IMMERSE minutes
18-5-21
Datamonitoring

Present

WP1	Inez Germeys Martine van Nierop	
WP2	Jörg Ottenbacher Simon Krause	
WP3	Thomas Ganslandt	
WP4		
WP5		
WP6	Luca Marelli	
WP7	Uli Reininghaus Anita Schick	
WP8		

Thomas spoke to his 'friend'. He said that there is a clear legal obligation to get approval and a classification from BFarm for our project/tool. They have to do consultancy, which will cost about 3500 euros. He's not sure if this classification will count for other countries as well, but this is something we will ask them. If not, it might already help that we got classification in Germany and may speed up the process (if needed) in the other countries, hopefully we son't get different classifications across countries.

We need to have a super clear description ready for BFarm, to make sure they will say this is an 'other clinical classification', because if they rate it as 'clinical investigation' we are in major trouble (that would not fit in the duration and budget of IMMERSE). At the same time, it might pose an ethical issue if we under-sell it, as then it's not clear why there is a need to subject participants to our study.

Ethics applications will not have to wait for this consultancy.

We will ask medX to consult on how we can best do this application with BFarm. We'll email them to ask for a meeting, saying that we definitely want to do our datamonitoring with them, and hopefully in this meeting they can help with the BFarm application already (as part of the package of the rest of the quote, which still needs finalizing. If they can't do that, we can go through movisens' consultant Jona.

So our tool is definitely a medical class, probably class IIb.

Simon will draft an email for BFarm, circulate in this group, then KU Leuven (Martine) will send this email, to let medX know this is an official confirmation of us contracting them.

In the meeting with medX, the following questions need to be discussed:

-How do we get this to be classified as an ‘other clinical investigation’

-Will this classification count in other countries

-what is the risk classification

-what do we need from them / what should be included in the quote

    -datamanagement

    -GCP conformity

    -CRF / eCRF