



IMMERSE minutes
22-04-21
Consortium meeting

Present

| | | |
|------------|--|--|
| WP1 | Inez Germeys Martine van Nierop Daphne Tuyaeerts Silke Apers Davinia Verhoeven | |
| WP2 | Jörg Ottenbacher Johannes Schneider Simon Krause | |
| WP3 | | |
| WP4 | Daniel Dürstewitz Peter Kuppens Manuel Brenner | |
| WP5 | | |
| WP6 | Ine van Hoyweghen Luca Marelli Irene Schluender | |
| WP7 | Uli Reininghaus Matthias Schwannauer Anty Heretik Michel Wensing Michal Hajduk Manuela de Allegri Glenn Kiekens Lena de Thurah Zuzana Katreniakova | Iveta Nagyova Ana Teixeira Yvonne Beauge Andrea Pavlickova Julia Schulte-Strathaus Rafael Bonnier Simona DiFolco Lena de Thurah Anita Schick |
| WP8 | Evelyne van Aubel | |

1. Anouncements

- The project officer of EC, Cornel Riscano, will be joining the kick-off meeting.
- We did a round of introductions, as more and more new staff is joining our team!

2. Action points

- The SEAB has been notified, and they will join in the kick-off meeting in May.

-Stefan Wellek has been notified, not confirmation yet that he can join at the kick-off meeting.

-Peter will send data to Georgia and Daniel, but this is still pending as we need a data sharing agreement first. Martine will look into this.

-Luca has now contacted the Leuven DPO, depending on what they say he will contact the clinical site leads for contact info on their DPOs

-Matthias has found statisticians who can be part of the DMEC, he will send contact info to Martine so she can add them to the kick-off meeting.

3. General management

-The WP leads will do quarterly reports, to make the scientific reporting a bit easier. Martine will provide template.

-There will be monthly Steering Committee meetings, with 1 or 2 members per WP joining. Moving forward, we will only meet as general assembly at the general assembly meetings (next one in May, then December). The WPs will meet amongst themselves, and then send a representative / lead to the SC meetings for updates.

-Martine will send around a template power point for the WP presentations at the kick-off meeting.

4. WP updates

WP2

Simon has provided slides with an overview of the progress of Movisens so far (see attached and on internal website). They will need contact persons for certain activities, so they won't have to email everyone when they need input. The WP leads will provide a list of names, based on the descriptions of the activities that Simon will send to the leads.

WP3

Thomas could not join, he sent this:

The status of the DMP is that we have drafted an outline based on the EU requirements as well as the IDEA-FAST DMP provided by Irene. For filling the outline with content, we will need input from the study protocol (regarding data content) and the whole group (regarding which open access license to use, also how to sustain a data use & access committee after the funding period). Any input on this would be very helpful.

Uli is working on the study protocol, the 2nd point is not too urgent and can be discussed in the kick-off meeting.

WP4

Peter and Manuel have discussed the 1st part of the analyses (simple robust statistics), but is a bit delayed due to move of Peter. Peter has compiled a list of important parts for visualization from the proposal, and has added this to the requirement doc for Movisens.

Daniel has started running analyses based on Uli's data, and there are some first results.

Peter, Daniel, and Manuel will have a follow-up meeting, after that Peter will reach out to Lena dT to discuss what needs to be added to the requirement/intervention doc they are working on in terms of visualization and feedback.

WP5

Maria could not join, she has sent this update:

- we are interviewing for the 50% 1 year position in WP5 next Friday, hoping to get a start date of June 1.
- we have an open and active communication with the IMPROVE group
- I am preparing the questionnaire (WP5.1)
- There is a WP5 area in BaseCamp

If people would like to be kept up to date with WP5 related discussions, please email me and I will set up a mailing list at Edinburgh for WP5

WP6

Luca needs ethics contact points, so he can compile an overview of what is needed in the different clinical sites.

We will submit for ethics approval in parallel, to make sure the process will be as fast as possible.

Luca will start a folder on basecamp which includes a repository of all ethics process requirements. He has been working on the Informed Consent and Information sheets, and will send this around soon to clinical site leads for translating. (although there will be very strict requirements on the form of the ICFs, depending on the location) Luca will liaise with Uli to make sure to not duplicate work.

WP7

Everyone who hasn't done so: please comment on the protocol Uli has sent around, and comment on which details need to be added to comply with local ethics requirements. We will then have 1 comprehensive protocol, if some sites need to submit a shorter version that is fine. But the core doc should have all details in there, to prevent having details available only at certain sites and overview gets lost.

WP5 needs to be added to the protocol as well. We will first attempt to submit the entire project to the ethics committees, so including WP5, but may adapt later if this takes too long.

The will be 1 registration for the entire trial (no separate registrations).

Lena dT, Rafael, and Julia have been working on the requirements file that Movisens needs (soon!). This doc is a comprehensive description of the intervention, not a manual for the clinicians. The latter (in the form of a cheat sheet?) can wait a bit. They will be joined by Simona, Anita, Lena W, and Glenn.

Julia will compile a list of questionnaires, so Iveta can start getting the Slovak translations (also needed for ethics approval)

All clinical site leads need to let Uli know ASAP what the regulations are in terms of safety:

Does there needs to be a separate registration/approval at their site/country from local medical product agencies? E.g. in Germany the trial needs to be registered at Bfarm. For this, we need to to a risk classification. Matthias has experience with this and will share info with Uli.

WP8

No updates, Evelyne van Aubel has just joined IMMERSE and will lead on WP8.

5. Meetings

27-28 May Kick-off

2-3 December live GA meeting

GA meetings every year in May

SC live meetings every year in May / November

The next GA meeting (May 2022) will be in Edinburgh! Matthias will connect people with Martine in time for organization.

Actions

| Who | What |
|-------------------------|---|
| All clinical site leads | Send Luca contact points for local ethic committees |
| All clinical site leads | Comment on protocol (Uli will compile final version) |
| Maria / Uli | Liaise to get WP5 study in protocol |
| Matthias | Send contact info statistician to Martine |
| Julia | Compile questionnaires on Basecamp. |
| Martine | Send template for quarterly reports to WP leads. |
| Simon | Send descriptions of activities to WP leads (or Martine) so they can send list of names for contact points in the consortium. |
| Peter / Daniel / Manuel | Have meeting and liaise with Lena dT about adding visualization/feedback info to requirement doc. |
| All clinical site leads | Find out if there needs to be a separate registration/approval at their site/country from local medical product agencies |
| Matthias | Dig up info on risk classification and share with Uli. |
| All | Please do not forget to complete sheet for contacts with clinicians – CAN SOMEONE ADD THAT LINK TO BASECAMP? |