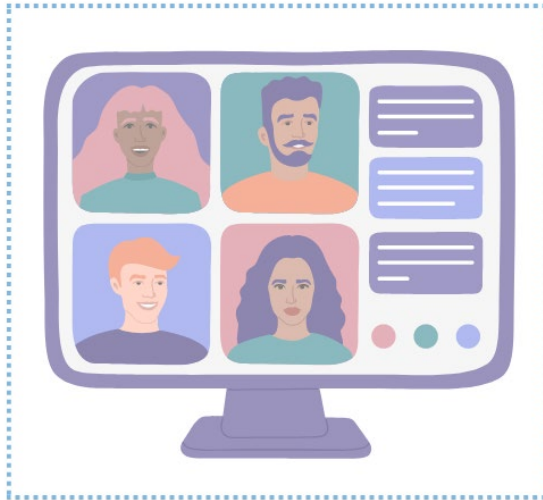
Which regulatory challenges did you encounter in the development of the TherapyDesign app?
What are the regulatory barriers and opportunities for digital health?

**Conversation invitations will be sent in
Autumn 2023 !**



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





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