IMMERSE minutes
March 3rd 2021
3rd pre-project meeting

Present

WP1	Inez Germeys Martine van Nierop Daphne Tuyaerts Silke Apers
WP2	Jörg Ottenbacher Johannes Schneider
WP3	Thomas Ganslandt Tariq Elahi
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 Ana Teixeira Yvonne Beauge Andrea Pavlickova
WP8	

1. **Minutes last meeting / action points last meeting**
   Were approved, Martine will add them to future consortium meeting requests
   For action points see table below.

2. **Announcements**
   2.1 Kick-off meeting
   Will be online, Inez and Martine will work on a doable schedule for 2 full days.

2.2 Covid X

Jörg will have a look at COVID X (covid-x.ea/program/) for possible additional funding.

3. **General management**

3.1 Publication strategy

Will be worked on later, but apart from agreements on authors / co-authors etc, we also need a plan for general topics for the different PhD students (especially those working on WP7).

3.2 DMEC

Will be SEAB + separate statistician (not Stefan). Matthias may know a more junior option who will actually have time to work on this – he will contact them.

3.3 Consortium agreement

Please all lean on your legal department so we can get this sorted as soon as possible!

3.4 Data sharing agreement

Will also be part of the CA. Irene/Peter can share a template – final version will be checked by Irene.

3.5 Data monitoring

Jörg has found a 2nd and 3rd quote, will be circulated. In March Uli, Jörg, Thomas, and Martine will meet to look at the different quotes to get more alignment.

4. **All WP updates**

WP2

Started process on requirements engineering, have started docs:
-explanation on Therapy Designer platform
-acquisition of the requirements
Still needs input from everyone who got this last document (Uli, Inez, Matthias, Maria). Stats analyses (how to get from raw data to processed data – what is shown to client) will be integrated. Requirements doc will be sent to Peter and Daniel as well.

WP3

Had meeting on starting early collection of content for the DMP, based on example provided by Irene. We will need to add more detail on inventory of data items / questionnaires we use, which also needs to be part of the study protocol (overlapping with clinician's manual) anyway (appendix DMP) + implementation of the technical platform.
Draft version of collection form on datasets / data items / artifacts from January meeting – for now just focus on datasets, Thomas now has the reduced version ready. Follow-up meeting next week to work on this form, then will be distributed to relevant members.

WP4

No further updates. Person that they wanted for PhD dropped out, they do have someone who can help temporarily.

WP5

Maria has met with WP7, but still needs specifics of intervention, as described in the Improve manual. Johannes also provided an example for a user requirements doc,

Matthias, Thomas and Inez will look at this one. We can use a lot of information from there.
2 tight timescales: -Requirements gathering for software (all needs to be signed off early on for procedure for medical devices), and -Ethics
Maria will have more ethics meetings with relevant members. Johannes and Maria will pin down which requirements will be needed by when.
Another meeting for WP7 + Maria – finalizing intervention. (Maria will start working doc)
Will probably have RA by June 1st, does have temporary help. Maria is working on questionnaire design, will get Lena to help.

WP6

Luca will contact the Leuven DPO (using the IMMERSE application), but he also still needs the contact details of the other DPOs.
Irene provided an ICF template, which he will adapt for IMMERSE (needs more info on data governance and sharing)
Luca needs the protocol, will coordinate with Uli. Uli will also send around the clinical trial form to the different WP7 leads, they will provide feedback on whether more detail is needed at their site. Luca will send the template for UZ Leuven.
All different sites will get separate ethical approval, try to get full approval for whole project if possible (with amendments later)

WP7

Michel/Uli have started a doc on documenting contact (meeting / email / etc) with clinical sites, which Anita has prepared in RedCap (does not need to be part of DMP)
WP7 will have monthly meetings starting in April.

Andrea has joined (officially in April) for Slovakia. Yvonne (official start in July) has started with Manuela. Matthias will try to get his PhD student to start earlier than September, and now has a parttime postdoc (funded elsewhere) helping out.

All have had first general meetings with clinical leads, more specific meetings will follow.
Inez/Lena will make sure there will be wards where Improve has not been piloted.

WP8

No news yet.

5. **Communication**

5.1 Twitter

Will launch April 1st, Martine will send monthly mail to get content from everyone.

5.2 Website

Please all keep sending bios and headshots.

6. **Meetings**

There will be another consortium meeting before the kick-off, somewhere in April.
End of year we will try to have a live meeting in Leuven.

7. **AOB (any other business)**

none

Action points

Who	What
Inez	Inform + invite SEAB to kick-off
Uli	Inform + invite Stefan Wellek to kick-off
Peter, Inez	Send Daniel/Georgia data to start testing with (ESM /sensing data) + data sharing agreement
All	Send Luca contact info on DPOs, plus overviews of ethics requirements, and possible ethics reviewers
Matthias	Contact statistician for DMEC
Jörg, Thomas, Matthias, Inez	Send and look at user requirements doc from Movisens
Uli, Inez, Matthias, Maria, Peter, Daniel, Lena, Glenn, Ana	Send input to Jörg on requirements google doc. Deadline **March 24th**
Uli	Send around clinical trial template to WP7 leads, get feedback if more details are needed.
Luca	Send UZ Leuven template for METC
Uli	Plan monthly meetings for WP7

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