

IMMERSE minutes 18/11/22 Steering Committee

PRESENT

WP1	Inez Germeys	Silke Apers	
	Martine van Nierop	Blijke Van Loon	
WP2	Simon Krause		
WP3	Thomas Ganslandt		
WP4	Georgia Koppe		
	Daniel Durstewitz (online)		
WP5	Maria Wolters		
WP6	Luca Marelli		
WP7	Ulrich Reininghaus	Michal Hajduk	
	Anita Schick	Adam Kurilla	
	Michel Wensing (online)	Matthias Schwannauer	
	Iveta Nagyova (online)	Rafaël Bonnier	
	Zuzana Katreniakova (online)		
WP8	Evelyne van Aubel		
	Jeroen Weermeijer		

1. General Management

(see slides on https://immerse-project-members.eu/meetings)

Blijke Van Loon is new in the team at KU Leuven, please let her know any possible topics for the newsletter and for Twitter, she will also be contacting you for content. Evelyne van Aubel will be leaving us, Jeroen Weermeijer is taking over as WP8 lead.

The technical report of the first period is done, the financial report will be submitted soon. WP1 will share the results of the KU Leuven audit to show which documents/costs are accepted and which are not, as help for future financial reporting.

Please all keep up with your quarterly reports to make it less stressful at the end of a period, and use the templates Martine sends as a documents that builds (so keep working on text from the last quarterly).

Next General Assembly meeting is on May 4th/5th in Bratislava.

Next week there will be 3 practice sessions for the EC evaluation on December 1st. All WP leads (plus WP7 local leads) need to be present (online).

Updates on contracts:

DPA phase 2 is now sent out to everyone, still missing signatures from Edinburgh, UKHP, and UKER, please ask your legal depts to sign asap. DPA Maganamed is done soon (now still at Maganamed). There will be an update on the DPA with medX (now at KU Leuven). JCA signatory version will be sent on Tuesday Nov 22nd.

2. WP5

(see slides on https://immerse-project-members.eu/meetings)

Full targets have been achieved (partly by extra recruitment in some sites), it's a very heterogeneous sample. There are differences in age and gender distribution, as well as sample size, per country, so needs to be addressed in analyses. Some free-text data (self-reported diagnoses, app use) is still missing, needs to be coded. In general, most respondents see benefits of use. For implementation handbook is necessary but will probably not be used, mostly having experienced person to talk to is important.

For the interviews the transcriptions and coding are bottlenecks. Cleaned survey data set will hopefully be ready by beginning next year. All transcribed interview data will be kept in NVivo, can be exported to MaxQDA. WP5 is still working on inter-rater agreement and codebook. Theresa can help until March 31st 2023 with coding. As this is a bog task that needs to be finished, proposed strategies: (1) coding in order of papers; (2) authors of paper code based on DeepL translations (redacted data to avoid data security issues). Essentially everything is transcribed except for Kosice (suggest to outsource?). Iveta will take this up with Matej.

For in-depth studies on the qualitative data, full interview subsample will be used (not all data translated with DeepL), or collaboration between 2 PhDs from 2 countries. We will plan ahead collectively on topics. Maria and Theresa will be working on overall phase 1 (quantitative) paper, and 2 qualitative papers (1 on data sharing between stakeholders, other abstract under discussion).

A lot of coding of the interviews still needs to be done. Proposed to get at least 1 student from each country on a team who are interested in using these data, to get coding underway, although phase 2 right now has priority (there is such a team now but they are very busy). Each site should make sure that PhD students still have time (like 1 day a week) to write, for them but also we will be assessed based on our scientific output.

Proposed: google doc on Basecamp where people can list potential ideas for papers as brainstorm doc (Jeroen will set this up).

3. DROPS

(see slides - WP8 - on https://immerse-project-members.eu/meetings)

DROPS (abstract submission system) is now online, so all abstracts should be submitted there. It also allows archiving of papers that are being worked on, and allows for data sharing with externals. See steps in slides. There will be automatic emails from RedCap to all relevant parties (DGB, full consortium), and it monitors how long ago people submitted abstracts. In principle (but exceptions are possible), authors should have preregistration ready within 6 months and (depending on data availability) the papers should be submitted within a year after data became available. Written papers should be shared with all co-authors by the author (not WP8). When abstract is registered (by DBG) as key paper clinicians will be allowed co-authorship, to be forwarded by the authors. Opt-in co-authors need to react within a month. Pre-registration and OA is mandatory (free version of OA is possible, for example KUL database or with EC). See slides for which information is needed for an abstract submission.

Which measurement of data (baseline, follow-up) will be added to DROPS.

4. Abstracts

We will provide dummy datasets so people can already submit abstracts and write code for analyses (to keep things moving and we won't have to wait until data is ready). We will use the IMMERSE group name only for abstracts for conferences. Clinicians could also be added as 'investigators', also if they haven't commented on the papers (so they can be found via Pubmed). Jeroen will figure out how this works.

Decisions on submitted abstracts:

https://docs.google.com/spreadsheets/d/18O3VEmojow0oPs8o7Ag3XHHOW1qALcuBY E4r8C4YRI/edit?usp=sharing (green is approved, orange needs some work). Jeroen will contact all authors to submit these in DROPS.

All abstracts submitted 1 week before the SC meeting will be discussed in that SC meeting (which is the DGB). Martine has posted the abstract submission deadlines on Basecamp.

Julia's abstracts: Julia, Lena, Adam, Theresa, and Islay will sit together and divide the topics a bit more and make them more specific. Jeroen had some comments on Anita's abstract (a bit too broad), he will share with her.

Rafael's abstracts are a bit close to main papers, we'll look at whether we have PhD projects connected to main papers later. Rafael will discuss further refinement with Uli, Anita and Matthias.

Iveta added another abstract during the meeting, this will be discussed in the next DGB meeting.

Inez was invited by Psychol Med to write a review on mobile health and its clinical applications (in 2020), and they asked again. **Any PhD students who want to team up with Inez can let her know**. Maria also wants to join. This will be written at least within a year (not an IMMERSE paper, is a separate review).

There is a no data option in DROPS so overview papers can be submitted there as well.

5. WP7

(see slides on https://immerse-project-members.eu/meetings)

Kosice is still working on ethics for phase 2 (meeting of committee on December 6th), and notification of competent authority (not clear if this can be combined with Bratislave, which is done). Site initiation visits still need to be planned in Wiesloch and Kosice. D7.1 and 7.2 have been submitted.

Multiple workshops have been done, tailored to needs in local sites.

Site contracts are being worked on, only Leuven and Wiesloch are done. (update 25/11 signatory version is sent to Bierbeek) Everyone please chase your legal departments! Trial is registered (link in slides), recruitment will start very soon. There are some delays for upcoming milestones, D7.3 may have to be delayed (we will let the PO know this well ahead of time). Recruitment will also be a bit delayed, if recruitment is too slow we can add additional sites. See recruitment target graphs in slides.

We need to really make sure to finalize and clean all data directly after last measurements are done, so this becomes available within the project.

Blinding may prove to be a big bottleneck in terms of available staff, especially when recruitment becomes more compressed, and our measures have low risk of bias. Also the blind researchers can't fill out the 1 questionnaire that have higher risk of bias. We will rediscuss deblinding later on in the project.

6. WP6

(see slides on https://immerse-project-members.eu/meetings)

Luca has taken a new position in Milan, he will remain part of IMMERSE.

He needs all ethic packages phase 2 for the evaluation meeting. Everyone please jump in during evaluation in case of questions about local situation.

DMEC is about monitoring patient safety, the EAB will be informed by DMEC and asked to look at overall ethics of the project. There is a December meeting with EAB, they will be sent our technical report. See slide on the IMMERSE organizational structure for IMMERSE, also to be used for evaluation. Luca will send out doodle for EAB meeting.

Luca will write a (critical) paper on proposed Regulation on the European Health Data Space (abstract is approved, see list of critical issues in slides WP6).

WP6 is on track with all deliverables, Luca will discuss issue with ethical monitoring with Martine (update 25/11 is clarified).

7. WP2

(see slides on https://immerse-project-members.eu/meetings)

D2.1 has been submitted. The app is now available in PlayStore and AppleStore. See app and dasboard in the slides (video version in recording of afternoon session, starting 2:00 point). Apple required some changes in mandatory settings (such as notifications, is now not mandatory, so inform your participants to give permission for that!). There is now also feedback (simpler) in the app. Translations still need to be checked. Gamification (growing tree) is done. When people make changes in the dashboard they can see a list of all changes, and therapy can be paused. Simon is continuously testing, and has started conducting systemtests. We can ask competent authorities if they want updated tests. movisens needs all JCA's to be in place to be able to collect any data. Please let movisens know when there are still bugs throughout the project.

They are now getting offers for PEN-testing (external security experts), and will decide on scope for testing.

Issue for scheduling of beeps; in some locations reception is bad (is being worked on), and some participants are not allowed access to phones during certain periods, but can during break times. If movisens would change it to account for this it might have to go through risk testing and ethics again. Or extend the period that people are able to respond to beeps? We keep as is for now, see how big the problem is after start of data collection.

We will start systematically collecting suggestions for changes, and based on that decisions will be made if changes are relevant, feasible, etc, if so they will be implemented in 1 go for a new version.

There's a cut-off after a certain time after a beep, movisens will look at options to at least allow to finish questionnaire if that deadline is in the middle of filling it out.

8. WP4

(see slides on https://immerse-project-members.eu/meetings)

For explanation on background video afternoon session starting 41:00 point. Suggestions for analysis: (1) short term forecasting (e.g., impact sleep quality on affect); (2) Long term forecasting (e.g., cyclic pattern in days/weeks in behavior); (3) Integration of sensor data with ESM data (does passive data improve prediction of active data?); (4) DMMH effects; (5) comparison of sampling periods.

The goal of these analyses - how will it improve intervention?

- -(ad 1) to give interventions via phone;
- -or to predict what the dashboard (intervention) has as effects (data for this is currently not collected)
- -to find targets / patterns to change/improve outcome (e.g., through network analyses)

-to find which items are most relevant to choose in the app (based on previous week, which modules to choose for next week). But data and available models are probably not sufficient for that.

(Michel) suggestion: try to show that these models are more helpful than simpler models or clinician predictions. And show that the model can handle missing values.

9. WP3

(see slides on https://immerse-project-members.eu/meetings)

3.1:

1st version DMP has been submitted, this will be adapted to 2nd release including extra details, such as metadata annotation. Proposed to use DataCite schema. This way, even if data is not yet available, the metadata will be public. This will be hosted in Erlangen. The 'creator' could be the IMMERSE consortium, with individual contributors below. For identifiers we will use ORCHID (so everyone should get an account). Long term archiving of the data can be hosted as Erlangen (for free). Content data should not be available without decision of DGB, but for example construction of questionnaires should? ESM items will be added to KUL ESM Item Repository. Description of clean data will be on OSF, WP8 will look at possible other descriptions to put on OSF.

3.2:

Also submitted. Now working on semantic annotation of questionnaire items, which will be a lot of work. See slide on changes in architecture (change in ID management).

3.3: Ongoing (see overview on slides).

-dummy datasets specifications: only technically correct data is good for now (would not necessarily make sense), with correct labels. But for power calculation that would not work - WP3 will then run the power calculations on actual data (is quicker then to create a dataset). Ginette Lafit (KUL) can help with that.

All audio recordings of phase 1 will stay locally, transcripts will be stored in Erlangen. This will be moved step by step, as soon as some data is clean it will be moved.

Local sites (e.g., NHS) will have access to data via DROPS, also if it's not for a paper but for a report. But this comes with the same limitations (so no playing around with the data after they receive it). An extra question about abstract / local use (which site) will be added to DROPS.

10. WP8

(see slides on https://immerse-project-members.eu/meetings)

Dissemination plan will be updated each 12/18 months. WP8 will work on new acknowledgements for papers.

There's no dissemination strategy yet for 2 deliverable reports (3.2 and 5.1, but these have not been approved yet (so that will happen after EC approves). 5.1 can do a blog, twitter and mastodon. Also Mental Elf? And of course the papers.

3.2 is already public after EC approves, and the implementation guide profile is already available via Erlangen platform. This information is also a service, and more exploitation. This can be discussed in next Exploitation Steering Group (15/12) - here also other exploitation routes will be discussed. 3.2 can also be submitted to the community for balloting, then people are publicly asked to comment. After that it gets an official stamp of approval. Or we can introduce FIHR profiles into German Medical Informatics Initiative. Or using FAIR metrics: this describes how FAIR a project is, regarding amount of metadata etc, so we would assign FAIR metrics over time (now too early).

We need a clear timeline for the website. Martine and Jeroen will discuss.

Please all let Jeroen know if you have other ideas for dissemination.

Educational / promotional videos: we'll collect testimonials. The videos will come later (now only short mouse over videos, but these are not fully public, only available for clinicians). UK is planning to do animated videos, which are easily changed in each language with a different voice over.

11. AOB

PABs: UK is actively recruiting for their PABs. Rafaël and Lena are working on it in Belgium. Bratislava will start working on this, Kosice will collaborate on that with them. Germany will join a meeting where they can present an abstract, then this board (?) will decide if they will support IMMERSE.

SAB needs to be contacted again, and invited to GA. Some dialogue between SAB and PAB would also be good, so also invite members of PAB to GA.

Actions

Who	What
Jeroen	Figure out 'investigators' for clinicians to
	be on papers.
Jeroen	set up brainstorm doc for paper topics
Local WP7 leads	Send Luca ethics phase 2 approval
	package
Everyone	get ORCHID
WP8	send around new version of
	acknowledgements for papers
Martine + Blijke	start Mastodon account
WP7	keep in mind we need testimonials
WP7 clinical sites	don't forget the PABs!