

IMMERSE minutes 14/7/22 Steering Committee

Present

WP1	-	
WP2	Simon Krause Johannes Schneider	
WP3	Thomas Ganslandt	
WP4	Georgia Koppe	
WP5	Maria Wolters	
WP6	Luca Marelli	
WP7	Uli Reininghaus	
	Anita Schick	
	Michel Wensing	
	Rafael Bonnier	
WP8	-	

1) Approval of minutes of last SC meeting

2) Status of workpackages

1. General Management

Distribution of work and communication among and between workpackages:

- a) There are differences in how PhDs are handled in the different countries, need to communicate if there is staff available or not to share workload
- b)Difficult to find information in Basecamp, agreed to use task list in basecamp more often to allocate tasks

2. WP2

Usability test of dashboard is completed, usability test with app is ongoing. They are working on visualizations for the app. Verification by researchers will start 25.7.22. They will prepare test descriptions, so that the verification test is done quickly.

The deadline of 15.8. to upload documents to ethics is tight but feasible.

Question on use of MovisensXS software for ESM outcome data collection: Agreed to disentangle the question of costing from impementation, so that PhDs will be able to start translating/impementing the ESM in the respective languanges. Simon will ask Jörg about the process.

3. WP3

There will be a NextCloud from Uni Erlangen for data exchange. Maria volunteered to test the link. Evelyne shared the Redcap zip of the Abstract system. Will be transferred to Uni Erlangen aswell. Not yet available.

4. WP4

Finished implementation of statistics with WP1. Working on modeling and movement data. No conclusions on the use of mobile sensing data yet.

5. WP5

Phase 1 data analysis ongoing. The process of codebook development is delayed. In the deliverable report only the qualitative data from Mannheim site will be included. Data collected until 01.08.22

Question: Who wants to co-write the report? Who wants to provide feedback and by when should the first version of the report be circulated? (Deadline is Mid September)

6. WP6

Status of DTA of phase1: Thomas forwared DTA to legal department Uni Heidelberg. 3rd round of feedback collection is ongoing until 1.8.22

Phase 2: Discussion within Leuven LRD and CTC on who works on DTA phase2. Luca wants to ask Katrjien to take on the lead.

DMEC: First meeting will be scheduled for 3rd week of September. Separate meetings of DMEC and ethics advisory board. All board members need to sign the non-disclosure agreement.

7. WP7

Rafael submitted phase 2 ethics application to CTC and received the feedback on safety which was included in the final version of the clinical investigation plan. However, the application also has to go the the competent authority in Belgium and thus, the results of the usability tests and verification are also necessary.

There will be a separate statistician for randomization, ESM will additionally be randomized.

We need to work on measures (e.g. ESM outcome collection), eCRF testing. A second database (eCRF) is needed for blinding, which may come with additional costs!

8. WP8

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9. Papers

Suggestion by Uli: Collect synopses for some months to then hold them along each other and discuss overlap. Where there is synergy, synopses can go together.

There were no comments on this proposition. It will be discussed in the next SC meeting.

10. AOB

Actions

Who	What
Thomas	Provide Maria access to Cloud
Luca	Ask Katrjien to set up DTA phase 2