



IMMERSE minutes
16/11/21
Exploitation Steering Group

Present

WP1	Inez Germeys Martine van Nierop
WP2	Jörg Ottenbacher Simon Krause
WP3	
WP4	
WP5	
WP6	Luca Marelli
WP7	Uli Reininghaus
WP8	
LRD	Zuzana Kasanova

Based on D8.1 (Exploitation Steering Charter) we will now have ESG meetings every 3 months. Evelyne van Aubel will start as postdoc for WP8 in January.

We should work towards a clear plan for valorisation / reimbursement for the app. In Germany for now only private practices could charge for app use through insurances, in clinics the app should be on the market and registered. In Belgium it's nearly impossible and the app itself should not be relied on as a source of income – only therapy using the app can be charged, never just an app (no difference private practice / clinic).

→ After Evelyne starts she will find out what the regulations are in the other countries as well.

Right now the plan is that we will register the trial in Germany (no approval from that regulatory body needed, only registration), and then go to the regulatory bodies of the other countries. Zuzana advised to contact CTC in Belgium to ask what the regulations there are (FAG). WP7 Belgium + LRD contact Katrijn de Brucker are on this. It is unclear if this needs to be done in a national level / European level / or both.

We also need a clear plan / description of the next steps to get to CE marking, this is part of WP8 and will also be started by Evelyne. medX can advise on this. In any case, after our study follows a clinical evaluation, and we need to make sure that we won't have to do a full clinical investigation. For now we will only focus on European + UK market, so not on FDA approval.

There are specialized 'bringing into market' companies, which could be contracted to help after IMMERSE, we can get follow-up funding for this through EC (Pathfinder, Transition), and there are also German funds we could apply for.

Inez, Evelyne, Martine and Zuzana will meet with an IP officer at LRD to discuss IP (after start Evelyne).

Martine will plan quarterly ESG meetings and will invite Zuzana as well (but she can't join all meetings).

Actions

Who	What	When