



IMMERSE minutes
25/01/21
2nd pre-project meeting

Present

WP1	Inez Germeys Martine van Nierop
WP2	Jörg Ottenbacher Johannes Schneider
WP3	Thomas Ganslandt
WP4	Daniel Dürstewitz Peter Kuppens
WP5	Maria Wolters
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
WP8	

1. GA / CA

The Grant Agreement is now signed. WP1 will have meeting with grants office, and a first draft will be sent around soon. Apart from KUL, for all other participants 1 person needs to eventually sign the CA. For KUL it doesn't matter who that is, but for some partners it is likely that your legal department will want to check to agreement before you sign.

2. Shift in WP7

Peter Kuppens will no longer be part of WP7, but will stay involved in WP4.

3. CIMH budget

Due to a mistake CIMH is now lacking 96.000 for a fulltime 4 year PhD student. WP1 can shift some of the budget (ca.20.000) earmarked for the monitoring company, depending on the amount of that estimate. If anyone has some budget left that they will not need, please let Martine know.

For now, they will start with a 3-year contract (then still missing a bit), and will try to get other funding for the last bit.

4. WP1

Any admin / forms etc needed for the clinical trials (not informed consents or any other ethics related documents) can be provided by WP1, if needed.

Inez will inform the SEAB about the start of the project, and will invite them to the end of our kick-off meeting end of May (28-29/5). Uli will inform and invite Stefan Wellek (statistician who will also be on Clinical Trial Committee).

No vacancies needed for WP1

5. WP2

Nothing new to report. Thomas, Jörg, Maria and Luca will meet to get started on requirements engineering (task 2.1). If they need additional input they will reach out. Movisens would like a 'main customer' who makes final decisions, this will be Inez.

No vacancies needed for WP2

6. WP3

Thomas is starting on the DMP, which will be a 'living document' (changed as needed along the way), but there will need to be a clear shift from 'draft' to 'formal' form, where at least some of the requirements are fixed (for medical monitoring?).

Thomas has prepared a document with an overview of how he will be needing all input on data, see below the minutes. He needs feedback on this, and will meet in a separate smaller group first, then sends around another draft to all WP leads. We will discuss further in the next full consortium meeting.

A vacancy will follow later.

7. WP4

Found someone for the PhD vacancy, will try to move forward with the 3-year contract option for now.

They need data (not for formal/publishing reasons) to start testing with. Uli has already provided some, Peter and Inez can also send data.

8. WP5

Has a person in mind for the vacancy, will probably start in May or June. Maria is now already beginning on the questionnaire, there will be a first draft in April. She will plan various meetings with people who have experience in doing ESM studies, to plan ahead for possible barriers etc., and will meet with Movisens to see what needs to be done now.

There will be a meeting in February for Maria and WP7 to see how WP5 will inform WP7 etc.

9. WP6

There are already deliverables for ethics in month 3 (deadline before July 1st). Luca will start contacting people directly for input. He also needs to be in contact with the various DPOs of all institutions, and needs to know the different ethics requirements.

He needs 1 or 2 extra names for the ethics board, please all send ideas (preferably of people who don't need to be paid).

No vacancies for WP6.

10. WP7

Mannheim (CIMH) has advertised for a postdoc, and has already found a PhD student. Manuela (UKHD) has advertised, deadline end of January.

Iveta (UPJS) is in contact with a possible person for the vacancy, will probably start April 1st. A PhD student (not IMMERSE budget) will start in September, but can already be involved in meetings before that.

Anty (UK BA) is working on a vacancy.

Matthias (UEDIN) will advertise next week. This person will also start in September. He also now has some internal funding for additional staff.

Inez (KUL) is meeting with a potential PhD student this week, who could start April 1st.

Clinical sites (leads, not all involved clinicians) need to be more or less involved early on, as they will have to be on board with all we do, and they will need to be included in the ethical applications (delivery M3). WP will already be including them early in the study. We will revisit this topic at the start of the next meeting.

11. Data monitoring

We now have 1 quote for data monitoring, but we need 3 for EC and KUL financial rules. Jörg is in contact with a 2nd company, will follow up for the quote. We need a third, not from Germany!

Actions

Who	What	When
Inez	Inform + invite SEAB to kick-off	asap
Uli	Inform + invite Stefan Wellek to kick-off	asap
Thomas, Jörg, Maria, Luca	Meet to get started on task 2.1, Requirements Engineering	asap
Thomas	Plan small group meeting on data draft	asap
Peter, Inez	Send Daniel/Georgia data to start testing with (ESM /sensing data)	asap

All	Find 3 rd company that can provide data monitoring, and get quote.	Asap
Maria	Plan meetings to get input on know barriers for ESM studies, and meet with Movisens	asap
Martine	Sent doodle 25/1 for WP7 + Maria meeting in february, plan Zoom	--
All	Send Luca contact info on DPOs, plus overviews of ethics requirements, and possible ethics reviewers	Asap
Martine	Sent doodle 25/1 for next full consortium meeting	--

Data Collection for the IMMERSE Data Inventory & Data Management Plan

(DRAFT VERSION, not yet coordinated, 25.01.2021)

Collection of source data items

Datasets

Source Dataset ID	Source Dataset Name	Description of dataset	Expected data sources	Data protection aspects of dataset	Partner(s) responsible for capture

Data items

Source Dataset ID	Source Data item ID	Data item name	Data type	Terminology or Valueset	Description of item	Data protection aspects of item

Collection of expected artifacts & result data sets

Artifacts

Artifact ID	Artifact name	Type of artifact	Description of artifact	Expected data sources	Data protection / IP aspects of artifact	Partner responsible for creation

Artifact Content

- for datasets: like above
- for other artifacts (e.g. algorithm, program code): TBD

Collection of attributes & terminologies for FAIR metadata annotation

Dataset or Artifact ID	Metadata attribute	Relevant terminology or Valueset	Description of attribute	Partner responsible for annotation

Requirements for the Data Sharing Policy

- Implications of data re-use for patient informed consent & ethics application
- Deposition of data & artifacts in central vs. local repositories for long-term archiving
- License(s) to be used for data sharing
- Embargo periods for external use
- formal process for requesting & granting access to IMMERSE data/artifacts