



PRESENT

WP1	Inez Germeys Martine van Nierop	
WP2	Simon Krause	
WP3		
WP4		
WP5	Maria Wolters	
WP6		
WP7	Ulrich Reininghaus Iveta Nagyova Rafaël Bonnier	Matthias Schwannauer Michel Wensing Anita Schick
WP8	Jeroen Weermeijer	

1. General Management

The clinicians zoom will be planned somewhere late Spring - we will try to find a date next SC meeting.

All ethics for phase 2 are done!

No updates yet on the EC evaluation.

We will have some centralized main topics for the PAB meetings, but what members bring into the meeting can be different of course. Lena will get in touch with Maria and Simona to discuss this.

We will not have a licence for the digital CTQ (their contract suggestion was way to extensive). We will order (KUL) paper versions of the English CTQ, there are no licenses for the paper versions of the other languages.

The last DPA with Heidelberg is in the works - this will be a slimmed down version of the existing DPA phase 2 to fit Manuela's purposes.

We need to discuss with Luca to have a central person driving the ethics amendments that are bound to come up. We will discuss this next SC meeting.
Adverse events monitoring will remain in WP7.

'Lingering topics' etc, so tasks that we still need to distribute will remain on the agenda all SC meetings.

2. WP2

Has been working on bug fixes, and interface for big data system. UK has requirement of a penetration test. They are now looking at different options and go with the one that is quickest. One of the options is that movisens does it themselves, but they haven't done that before so they will need some time to figure it out. Simona has sent some options of companies who do this in the UK. Or Matthias knows a PhD student in the UK who can conduct this test.

Moving forward, we need to be more on top of who's responsibility some tasks are, so we need to make this very clear once a certain issue is flagged up (now they need to do this in the last minute and it could have been done months ago).

Usage data of the dashboard: login data of users is now tracked, they can see with Thomas how this can be included in the overall database. This can help to prevent recall bias. WP7 can use those data to check with the clinicians whether a login was actual usage or something else.

Feedback system: we need to report technical events to DMEC, so that includes bug fixes. movisens is working on a service desk; we would send an email, and these data are then stored in their ticket system. We need these data continuously, as we need to report on a quarterly basis. Maybe via also entering this info in RedCap?

3. WP3

- Geun-Hyun Kim has started her new contract in Erlangen
- we have provided access to several additional users for the randomization REDCap
- we are continuing to work on the structured export of Maganamed data and semantic encoding of the eCRFs

No comments on this.

4. WP4

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5. WP5

Everything is now exported, including the free text. Martien will work on data cleaning for the complete file. They can now start with coding the self-reported illnesses. In the

next WP5 meeting next week this will be further discussed. The interviews still need to be coded. Kosice is behind on the transcriptions:

https://docs.google.com/spreadsheets/d/1Q_FoU3yaw3S_ChFFYIm_mcg_2a65LhIR-yF2gUikiQo/edit#gid=0

6. WP6

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7. WP7

UK can start after pen testing. Leuven has potential participants, Rafaël is meeting with all of them for ICF in the next 2 weeks. Bratislava still needs to sign site contract. Then they can submit to (??) and hopefully can afterwards start recruitment 2 weeks after that. Kosice same situation, but they foresee no issues. Workshops are planned here next week. So start recruitment end January or start February. Kosice and Bratislava might be able to do a joined submission to (?? - is that the competent authority?) to speed things up and cut costs, Iveta will contact Anty/Michal (not present today at SC). Mannheim has patients recruited (not sure if I deblind people with stating numbers and a blind researchers wanders into these minutes).

If all sites start recruiting now / beginning of February we don't have major issues for the recruitment numbers. If we start recruiting too late it's not just an issue for the trial, but also for the PhD students (to have data within their project period).

We need a full baseline for participants to be included in the analysis (for example if a patient gets discharged during testing, re. the intention-to-treat sample).

8. WP8

Jeroen is still waiting on feedback from some about his request for dissemination info, he will send reminders.

Papers:

If you don't have access to the link Jeroen sends for the abstracts, hit the button to request access and Jeroen will take care of that. Inez will discuss with Jeroen who exactly should be a reviewer.

Everyone was now assigned an abstract, not all were assessed due to access issues. Please review these abstracts for the next SC meeting (Jeroen will send reminder).

Authors of already approved abstracts still need to upload in DROPS, please do so asap.

WP5 will meet to discuss how to divide phase 1 data topics etc.

Jeroen will check whether the reviewer is not too involved in the paper, and Inez and Jeroen will discuss relevant reviewers (e.g., some abstracts should be reviewed by a WP7 person).

Inez will not review abstracts during her sabbatical.

Rules for the abstracts:

- Everyone of SC reads all abstracts (Inez and Jeroen will revise current reviewer list)
- Assigned person for abstract takes responsibility for briefly presenting the abstract in SC meeting, and taking notes on all feedback (and has already prepared reviewer comments before the meeting).
- Each DROPS submission / abstract is 1 paper
- NO DATA ACCESS possible before pre-registration and approved abstract
- If assigned reviewer can't be present in that SC meeting, they need to contact Jeroen to get someone else assigned.

9. AOB

Attendance for SC meetings: 1 member of each WP (usually lead, or alternative if they can't be present), and for WP7 also local site leads (or again alternative).
PS if people are interested in what goes on in these meetings they can all access minutes and recordings!

Actions

Who	What
Simon	Check how to get login data made available (via Thomas or otherwise?)
WP leads	respond to Jeroen's email about your dissemination plans
Iveta	discuss transcriptions with Matej
Authors of abstracts not in DROPS yet	upload your abstract in DROPS
Abstract reviewers	check access to Jeroen's file and review your paper before the next SC meeting.