

IMMERSE minutes 27-5-21 Kick-off meeting day 1

Present

WP1	Inez Germeys	Tessa Biesemans		
	Martine van Nierop	Daphne Tuyaerts		
	Silke Apers	Davinia Verhoeven		
WP2	Jörg Ottenbacher	Simon Krause		
	Johannes Schneider			
WP3	Thomas Ganslandt	nas Ganslandt		
WP4		Peter Kuppens		
		Manuel Brenner		
WP5	Maria Wolters			
	Theresa Ikegwuonu			
WP6	Ine van Hoyweghen	Irene Schluender		
	Luca Marelli			
WP7	Uli Reininghaus	Yvonne Beauge	Simona Di Folco	
	Matthias Schwannauer	Julia Schulte-Strathaus	Anita Schick	
	Michel Wensing	Rafael Bonnier	Lena Wieland	
	Michal Hajduk	Lena de Thurah	Anton Heretik	
	Manuela de Allegri	Zuzana Katreniakova	Daniel Dancik	
	Glenn Kiekens	Iveta Nagyova	Jan Pecenak	
WP8	Evelyne van Aubel			

EU project officer	Cornel Riscanu
SEAB	Lucia Valmaggia
	Stefan Wellek

1. WP1 – General management

Communication:

- Contact Martine van Nierop to access the internal website and basecamp.
- Provide your contact details to Martine van Nierop for the public website if applicable.
- Having a Twitter account is a requirement from the European Commission, so add your contact information if applicable to the google spreadsheet and share content on twitter during the entire project!

 $\frac{https://docs.google.com/spreadsheets/d/1Kufo8wa2okNB4BSUDSfhQGblvkjxlkAw2nro7-SWtSs/edit?usp=sharing}{}$

General Assembly Meetings:

- 1. December 2-3 in Leuven, Belgium
- 2. May 2022 in Edinburgh
- 3. May 2023 in Slovakia or Germany?
- 4. May 2024 in Slovakia or Germany?
- 5. February / March 2025 in Leuven, Belgium
- □ Determine location in May 2023 and May 2024

Reporting:

Funding depends on reaching our deliverables! Please stick to the deadlines, if delays occur you need to provide an explanation and propose a new deadline which requires an amendment, but that can always be declined by the European Commission.

⇒ Check reporting calendar on website

2. WP2 - Prototype development

Request: everyone needs to provide feedback to WP2 to further develop the app.

- ⇒ Simon will re-send request to appoint a contact person for each role
- ⇒ WP leads 3-4-6 still need to delegate a contact person for each role

3. WP3 - Data management, data security and interoperability

Task 3.1: FAIR data management:

Organize workshop to present a draft version of DMP so it can be finalized in the beginning of September 2021.

Steps to access the data:

- Submit abstract (explain what you want to do and which variables you need for that)
- Approval by WP representatives
- Pre-registration (detailed info on hypotheses and analyses plan) via Open Science Framework

Run analyses on the platform itself or distribute the data?

⇒ Schedule data governance meeting (Feasible? Requirements? Data linkage with other systems? Suited for all analyses, e.g. qualitative analysis?)

4. WP4 - Modeling

Questions:

- What kind of information / format do we provide to Movisens?
- Data interface (with WP3)
- Can we do (compute heavy) ML analysis without pulling the data?
- What kind of "simple statistics" are actually "simple" to understand?
- ⇒ Schedule meeting with WP7 to discuss more detailed guestions.

ML to optimize feedback to the clients. We need to guide clinicians so they don't get lost in the pool of data and all different associations. Can a model push forward what the most helpful feedback would be for a particular client in that particular moment?

⇒ Set up wider discussion with WP 5-7 on machine learning models and visualizations

5. WP5 – Stakeholder Experience

- Every site that will collect data will facilitate and participate in WP5 = collaboration with other PhD students and Postdocs.
- Set up training sessions for analysis.

6. WP6 – Ethical and legal framework

- ⇒ Provide a contact person within each partner institution: someone who's part of the consortium and can be a link with the ethical committee.
- ⇒ Provide input on study protocol (BC W7 folder)
- ⇒ Provide input on ICF and inform WP6 on local requirements
- ⇒ Appoint data protection officer (KUL, EUDIN, CIMH, UK BA and UPJS)

All local applications need to be harmonized within the consortium. If your local requirements differ from general template, you need to raise that issue with WP6.

WP 3 needs to provide a description of the following aspects:

- Security measures to prevent unauthorised access to personal data or the equipment used for processing
- Anonymisation/pseudonymisation techniques
- Technical safeguards measures for data subjects
- Implementation of data minimization principle

Medical device regulation: plan meeting with MedX

7. WP7 – Implementation strategies, processes, outcomes and costs

Uli will reach out to Maria Wolters, Matthias Schwannauer and Michel Wensing to finalize the study protocol.

Publish protocol papers of phase 1 and 2?

8. WP8 - Dissemination and exploitation

Exploitation Steering Committee charter: 31/07/2021

⇒ Set up a first meeting WP leads, leads of centers and LRD do discuss how to take this forward and lay out a road map. Schedule a meeting every 3 months.

9. DMMH intervention

Structure:

Monitoring: working on requirements of DMMH
 Action: make decision on CORE and add-on items

b. Feedback:

Action: make decision on visualizations and reflection of CORE and add-on items. How is everything displayed on the dashboard, automated with machine learning? Automized dashboard and pin different data modules or specific graphs? Pinning and reversing the order might not be so simple and needs to be discussed further with Movisense.

Movisens app will support both IOS and ANDROID.

- c. Discussion topics:
 - o Intervention design: when is the intervention provided and how and for how many days? We proposed it would be included every time an important decision had to be made in the clinical process. What do we do if clinicians don't use it? Do we go beyond important decisions? Flexibility or degree of freedom within frequency of beeps? Snooze function?
 - o Get a basic module ready for Movisens: Inez, Uli and Matthias
 - Passive sensing is not possible with IOS, development with MDR requirements will be
 a lot more complicated, then you'll have sensors instead of chats. Maybe include it in
 a second version at the end of IMMERSE. Sensing is provided as a research component
 but not part of the intervention.

⇒ Create a priority list

Provide CORE items within each category (e.g. mood, context, sleep). These can be equal for all and the specific content of the items within each category can be personalized. Discuss the degrees of freedom in CORE part.

- ⇒ Comment on the item repository document by 04/06/2021, add suggestions on what needs to be in the CORE of overall categories and items.

 (https://docs.google.com/spreadsheets/d/1kZQ2Va4LOdxNfsh4_H_gPYTLVSh-1Ggf7QAoVdSFIXs/edit#gid=1169975277)
- ⇒ Plan a meeting in the week of June 7 to discuss this further
- ⇒ Protocol ready by June 15th

Actions

Who	What	When
WP leads	Determinate location general assembly meeting in May 2023	
WP leads	Determinate location general assembly meeting in May 2024	
WP leads	Share content on twitter	
WP 3	Simon will re-send request to delegate different roles	ASAP
WP 3-4-6	Provide WP2 with list of contact persons per role	ASAP
WP 3	Organize workshop	ASAP
WP 3	Provide description to W 6	15-06-2021
WP 4	Reach out to WP 7 for basic statistics	
WP 4	Set up wider discussion with WP 5-7 on machine learning models	
	and visualizations	
WP 5	Set up training sessions	
WP leads	Provide contact person, link with ethical committee	ASAP
WP leads	Provide input on study protocol	15-06-2021
WP leads	Provide input on ICF and check local requirements	15-06-2021
WP leads	Appoint data protection officer	15-06-2021
WP 6	Data governance meeting	17-06-2021
WP 6	Submit protocol and ICF for ethical approval	15-07-2021
WP 6	Plan meeting with MedX	ASAP
WP 7	Finalize study protocol	07-06-2021
WP 8	Schedule meeting with steering group	ASAP
ALL	Comment on the item repository document	04-06-2021
ALL	Plan a meeting to discuss the CORE and add-on items	07-06/11-06