



**IMMERSE minutes**  
**2/12/21**  
**Steering Committee**

**Present**

<b>WP1</b>	Inez Germeys Martine van Nierop	
<b>WP2</b>	Simon Krause Johannes Schneider	
<b>WP3</b>		
<b>WP4</b>	Georgia Koppe Daniel Dürstewitz	
<b>WP5</b>	Maria Wolters	
<b>WP6</b>	Ine van Hoyweghen Luca Marelli	
<b>WP7</b>	Ulrich Reininghaus Michel Wensing Matthias Schwannauer Anty Heretik Michal Hajduk Iveta Nagyova Matej Hrabovsky Islay Barne Koraima Sotomayor Enriquez	Adam Kurilla Anita Schick Simge Celik Simona Di Folco Lena de Thurah Rafael Bonnier Glenn Kiekens Daniel Dancik
<b>WP8</b>	Inez Germeys	

**1. General Management**

-Amendment

We have an upcoming amendment, mostly about Thomas' transfer, but it's not ready for the SC vote yet. This will be done either via email or at the next SC meeting (2/3 of all participants [1 person per institution] needs to be present and it needs majority vote).

-Open Access publishing

All IMMERSE papers have to be Open Access, so either do an Open Access journal (there is some budget for this at each site) or use University repositories (like Lirias at KU Leuven) where postprints are uploaded. Libraries check any embargo regulations. Do not publish at journals (with IMMERSE) data where this embargo is not lifted for postprints, as it is a requirement of EC to have everything OA.

## -Authorships / Acknowledgements

Inez and Martine will work on a proposal for authorship rules, taking into account:

Not all IMMERSE members are automatically on all papers. All authors should comment on papers, if no comments are offered within a certain amount of time they will no longer be a co-author. Clinicians part of the clinical trials should be given the option to be co-authors (following the same rules), especially on 'main' papers. Per paper we need to (leniently) check who within a WP should be on a paper, always taking into account the more supportive WPs (like WP3 or 6). Supervisors of PhD students also need to be co-authors (even though they might not be part of IMMERSE). There needs to be rules about using data from a certain site (so people from that site should be included as co-authors). If someone has said that they want to write a paper, we need a deadline for starting that paper (if it takes too long it can go to someone else). We can have an 'IMMERSE' author, where people from IMMERSE (including clinical partners) could be described in the acknowledgements. Staged approach: longer list of authors for main (outcome) papers, possible group authorship (to be decided what this group is), smaller author list for additional papers.

Martine will set up google sheet for dissemination: all dissemination actions will be uploaded there (based on quarterly reports), like presentations etc, but also publications. The later will be a flow: 'abstract submitted' – 'approved' – 'paper submitted', etc (this can also be used to check if people are actually writing the papers on time.

Martine will send around doodle for new time for SC meetings in 2022.

### **2. WP5**

See slides uploaded on internal website.

Problem that the project call required a more or less completed and tested intervention to be available at the start of the project. Also some delays due to ethical approvals, and DTA issues. In order to deliver 5.1 on time (next year September) so simplification is needed, and use intermediate findings we get during the project. In D5.1 report the results will be split per site, also to accommodate differences in ethical approval timing. Due to DTA issues (Leuven) not all data from all sites could be available everywhere.

Alle sites need to start asap with data collection. Interviews can be adapted along the way. Mannheim can start interviewing, Bratislava has approval but is finalizing some last points, Kosice, Leuven and Edinburgh are waiting for approval.

If there are updates or hick-ups, please put them in relevant thread on Basecamp.

<https://3.basecamp.com/3635894/buckets/10764202/documents/4384091128>

### **3. WP7**

See doc with tasks uploaded on internal website.

Simge is the postdoc that now coordinates all WP7 matters. Service engagement scale will be primary outcome, at 2 month post baseline. Working on new sample size calculation to be able to pick up smaller effect size.

Translation process for validated measures used in phase 2 have to be more precise/thorough than translation schedule we now use for phase 1. Matthias/Uli will work on template for this.

When adding questionnaires for secondary outcome measures, they need to add to predictive validity, so questionnaires can't be too similar (social functioning scales?).

Overview of measures and copyright:

[https://docs.google.com/spreadsheets/d/1yGWbi\\_odGJTpicPUPMnAyPySISSo2UMF/edit#gid=1872019916](https://docs.google.com/spreadsheets/d/1yGWbi_odGJTpicPUPMnAyPySISSo2UMF/edit#gid=1872019916)

Simge will look into the measures regarding copyright, these will be arranged centrally.

Uli is working comments on CIP, hopefully finalized and sent to medX soon (but also needs input from Thomas).

We still need input from Leuven to check what FAGG requires – Glenn?

Martine will send around a doodle to have a 2 hour zoom with all clinical partners and SC, in April, to get them more involved in the project.

Link to CIP google doc:

<https://docs.google.com/document/d/1QVfAMyeufYRLFFCnl-xkRznhDIOfGqN0TPF2hdVGXS8/edit>

Martine will translate the public website with automated translations, and reach out to local sites to check translations.

#### **4. WP4**

See slides uploaded on internal website.

Deliverable report D4.1 will be based on what is available now, the content was always going to change due to progress of the project anyway.

WP4 needs input on which variables should be related to each other in the visualizations. Meetings should happen with Peter and people from clinical sites, unclear what came out of that. It's at least still going on, they're looking at usability etc. Mood is now already presented in different contexts (1 mood item related to all contexts per graph for clarity). Strength of correlations were left out as not useful for clinical perspective.

Still problematic to move forward with visualizations, someone needs to own it. Georgia will plan a workshop for visualizations and future developments.

List of variables:

[https://docs.google.com/spreadsheets/d/1qsfJ3Y1eeK6TPaTyw4UY2hYr\\_I9I0L655a-9fb9DsqE/edit#gid=0](https://docs.google.com/spreadsheets/d/1qsfJ3Y1eeK6TPaTyw4UY2hYr_I9I0L655a-9fb9DsqE/edit#gid=0)

We need to check this list and finalize (needs to go into CIP). Georgia will suggest what they will want and prioritize, and WP7 will see what is feasible. Georgia will add placeholder in CIP about variables.

## **5. WP2**

See slides uploaded on internal website.

Original roadmap is now changed due to delays. They are now trying to do tasks in parallel to make up time. Risk Management is now needed earlier (January instead of June 2022) for CIP and ethical application for phase 2. Also the risk management is now theoretical instead of based on development, so amendments may be needed later on.

They need final definition on visualization of dashboard and app urgently, as well as the final question items, and translations (decided in WP4 workshop).

For Risk Management, Simon will send a doodle for Risk Policy meeting with Inez and Uli (they need to make final decisions, before Christmas).

Once Evelyne starts (January) she will work with movisens on IP and billing systems.

Simon will make the content of app and dashboard available through PDF or web version to get feedback on for example language.

## **6. WP3**

Thomas couldn't join, the following points were raised:

Uli needs feedback on CIP (DMP) – due beginning January.

Inez needs input on interoperability for contact with clinical sites.

Simon: FHIR model for data

General question: which things can we ask from your PhD student?

How is upcoming deliverable going?

Thomas will present update on WP3 at next SC meeting on December 16<sup>th</sup>.

## **7. WP6**

See slides uploaded on internal website.

Definition of data flow of phase 1 is needed for DTA, Luca will send suggestion to Maria to check. In general, interview data will be pseudonymized before they go into datafile that's used by the rest of the consortium, so personal data is only known locally and in Heidelberg.

Luca needs feedback on IC template for phase 2 (available on Basecamp).

DGF: LRD is working on DGF and DTA. Luca will provide details for web interface for data access by third parties to Martine, she will put on public website once data is available to share.

Milestone (M12, March 2022): first analysis of regulatory requirements. Luca will describe what steps have been taken so far, and is gathering info from medX. Luca will also be involved in discussion between WP8 and movisens on IP and billing, and Irene will be involved.

**Actions**

<b>Who</b>	<b>What</b>
Glenn/Lena	Find out if we need clinicians as part of the study for ethical approval of phase 1 (and 2)
Glenn	Find out what is needed for MDR – only registration or also approval from local authority? (FAGG)
Inez, Martine	Prepare proposal for authorships, present at next SC meeting
Matthias/Uli	Work on translation schedule for phase 2 measures
Simge	Look at measures / copyright
Martine	Translate public website
Georgia	Plan workshop on visualization
WP4	Work on variable / measure list, ask feedback from WP7
Luca	Send suggested data flow to Maria for check
WP7	Give Luca feedback on IC template for phase 2