**IMMERSE minutes 15/9/22**
**Steering Committee**

**PRESENT**

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|---|---|---|
| **WP1** | **Inez Germeys** | |
| **WP2** | **Simon Krause**<br>**Johannes Schneider** | |
| **WP3** | **Thomas Ganslandt** | |
| **WP4** | **Manuel Brenner** | |
| **WP5** | **Maria Wolters**<br>**Martien Wampers** | |
| **WP6** | | |
| **WP7** | **Ulrich Reininghaus**<br>**Anita Schick**<br>**Michel Wensing** | **Matthias Schwannauer**<br>**Rafael Bonnier** |
| **WP8** | | |

1. **General Management**

All periodic reports need to be sent to Martine no later than September 30th. All outstanding Deliverables now have a deadline of end of October (no possibility of any delay after that, due to evaluation – D2.1, 5.1, 7.1 and 7.2)

DPA phase 1 is signed.

2. **WP2**

Documents for ethics are finalized. Now working on missing systems tests and deliverable report. By end of September they can provide a system with all translated texts in dashboard and in app, after that they will work on gamification part. The clinician workshops can start as soon as the dashboard and app are available in all languages (26th September). The gamification is not important for the workshops. Should be no problem to have everything available for sure so workshop dates can be in mid October.

3. **WP3**

University of Heidelberg is officially no longer part of the consortium.
There is now an interface to export the ESM data and sensing data collected on movisens xs. Right now that export is done manually but will be automated on nightly basis. There is now a shared network drive in Erlangen (UKER cloud), where data can be made (selectively) available to consortium members. The anonymization of geo data needs to be finalized

before this system can be live (for now just ESM data will be uploaded, not mobile sensing data). eCRF forms and items have been finalized in english version. We requested an export file from medX but hasn't been received yet.
Thomas and Simon will discuss how to extract data from moment app.
What is unclear now is what we do with the extra data we collect from participants in the experimental condition, as it was financially not feasible to have this in MaganaMed. It is technically possible to do this in RedCap, but it is unclear whether this is allowed for our project. There are other studies in Erlangen using RedCap for similar purposes (GCP compliant), but there is also a cost attached to that (not sure how much).
Anita has worked on preparations that we can collect that data via movisens XS. This should all be ok as we are already using that system for other data.
Randomisation will be done via an internet randomizer. The allocation will be part of the process documentation. Details will be discussed later.
The status now is that all translations for the eCRF are done, but still needs to be implemented by medX.
Thomas will look into a way to make sure researchers can see for example how much the participants are using ESM, without them seeing the actual raw data.
The UK doesn't allow any identifying data to be stored outside of the UK, which is an issue for the ID management system (personal data needs to be entered in MaganaMed to get pseudonym for the patient). Workaround: local ID management for UK, that generated identifier will be put into the central system.

4. **WP4**

Manuel worked with Johannes to translate the statistical tests. WP4 is now focusing on developing models, and has developed evaluation framework from existing EMA data. They are testing 4 different models in this framework.

5. **WP5**

Martien Wampers (datamanager at CCP) has joined WP5 to help with the data, datascripts are now with Martien. Survey data is coming along well. All sites (except from Julia?) have sent recruitment reports, these describe how phase 1 went. Therese is now working on the qualitative findings. By the first week of October they should have a doc ready for people to comment on. Especially comments from PIs are very welcome (to make sure the right interpretations have been made on recruitment).
There is still an outstanding issue with the open text fields of the survey, but there was no time to deal with that yet. After the deliverable is out, Maria an Theresa will start sorting through the data and will start preparing the initial papers. When PhDs will have time again (as they are the working on WP7) they can start publishing on phase 1 data. Then they will start working on those open text fields (we still need agreement on classification for these texts).

6. **WP6**

Inez has contacted Luca after this meeting to discuss progress on DTA for phase 2 – there now is a first draft sent out to all partners. JCA will also be done soon.

## 7. WP7

See slides on update WP7.
The trial has been registered by Anita. Most sites have submitted their ethics and notified competent authorities where this was required. Approval is in place in Bratislava. Kosice has not submitted yet but is confident approval will be in place fairly quickly. See timeline on slides, which can feasibly be uphold in Bratislava, Edinburgh, and Mannheim (due to advanced ethics status).
Site visits by medX will happen over the course of October.
Uli and Anita would like to sometimes join the local recruitment meetings to get a good start of the trial.
The plan now is to start randomizing only part of the units, and do a 2nd randomization later if needed. I can be considered to randomize more units in UK, as they have more available, but this is not needed for the other sites. We mostly need to make sure there will be enough participants in each site.
Attendance was rather low at the last clinicians meeting (only 2 sites were there). Everyone make sure your clinicians are aware of these meetings. We will plan another one in November/December. Right now we are only inviting clinical heads, but as soon as the units are in we will open these meetings up for unit leads. No researchers can be present at those meetings to prevent deblinding.

## 8. WP8

We have a vacancy for a student (at KUL) to work on the newsletter.
Evelyne is still ill.
**@Thomas what is the status of the abstract submission system?**

## 9. AOB

## 10. Papers

-Inez' paper – conceptual based on application (still in progress, not super urgent)
-We need a protocol paper for the trial – Anita will take the lead, first draft of the statistical analysis plan is ready, will be published on OSF. After that the paper will follow.

## Actions

| Who | What |
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