

# IMMERSE minutes 15/6/2023 Steering Committee

#### **PRESENT**

WP1	Inez Germeys	
	Martine van Nierop	
WP2	Simon Krause	
WP3	Thomas Ganslandt	
WP4	Georgia Koppe	
WP5	Maria Wolters	
WP6		
WP7	Uli Reininghaus	Matthias Schwannauer
	Anita Schick	Zuzana Katreniakova
	Michel Wensing	Michal Hajduk
WP8	Jeroen Weermeijer	

# 1. General Management

No updates or lingering tasks

#### 2. WP2

Is supporting WP7 with any needed documentation for the inspection, and is working on bug reports. The task on export (?) interfaces will now have to wait a bit, as the audit is a higher priority.

They are collecting feature requests from different sites, so they can prepare a list and discuss this during a SC meeting. Simon has sent a doodle request for WP7 to have a meeting on this, but only got 1 reply (maybe because of inspection?). This will be delayed until after inspection.

#### 3. WP3

Is working on a dashboard to show the documentation status, so which questionnaires were done (see video starting 27:42 for a visual). The documents will be in PDF, and will give a completion status. The graph that shows completion by site and visit still needs to be sorted chronologically. They will change the graph in such a way that the bars will show grey instead of red when a form is not due yet. They will discuss further with Anita which reports will also be relevant. And later the movisensXS data and TherapyDesigner data will be included.

They have 2 students working on generating dummy data.

Edinburgh came across an issue with MaganaMed: if patients partially finish a questionnaire or if they skip an item, it stops the MaganaMed entry. The clinician baseline is generated on the same instance their links take them to the last data entry point of the patient. They had to report this as an adverse event because this is a data breach. This now happened twice, and they run the risk that they have to stop using MaganaMed as it is a data security risk. This is definitely not a user error, no solution is there yet. Similar things have happened in Belgium.

Matthias will send Thomas the patient IDs of where this happened and when, he will check the audit trail. Maganamed might have additional data that he can't access. Anita is in contact with MaganaMed to try and figure out what happened.

For now, everyone needs to make sure items can be intentionally skipped, which is very simple, Simona should have contacted everyone about it, but the still need confirmation from Anita whether this is done.

#### 4. WP4

Are still working on updating and improving the algorithm that Manuel is working on. For example he is looking at which features will enhance performance, and what can be dropped, and he's looking at different ways of visualizing the data. Georgia is talking with someone who may have a toolbox that can help with the problem of not being allowed to use GPS data now, via a local geocoding service. Thomas knows someone who also has experience with this.

#### 5. WP5

Had a kick-off meeting for the PABs. Belgium already did the workshop on website/outreach, this will also be done in the other countries. The next one in Belgium will be on D5.1 results. They decided that the process evaluation will not be feasible for the PABs. Maria will email all WP leads a week before the SC meetings asking for suggestions, which will be discussed in the SC meeting.

Maria will meet with Thomas about the phase 1 data, survey data will hopefully be available centrally by August.

Theresa will definitely leave by end of July.

UK is done with coding, Kosice team is being brought up to speed (Bratislava is done), Belgium is still ongoing, and Germany is nearly done with patient data, other participants still ongoing.

DROPS for D5.1 has been submitted, pre-reg for Theresa's paper is nearly done.

## 6. WP6

# 7. WP7

Anita and Uli need input from all WP7 clinical leads for the quarterly reports. From now on, Martine will copy them into the email reminders of upcoming reports. Anita will create a google doc where all can add the updates needed for the quarterly. Anita and Uli also urgently need description of reasons for delay from all WP7 clinical leads, this information is needed for Martine who will use this in her email to the Project Officer requesting a delay for D7.3 (midterm report). In Belgium turnover is the main problem of slowing down of recruitment, in Bratislava it seems that clinicians are less interested to be part of the control group.

Across all sites we are now at 36%, and we should be at 50% now.

There is an ethics amendment coming up, which needs to happen by next month. This is because originally we said that recruitment would end by end of July, but we need more time. The amendment would then allow us to recruit longer. Elisa will coordinate this. Edinburgh has everything ready, they just need the updated CIP. Anita has a document for this which is a work in progress on Basecamp, and she still needs local input.

All WP7 leads also need to check local laws in terms of differences between GDPR and MDR regulations: under GDPR participants have a right to get their data deleted, which is not allowed under MDR rules. There we need to prove that data stays as is, because then results might change and we can't prove that it works. None of the ethics committees picked up on this unfortunately. In Germany they now have to go back to all patients for a new ICF.

Mannheim has an audit coming up. They will first do a mock inspection next week, to make sure that they are ready for the real audit. This is a massive amount of work, and has a price tag. They need signatures on certain documents, so make sure when you get a request to respond quickly. And any contribution for the costs would be very welcome. Please contact Uli about how much you are able to chip in. A practical matter: other sites (so not Germany) can't book this on IMMERSE budget, as the EC will not accept these costs, so it will have to come from some other budget.

# 8. WP8

There is now a PhD student blog on the website, please share on any social media <a href="https://immerse-project.eu/home-en/blog/">https://immerse-project.eu/home-en/blog/</a>

Newsletter is also underway, with an update to all clinicians every month. In the next ESG the will talk about IP.

## 9. Papers

Lena will get an extension (according to DROPS timeline she should now submit her prereg).

Main papers will have 2 reviewers, Jeroen will choose them.

Paper authorship

We will not work with the opt-in and opt-out system anymore, the process will now be as follows:

As soon as an abstract is approved, the whole consortium will be emailed, asking if they want to be a key-author (so also work on the pre-registration). There will be a hard deadline for this response, no response within 3 weeks means no key-authorship. If someone has their automated response due to holidays on they get more time. After a paper is done, it will be sent out to the whole consortium again, and everyone who provides comments on time (3 weeks) will be a co-author.

Jeroen will update the slide on this process, and the co-author message.

## Actions

Who	What
WP7 leads	Send info for the quarterly report to Anita (or fill in google doc
	if that is already available)
WP7 leads - URGENT	Send info on reasons for recruitment delays to Anita
WP7 leads	Have a look at last version of <u>CIP</u> and update where needed
WP7 leads	Check local laws in differences between GDPR and MDR rules
	about the right to have data deleted.