IMMERSE minutes
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Datamonitoring

Present

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Although Zuzana Kasanova had mentioned 2 types of studies (clinical investigation versus clinical experiment), there are actually 3 types:

1. **Clinical Investigation**

This is the most extensive type in terms of time investment, and would be outside the scope of IMMERSE. Here you investigate a tool and its efficacy, so the device is the subject of the study.

2. **Other Clinical Investigation**

Here, you use a tool as a means to conduct the study, but it's not the subject. The tool doesn't have to be a product yet. This takes less time than 1.

3. **Clinical experiment**

Here you use something that is already a product for a different use. So the tool is already registered, you just want to investigate whether it is effective for a different medical purpose than it's registered for. N.a. for IMMERSE.

So, we want to do an 'Other Clinical Investigation'. The quotes we have received are probably for this as well, but not sure.

Then there are 3 topics we need to think about to make sure the chance that the results of IMMERSE can be used to bring the app/platform to the market:

1 and 2: Datamonitoring and Data management.

This will be done by the datamonitoring company we are talking to now. They will make sure that the quality of the data is high enough and GCP compliant.

3: Safety

This can be different across sites. For example, in Germany the study needs to be registered at BFarm. So we need to know what the different local situations are. It is possible that the local ethical committees will raise this issue anyway, as soon as we submit the study there, but it would be good if we're prepared on what is to come. **So each site needs to find this out!** This will also depend on our risk classification. Matthias has some experience with this, and has been asked in the consortium meeting to dig this up.

We have now decided on going for Medex for datamonitoring and data management. **Martine needs a precise quote to start up the process of setting up a contract with them**.