Work package number [9]	WP2	Lead beneficiary [10]	8 - MOVISENS
Work package title	Prototype development		
Start month	1	End month	48

Objectives

1. Development of the prototype of the DMMH system under medical device regulation
2. Deploy, run and maintain the DMMH system during study

Description of work and role of partners

WP2 - Prototype development [Months: 1-48]
MOVISENS
The main goal of this work package is to develop, deploy, run and maintain a prototype of the DMMH system to be used in the study during the project. The whole development will be done under medical device regulations so that the effort to realize the final product after the IMMERSE project we be as small as possible. The prototype will be developed based on the TherapyBuilder platform. TherapyBuilder consists of a set of components usually used in DMMH systems, a configuration/authoring tool to configure and generate specific DMMH systems and a complete product life cycle process that is tailored to research based medical product development, i.e. from idea to prototype to feasibility study, clinical evaluation, certification and placing the medical device on the market. The architecture of TherapyBuilder will enable a smooth scale-up from a technical perspective. For the IMMERSE DMMH additional components have to be developed (e.g. for visualization).

Task 2.1. Requirements engineering (M1-M6) (Movisens)
Within Task 1, the use scenarios identified in WP5 and WP6 will be analysed in detail to identify the stakeholders involved and to derive their requirements for the IMMERSE DMMH. The requirements include the usage requirements of patients, researchers and therapists as well as regulatory requirements (MDR, GDPR, clinical evaluation), data security aspects (WP3) and market requirements (WP8), which result in particular from the best possible reimbursement scenarios for a future product. Additional requirements are related to scalability and deployability. Based on these requirements, the functional scope of the IMMERSE DMMH prototype is then specified and the associated software requirements and test specifications are derived. All requirements are documented and tracked in a requirements management tool in accordance with IEC62304 (medical device software - software life cycle processes).

Task 2.2. Risk analysis (M3-M16) (Movisens)
As a basis for the assessment of the risks, a preliminary hazard analysis (PHA) is carried out in a first step. This is followed by a detailed risk analysis together with domain experts in order to identify internal and external chains of causes as well as hazard situations and possible harm to the patient. To evaluate the resulting risk, acceptance criteria must be defined together with the clinical experts (WP5 and WP7). These criteria define whether a risk is acceptable or whether measures must be taken to reduce the risk. All risks and defined control measures are documented and made available to the ethics committee. Risk analysis is an ongoing process that requires continuous updating throughout the project. The risk analysis as well as the documentation and tracking of risks is based on the ISO14971 standard (Application of risk management to medical devices).

Task 2.3. Prototype development (M7-M16) (Movisens)
The DMMH prototype will be based on the TherapyBuilder platform developed by movisens. This will accelerate the development process, since the basic software components are already available. In addition to these building blocks, the project- or therapy-specific software components must be developed within Task 3. This includes the specification and development of a web-based dashboard (including visualization components for data analysis) for the therapist as well as specific visualization components for the patient app. The UI engineering is user-centric and based on the IEC62366 standard (Medical Devices - Application of Usability Engineering to Medical Devices). In addition to the UI components, a standardized data interface is integrated, which enables the exchange with the research database (WP3). An interface to the master ID system (WP3) will enable transparent display of identifying personal data without storage of this data in the DMMH platform. Finally, the configuration/generation of the DMMH system prototype (EMA, questionnaires, intervention content, data analysis, feedback, visualization) as well as the deployment as a cloud solution in a test environment is performed. The development process takes place within the scope of a quality management system in accordance with the medical device regulations, applying the mentioned standards and guidelines.

Task 2.4. Prototype testing (M10-M18) (Movisens)
The testing of the DMMH prototype as well as of single components is done in an iterative process parallel to the development in task 2.3. Several usability tests (first with mockups and later with an executable prototype version) are conducted and documented with the respective user groups. The results of the tests flow back into the further development of the DMMH system in task 2.3. In parallel to the usability tests, automated unit and integration tests are specified and the necessary test infrastructure is set up.

Task 2.5. System deployment, operation and maintenance (M18-M48) (Movisens)
In this task we will gather the boundary conditions for technical scalability of the DMMH platform like monitoring (telemetry of running systems), integration into the clinical authentication landscape, deployability (e.g. containerized Docker instances running on Kubernetes), deployment variants (Cloud, On-premise, SAAS) and high availability aspects. For productive use in the study (WP7), the DMMH system will be deployed as a multitenant SAAS on a cloud infrastructure provider.

Throughout the entire project, movisens will monitor the operation of the cloud/app-based DMMH prototype system to ensure that the study runs as smoothly as possible. This includes continuous performance monitoring of the servers, regular data backups and, if necessary, the correction of bugs and the associated rollout of application updates.

Participation per Partner

Partner number and short name	WP2 effort
8 - MOVISENS	49.00
Total	49.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.1	DMMH prototype for study	8 - MOVISENS	Other	Confidential, only for members of the consortium (including the Commission Services)	18
D2.2	Final prototype of DMMH including corrections	8 - MOVISENS	Other	Confidential, only for members of the consortium (including the Commission Services)	48

Description of deliverables

- D2.1: DMMH prototype for study
- D2.2: Final prototype of DMMH including corrections

D2.1 : DMMH prototype for study [18]

The DMMH prototype will be a Cloud/Smartphone based system. It will be realized on the basis of the movisens TherapyBuilder platform with the addition of project-specific software components. The prototype will be deployable on a cloud infrastructure.

D2.2 : Final prototype of DMMH including corrections [48]

The final DMMH prototype will be a revised version of the study prototype (D2.1). It will include bug fixes and necessary corrections that came up during the study.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Requirement engineering done	8 - MOVISENS	6	
MS4	Preliminary hazard analysis (PHA)	8 - MOVISENS	12	
MS7	Interface to big data system	8 - MOVISENS	18	