IMMERSE minutes
18/11/21
Steering Committee

Present

WP1	Martine van Nierop
WP2	Simon Krause Johannes Schneider
WP3	Thomas Ganslandt
WP4	
WP5	Maria Wolters
WP6	Luca Marelli
WP7	Ulrich Reininghaus Michel Wensing Matthias Schwannauer Michal Hajduk Iveta Nagyova Adam Kurilla Anita Schick Simge Celik Lena de Thurah
WP8	

1. General Management

Agenda SC meeting December is approved (will be sent around soon). Martine will have the amendment ready that describes the transfer of Thomas (and his budget). This needs to be approved by 2/3 of all participants at the SC meeting. Budget transfer can't happen until after the amendment is approved by EC.

LRD + KUL is working hard on getting the DTA finalized, this is needed for METC approval of phase 1 in Belgium.

We'll try to find better suited dates for the SC meeting on December 2nd.

2. WP7

Still working on ethics for phase 1, but all are very close (see comment on Belgian situation above). Simge has now started parttime as postdoc (will change to fulltime later).

In Germany they need to have clinical staff employed / affiliated with the study for ethical approval. Slovakia has clinicians, UK also, in Belgium (I think?) is not necessary? Lena and Glenn will find out.

All sites (except Germany) need to check what is needed in their country in terms of MDR: only registration (like in Germany) or also approval?

CIP is now the most urgent matter – there are comments in this doc, please all look at them! Aim is to get this done and sent to medX in January.

KUL is now sponsor for phase 1 for UK (was mandatory for their approval). UK's ethics have been submitted and will get a response in about 2 weeks.

Kosice is submitting phase 1 this week.

3. WP3

There will be a possibility to have Redcap in Erlangen, but we'll keep the instance in Mannheim for now. Then we'll move the data in about March '22, and do an amendment for the DTA later.

In January Thomas, Uli, and medX will meet about the eCRF / DMP.

Thomas will have comments for Simon in the technical requirements doc done soon.

4. WP2

Is working on Risk Management. Simon has assigned to do's – please all look at these! They are now working on it without the prototype, so these will change as we go along.

5. WP4

Not present.

6. WP5

Is preparing a doc on data collection and will send around, to make new planning on specific info Maria needs from the different sites.

7. WP6

If anything is needed for streamlining ethics submission please let Luca know!

The aim is still to have at least submitted for ethics of phase 1 and 2 by December, which is the deadline for that deliverable (in which he will describe delay as we were supposed to have approval for all by then). Phase 2 will be first submitted in Mannheim, get their feedback, and then we aim to submit in the other sites in January/February. Data collection should start in September, but randomizing will already start right before or during summer (there will be workshops for this before Summer.

8. WP8

Not present.

Actions

Who	What
Glenn/Lena	Find out if we need clinicians as part of the study for ethical approval of phase 1 (and 2)

All but Germany sites	Find out what is needed for MDR – only registration or also approval from local authority?
WP7 staff	Provide comments on CIP document.
all	Simon needs comments on Risk Management doc

IMMERSE Ethics Advisory Board (EAB) Meeting, 18 October 2021

Participants:

Els Maeckelberghe, University of Groningen

Peter Schröder-Bäck, Maastricht University

Luca Marelli, KU Leuven

Ine Van Hoyweghen, KU Leuven

Anita Schick, Zentralinstitut für Seelische Gesundheit Mannheim

Michal Hajdúk, Comenius University Bratislava

Iveta Nagyova, Pavol Jozef Safarik University Kosice

Report of meeting

1. **Discussion of data governance framework**
   - Even though the DGF describes well the process for making amendments to it, the conception of the DGF as a "living document" may be a bit problematic from the perspective of the EU Commission, as they may not appreciate a high rate of amendments/changes. This issue could be checked with the PO.
   - DGF provisions regarding the approval of scientific publications from the DGB lack transparent criteria, which should be provided (to avoid risk of political infighting within consortium, keeping in mind that DGF is for the turbulent and not for the peaceful times).
   - The aspects concerning scientific publications do not really matter in this document, consider taking them out.
   - The notion of "scientific research" should be better clarified in the document (also in light of the GDPR, etc.)

2. **Discussion on ethics approval and informed consent, Phase I**
   - Suggestions for negotiating with Mannheim's ethics committee (which has raised issue with the broad consent currently in place):
     - Specify that secondary processing of data will just be for non-commercial uses (though it may be difficult giving the specificities of this field of research).
     - Point to the existence of the DGB as an additional safeguard measure, and its role in overseeing data access procedures.
     - Consider that, even if IMMERSE partners will process pseudonymized data when it comes to interviews, it could be feasible to insert a clause in the DTA so that third party entities only receive and process anonymous data.

3. **Discussion on data minimization strategy**
    - There is general consensus on the approach devised in the consortium (broad principles + essential items list to be periodically revised according to project evolution)