

Work package number ⁹	WP3	Lead beneficiary ¹⁰	6 - UHEI
Work package title	Data Management, Data Security and Interoperability		
Start month	1	End month	48

Objectives

Interoperability, data security and an overarching data management concept are core aspects of the IMMERSE consortium. The following objectives will be actively pursued by WP3:

1. Ensure the acquisition, processing and deposition of data according to the FAIR guiding principles by means of a comprehensive data management plan
2. Define interoperable data structures and interfaces for the capture and transfer of data in the consortium based on established standards and terminologies
3. Implement and operate central IT components (ID- and Consent Management, Electronic Data Capture platform, Research database) conforming to security & data protection requirements

Description of work and role of partners

WP3 - Data Management, Data Security and Interoperability [Months: 1-48]
UHEI, UEDIN

IMMERSE combines data-driven clinical care and research as well as platform implementation and evaluation with academic and SME partners. A core prerequisite for their successful collaboration is the definition of a standards-based set of interoperable data structures and interfaces that enable data sharing between the implementation sites and work packages. WP3 will devise and implement a data management plan that ensures the structured annotation, deposition and reuse of data generated in the project according to the FAIR guiding principles. WP3 will implement and operate central IT infrastructure components (ID- and Consent Management, Electronic Data Capture platform, Research database) that enable the secure acquisition, processing and analysis of data throughout the consortium according to the requirements of the General Data Protection Regulation.

Towards a sustainable implementation, all WP3 tasks will leverage open source platforms and established open standards and terminologies. This will specifically include the use and extension of HL7 FHIR (Fast Healthcare Interoperability Resources) profiles that are currently being developed in the German Medical Informatics Initiative.

Task 3.1. Definition, Implementation and Maintenance of a Comprehensive Data Management Plan (UHEI, UEDIN)
 WP3 will create an inventory of data items to be acquired and processed based on input from the consortium partners. The inventory will also include artefacts expected to be generated in the form of datasets or program code in the course of the project. WP3 will organize a workshop including members of WPs 2, 4, 5 and 7 in order to acquire the relevant input. WP3 will consolidate the proposed data elements and artefacts and maintain it throughout the course of the project. WP3 will also in collaboration with WPs 2, 4, 5, 7 and 8 devise appropriate metadata annotations to describe the generated artefacts in a structured and interoperable manner. In collaboration with WPs 6 and 8 a data use policy will be devised regarding the license terms, potential embargo periods and ethics/data protection requirements for providing access to artefacts generated by IMMERSE. Additionally, a threat analysis will be carried out to define and capture the threat model that the IMMERSE project will consider in scope with regard to data security and privacy of patient data. This will act as an input for Tasks 3.2 and 3.3 to provide a frame of reference for mitigating and reducing the risks and threats that are inherent to collecting, processing, and storing patient and medical data in a mobile platform. Based on these efforts, a comprehensive data management plan will be provided that covers the acquisition, annotation and deposition of artefacts according to the FAIR guiding principles. The inventory of data items as well as the thread model will be made available as an appendix to the data management plan.

Task 3.2. Definition of interoperable data structures and interfaces (UHEI)
 Based on the requirements and inventory of data items generated in Task 3.1, WP3 will define interoperable data structures based on open international standards and terminologies to represent the data acquired & processed in IMMERSE. In order to enable a sustainable long-term (re-)use of data structures and platforms developed in IMMERSE, WP3 will prioritize standards that are actively and broadly used in clinical care, e.g. HL7 FHIR (Fast Healthcare Interoperability Resources) as well as in the academic setting (e.g. FHIR profiles implemented within the German Medical Informatics Initiative) and extend these as required in the project. WP3 will also design an overall IT architecture that specifies components, services and interfaces. The architecture will address security and data protection requirements described in the threat model provided by Task 3.1. WP3 will provide implementation guides for the

data structures and interfaces based on HL7 templates that will enable the project partners to implement the respective components and data structures according to WP3 specifications.

Task 3.3. Implementation and operation of central IT components (UHEI)

Based on the architecture & implementation guides developed in Task 3.2, WP3 will implement and operate the following central IT components (see Figure 3 for overall platform architecture):

- An ID- and Consent-Management platform will be set up to generate pseudonyms for patients and collect structured consent information upon enrolment into the implementation studies.
- A REDCap eCRF platform will be set up to collect pseudonymized data from service users in the context of RCTs in the project.

• The DMMH Research Database will provide a separate data platform for the analytic and scientific use of data collected both through the DMMH App and REDCap eCRF components in a pseudonymized context.

The central IT components will interface to the following components implemented by WP2:

- The DMMH Backend will provide a portal for treating clinicians to enrol service users, enter questionnaire prescriptions for the app frontend and receive reports about data collected through the platform. It also provides the database and server backend for the operation of the DMMH ESM App and Sensor Apps.
- The DMMH Frontend will be the patient-facing part of the platform, which receives questionnaire prescriptions from the Backend, provides means for ESM data collection entered by the user or through integrated sensors and delivers collected data to the Backend.

Data collected and processed in the platform will conform to specifications developed in Task 3.2 regarding data structures, value-set terminologies and semantic annotation. WP3 will address data protection requirements through the strict separation of identifying and medical data elements throughout the platform and hardening the IT systems according to current best practices, based on the threat analysis provided by Task 3.1. The central IT components will be provided through 3 consecutive releases, with the first release covering ID- & Consent Management and the eCRF and the second release adding the Research Database. The third release will be a maintenance release to address user feedback and potential technical issues. The central IT platform will be operated by WP3 throughout the funding period of the consortium.

To achieve a sustainable implementation, IMMERSE will strictly adhere to interoperable data structures and interfaces based on internationally accepted and adopted standards and terminologies. The DMMH platform will re-use and extend successfully implemented approaches from existing projects like the HL7 FHIR-based Core Dataset of the German Medical Informatics Initiative. Availability of terminologies in the participating countries due to licensing requirements (e.g. for SNOMED CT) is recognized as a risk that will need to be reflected in the choice of terminologies used to semantically annotate the data structures. Communication between components of the DMMH platform will be based on the data structures and interfaces defined in the data management plan and implementation guide.

Participation per Partner

Partner number and short name	WP3 effort
3 - UEDIN	2.40
6 - UHEI	34.00
Total	36.40

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D3.1	Data Management Plan	6 - UHEI	ORDP: Open Research Data Pilot	Public	6

List of deliverables

Deliverable Number¹⁴	Deliverable Title	Lead beneficiary	Type¹⁵	Dissemination level¹⁶	Due Date (in months)¹⁷
D3.2	Implementation Guide for interoperable data structures and interfaces	6 - UHEI	Report	Public	12
D3.3	Implementation report for 3rd platform release	6 - UHEI	Report	Public	36

Description of deliverables

- D3.1: Data Management Plan
- D3.2: Implementation Guide for interoperable data structures and interfaces
- D3.3: Implementation report for 3rd platform release

D3.1 : Data Management Plan [6]

WP3 will provide a comprehensive data management plan based on the Horizon 2020 template DMP. The DMP will cover aspects of data acquisition, processing, quality control, data privacy aspects, metadata annotation, data deposition, licensing and usage policy according to the FAIR guiding principles. The DMP will provide as appendices an inventory of data elements processed during the project and a threat analysis regarding data privacy.

D3.2 : Implementation Guide for interoperable data structures and interfaces [12]

WP3 will provide an implementation guide covering data structures, interfaces and an overall systems architecture for the DMMH platform. Open internationally adopted standards will be leveraged to ensure a sustainable implementation.

D3.3 : Implementation report for 3rd platform release [36]

WP3 will provide a report on the implementation and operation of the final release of the central IT components of the DMMH platform, covering an ID- & Consent-Management system, an eCRF system and a research database.

Schedule of relevant Milestones

Milestone number¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS8	First central IT platform release	6 - UHEI	18	
MS15	Second IT platform release	6 - UHEI	30	
MS22	Third central IT platform release	6 - UHEI	42	