IMMERSE minutes
19/5/22
Steering Committee

Present

WP1	Inez Germeys
	Martine van Nierop
WP2	Simon Krause
WP3	Thomas Ganslandt
WP4	Georgia Koppe
WP5	Maria Wolters
WP6	Luca Marelli
WP7	Anita Schick
	Matthias Schwannauer
	Glenn Kiekens
	Michal Hajduk
	Anty Heretik
	Simona Di Folco
	Ulrich Reininghaus
	Michel Wensing
	Iveta Nagyova
WP8	Evelyne van Aubel

1. General Management

The DMEC will be part of (some of) the Ethics Advisory Board meetings, and will be 1 or 2 of the people that Matthias suggested. They first need to sign the NDA that is still on progress. Martine will follow up. (DMEC will for example look at whether SAEs are related to DMMH) The reports of DMEC will be part of de EAB reports.
We'll have 2 dates for the clinicians meeting (so clinicians can choose when they join): June 23rd 18:00 and June 30th at 12:00. PLEASE ALL SEND contact details of clinicians that need to be invited. (update: I received Germany and UK, still need **Belgium and Slovakia**)
Martine and Inez will compare the DMEC charter proposal of Uli against the Dynamore example. (which we need to move forward with phase 2)

2. WP2

Worked on classification of the intervention, has sent around document on risk management, and has started working on visualizations for dashboard. Some issues with visualizations in manual, so which data is visualized in which plot, and the WP4 document where all calculations and different parts of visualizations are collected
https://docs.google.com/document/d/1O_XgNk7W9uLRTit2-Vea0lB8_6hW2Ki5oZj0u1d7og8/edit
20/5 there will be a meeting between Johannes, Simona, and WP4 to resolve this.

They need a responsible person to help with deciding on some of the content. Simona will do this. **But anyone who wants to have a say on this please check google doc above**! The time is now, if no response comes it will be too late to still change anything.

Deadline end of June for prototype will not be reached, this will be end of August. We need to check how this will affect the ethics applications. **All sites need to check when the ethics meetings are, so we can work towards those deadlines**.

3. WP3

Has been meeting with more IT departments. Wiesloch could probably also work with PDF imports/exports. Thomas discussed with Anty (direct contact with IT is difficult due to language barrier) – probably not possible to integrate in electronic patient record, as it is purely text. They can have paper copies in the patient charts.
Simona and Iveta will send Thomas contact details for Edinburgh and Kosice.

This will all be in place and done by the end of August.

4. WP4

Has been in contact with WP2 and Anita on how to move forward with visualizations. Manuel is now focusing more on movement data, as we're going to try and collect a longer period of GPS. Thomas will then need the definitions of these data.

5. WP5

Working on getting a weekly slot for WP5 meetings. Maria still needs 2 more questionnaires from Slovakia.
Maria and Glenn have worked on quantitative data. They're creating files for cleaning and scoring the survey data. There are some minor issues to fix to get a clean dataset, which will all be documented.
They'll check quantitative variables for consistency with master data dictionary (how are they coded, range, and sequence of items). (e.g., a mix-up of sequence already led to some items not being coded correctly).
They'll also check differences of operationalization between countries (e.g., ethnicity).
And they'll check the psychometric properties of all scales per country (translation effects) and overall.
All of this goes in an R-file, to have a common place where all of this can be looked up, and we'll also have a clean dataset, which can be found at OSF.
This plan has been approved by SC. (no objections were raised at least)

Evelyne will work on getting github in place for sharing code.

Katrijn will send around the revised version of the DPA for phase 1 soon (as this is really slowing us down now). **Please all urge your legal department to sign ASAP**!

Simona has submitted an amendment to be able to recruit for phase 1 via more channels, and is trying more avenues all to try and boost numbers for Scotland. There will be a meeting in the next two weeks to discuss further.

6. WP6

We need the DPA for phase 2 in place to be able to move forward. But in order to get this Belgium has to (pre)register at CTC. We can submit the protocol as we have it now (so even if we're still adapting). We also need a description of dataflows from Thomas. He will meet with Luca and Anita to look at whether what he has in D3.2 is sufficient. Glenn will send protocol to our contact in Belgium.

Next meeting with EAB will be soon, Anita will let Luca know soon when is feasible. Simon, Anita, and Uli will join this meeting. If anyone else wants be involved contact Luca.

7. WP7

Anita has prepared slides (https://immerse-project-members.eu/onewebmedia/WP7_RCT_planning.pdf) about recruitment numbers, and effects of delays. One solution when there is not enough recruitment is to add units, but only in groups of 3 (so you can't add 1 unit, but you can add 3) to keep 2:1 ratio. If 3 are added, they would need to include 3 participants per unit per month.
If we are delayed by 1 month, then number of participants per unit per month will of course also go up (see exact numbers in Anita's slides).
We have to be done with recruitment by May 2023 in order to meet deliverable deadlines (August 2023 will be end of assessments).

There is good progress on the outcome measures, will be discussed further in next WP7 meeting. There will likely be a core set of variables and an optional set.

Anita still urgently needs CVs and documents for the phase 2 ethics, see action points below!

Rafaël will take the lead on the patient advisory boards (possibly together with Lena after she gets back from her leave). He will set up a google doc, and contact all relevant members of the consortium to get input on practicalities of these boards, what everyone thinks is the information we would like to get out of these boards, how often they should meet, etc. Mannheim has a permanent advisory board, which can be asked for IMMERSE.

8. WP8

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9. Papers

2 abstracts were submitted, by Anita and Lena:

https://public.3.basecamp.com/p/ZyHXuXRAWUzXL3rKgGqrghGF

https://public.3.basecamp.com/p/Mph2pi6gu3BdJ75GVg9gaHwu

We need a plan on how we deal with these. When an abstract is very comprehensive (like Anita's is) the abstract will be discussed within a group of interested authors, and there it

could be decided whether it will be 1 paper with co-authors or it could be split in multiple papers.

Evelyne and Martine will work on template for abstracts, and possibly a redcap system where abstracts can be submitted.

We will have a deadline of 2 weeks before the SC meeting, Martine will send around the calendar for this.

10. AOB

We need more time in the SC meetings – they will now be from 13:00 – 15:00

Actions

Who	What
Belgium Slovakia WP7	Send Martine contact details for clinicians that need to be invited to clinicians meeting
All	Look and comment on https://docs.google.com/document/d/1O_XgNk7W9uLRTit2-Vea0lB8_6hW2Ki5oZj0u1d7og8/edit If interested.
Glenn	Send protocol to CTC
Thomas	Make dataflow for phase 2 CTC registration
All clinical sites	Find out meeting dates / deadlines of ethics committees
Simona + Iveta	Send Thomas IT contact details
All	Once DPA for phase 1 comes in urge your legal departments that we need this in place soon
Kosice (Iveta?)	Send Anita CV of Dagmar, as well as site document
Kosice (Anty?)	Send Anita site documents
Matthias	Send Anita your CV and site documents and CV of Cathy