IMMERSE minutes 17/8/23
Steering Committee

PRESENT

WP1	**Inez Germeys** **Martine van Nierop**	
WP2	**Simon Krause**	
WP3		
WP4		
WP5	**Maria Wolters**	
WP6		
WP7	**Ulrich Reininghaus** **Michel Wensing**	**Matthias Schwannauer** **Glenn Kiekens**
WP8	**Jeroen Weermeijer**	

1. **General Management**

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2. **WP2**

Is still working on bugs and a small update, which will be done in the beginning of September (bigger update end of September). Not much else due to the audit and the summer period.

3. **WP3**

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4. **WP4**

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5. **WP5**

No WP5 meetings in July and August. Theresa has moved on to a new job, and they will discuss how much time she will have to finish her IMMERSE paper. Maria is going to get a student research assistant to finalize some tasks Theresa was working on (processing qualitative data - for after data collection is done).
Maria is still working on getting all the metadata, not all sites have sent that yet. It's difficult to plan time for coding now that staff are testing participants, because this

requires to block of a few hours at a time. We need to focus on that once recruitment slows down.
Maria is waiting on response on her main paper submission in drops – to be discussed during WP7 bit. Pre-registration for Lena's paper in coming soon.
Leuven had a session for the PAB, Maria still needs to hear from Lena how that went. Topic here was findings of Deliverable 5.1, this topic will be used for future PABs of the other sites. Also they can discuss the IMMERSE website (already done in Belgium).
Jeroen will connect with Edinburgh team, as they had some questions about this (what exactly they should discuss in PAB). SC doesn't need to come up with a new topic yet – for Leuven it depends on outcome of last PAB, and when the next meeting will be.

6. WP6

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7. WP7

Uli prepared some slides.
We were the (un)lucky ones: the auditors chose us to audit because they wanted to validate a new checklist for other clinical investigations.
Atmosphere was very constructive, we could really show that we made an effort to prepare for the audit. Generally they were very impressed.
The (critical) findings are divided in 'critical' (rejection of data and/or legal action required), 'major' (data may be rejected and/or legal action required), and 'minor' (indicate need for improvements).

On the Sponsor inspection there were no critical findings. 1 Major finding on monitoring: plan is not adequate, not enough SDV (source data verification) done, monitoring staff qualification is not adequate, SIV (site initiation visit) reports were not complete, and monitoring reports were not signed by sponsor (which medX prevented). Back then, this resulted in Mannheim doing the Sponsor initiated monitoring with their Quality Assurance Officer (Stefanie Engelhardt), who is a trained and experienced monitor, and was super helpful through this whole audit process. Also big thank you for everyone in the different sites for all help and fast responses.
Then 6 minor findings (see slides). All can be addressed without too much difficulty (although some do require quite some effort).

Plan for how to deal with medX situation:
We're going to now use the monitoring plan we have from the quality assurance officer (overrides medX plan). Uli is going to confront medX with these findings, to give them a chance to seriously step up efforts (which needs to be very clear from their response, Stefanie has prepared a template that makes it very clear what we need from them in future). If they don't, Leuven will get their legal department involved to see how we can get out of the contract (still 20.000 left that is still open), or maybe even get money back. Communication remains a pain, it was for example really difficult to get basic documents needed for the audit. The rest of monitoring and training could be done with Stefanie, and possibly a freelancer, and cross-over monitoring between sites.

Uli will contact medX now, and follow up after his annual leave (2 weeks). Inez, Uli, Stefanie will meet 1st week of September to discuss further steps. In the meantime Martine will contact Katrijn to get things started without doing the official route with the legal department.

Site inspection:
1 major – was already worked on via the amendment, before not all investigators were approved by ethics committee. (this is not required in pharmaceutical studies, but is in MDR). 5 minor findings (see slides). Here again there were problems with what medX did – nonsensical monitoring, very few queries (which is very unusual), etc. WP7 will make sure that everything that needs to be done differently in the sites will be communicated.

It was very good we did the trial audit, as then there were many major findings, so now a lot of those and possible critical findings were prevented. The deadline for all the amendments based on the audit is end of September.

Recruitment needs to be picked up, because we are behind. And we need to take care that the distribution over the different units stays similar, and we don't end up with a convenience sample. Right now the goal is still until end of December, but we need to start thinking about what happens for PhD projects if we need to recruit longer. (for example if we go on until March) Right now, Uli and Anita are working with the trial statistician to explore for example whether it is ok to underrecruit at certain units (for example 10, in stead of 18), and compensate with other units/sites/countries. So is it enough to have a sufficient total sample, but not divided equally over the sites by December? We will discuss further in next SC in September when every site is represented.

8. WP8

Due to recruitment workload it is not feasible to always ask the PhD students for blog posts for the website, so he will ask other people from the consortium as well. And possibly also ask guest writers? Matthias has some people who he could ask. And everyone please tweet about the blogs (Jeroen will send DM).

Maria needs 2 reviewers for her main paper – Uli and Inez will do this.

9. AOB

Actions

Who	What