

WP3 Data Management, Data Security and Interoperability

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WP3 - Staff



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WP3 - Objectives



- 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**



Task 3.1: FAIR Data Management (1)



- **Development of a Data Management Plan (DMP)**
 - Inventory of data sets, data items and potential artifacts
 - Suitable metadata annotations & terminologies
 - Data Sharing & integration of Data Governance Policy, suitable license
 - Patient data protection & security aspects, including threat analysis
- **Maintenance of the DMP throughout the project**
- **Deposition & long-term archiving of datasets & artifacts**



Task 3.1: FAIR Data Management (2)



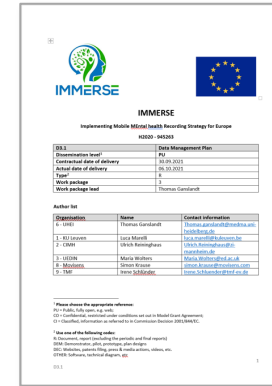
- **Interactions with other WPs:**
 - WP 2, 4, 7: requirements gathering regarding datasets & artifacts
 - WP 6: data sharing aspects in the informed consent, data governance policy
 - WP 5, 6, 8: licensing & dissemination



Task 3.1: FAIR Data Management (3)



- **Status after first year**
 - first release of DMP was delivered on time
 - covers phase I datasets
- **Next steps: preparation of second release**
 - extension with phase II datasets
 - addition of study-related data management aspects
 - for discussion: what needs to be part of the CIP or of the DMP?
 - potential topics: blinding, plausibility checks, monitoring
 - execution of privacy threat analysis
 - semantic annotation & deposition of phase I datasets & artefacts



Data Summary

- Purpose of data collection
- Data types and formats
- Re-use of existing data
- Data utility

FAIR Data

- Making data findable and accessible
- Making data interoperable & reusable
- Increase data re-use

Allocation of resources

Data security

Ethical aspects

Conclusions

References

Appendices

- Inventory of datasets & artifacts



Task 3.2: Interoperable Data Structures (1)



- **Goal: Interoperability with international clinical/scientific data platforms**
 - e.g. German Medical Informatics Initiative, French Health Data Hub, SPHN
 - by use of internationally adopted data structures & terminologies
- **Development of an Implementation guide**
 - based on the data inventory & FAIR guidelines from Task 3.1
 - specification of data structures based on HL7 FHIR standard
 - semantic annotation with terminologies like LOINC & SNOMED CT
- **Design of an architecture for the central IT platform**
- **Maintenance of the Implementation guide throughout the project**



Task 3.2: Interoperable Data Structures (2)



- **Interactions with other WPs:**
 - WP 2: Data source structures & interfaces for Movisens platform
 - WP 4: requirements regarding data provision for analysis
 - WP 7: requirements for ESM/eCRF data elements



Task 3.2: Interoperable Data Structures (3)



- **Status after first year**
 - draft version of Implementation guide available
 - will be submitted by April 8th
- **Next steps: preparation of second release**
 - semantic annotation of ESM forms & eCRF questionnaires
 - integrate potential changes based on partner feedback & experience from implementation of interfaces in T3.3



Approach for the Implementation Guide Architecture

Data Elements for Study & Participants

- IMMERSE_ResearchSubject
- IMMERSE_Patient
- IMMERSE_Organization

Data Elements for Questionnaires & Responses

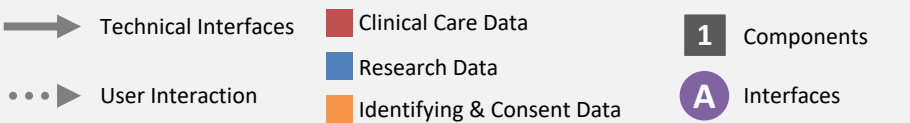
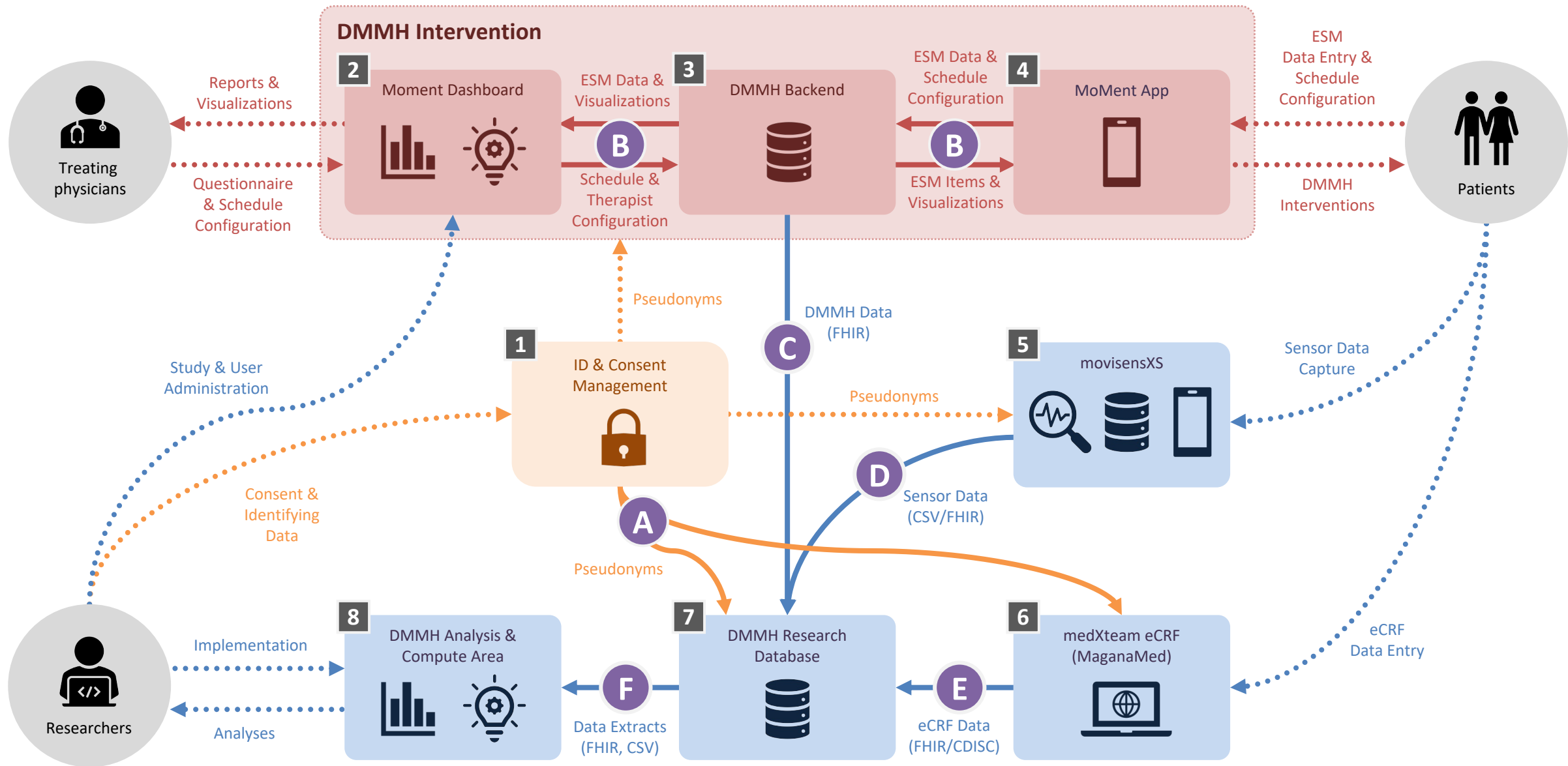
- IMMERSE_Questionnaire
- IMMERSE_QuestionnaireResponse
- IMMERSE_QuestionnaireResponseObservation

Data Elements for Mobile Sensor Data

- IMMERSE_GeolocationObservation
- IMMERSE_ActivityObservation
- IMMERSE_StepsObservation
- IMMERSE_DeviceOnOffObservation
- IMMERSE_DisplayOnOffObservation
- IMMERSE_AppUsageObservation
- IMMERSE_NotificationObservation



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Task 3.2: Interoperable Data Structures (5)

- **Specification & dissemination of IMMERSE FHIR Profiles**
 - based on basic FHIR resources: <https://www.hl7.org/fhir/resourcelist.html>
 - adapted to IMMERSE needs
 - resulting profiles available on Simplifier: <https://simplifier.net/IMMERSE-EU>

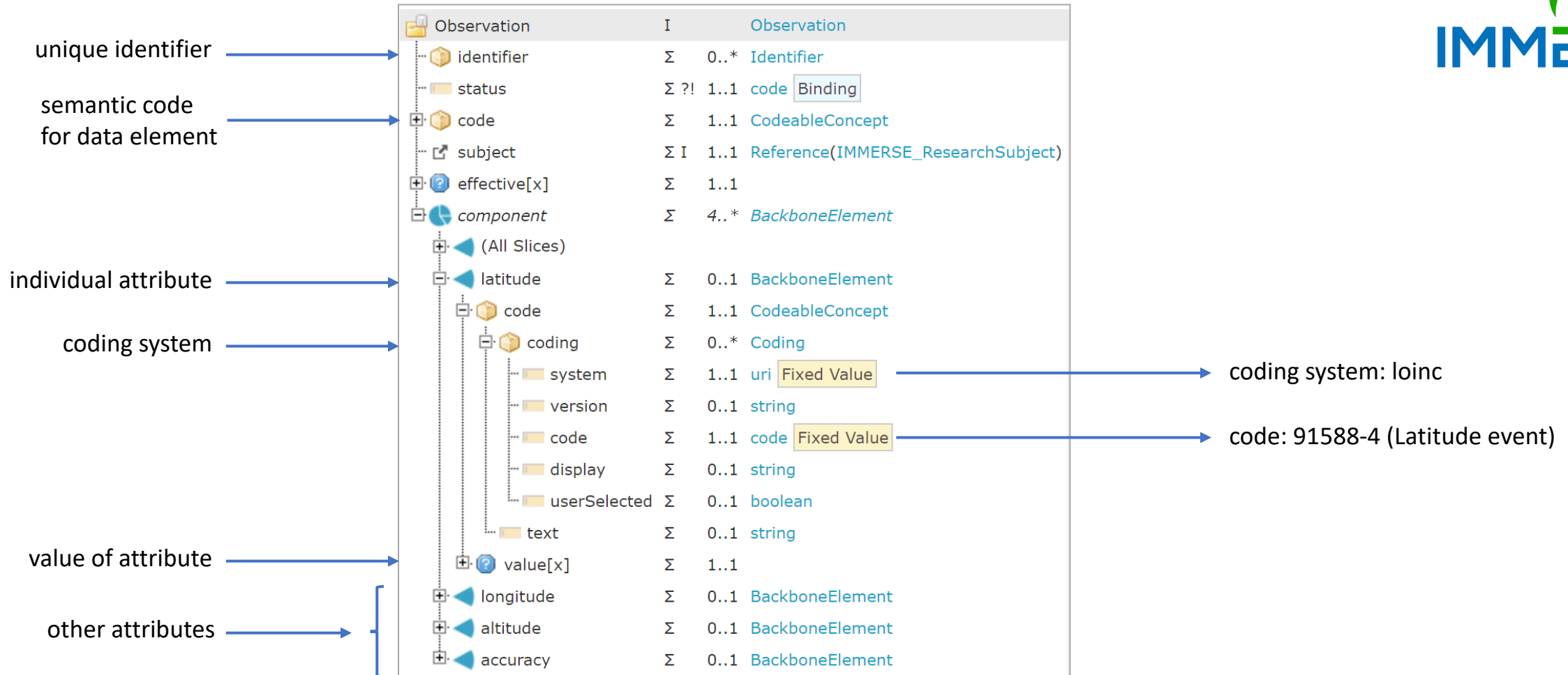
Observation	I	Observation
identifier	Σ 0..*	Identifier
basedOn	Σ I 0..*	Reference(CarePlan DeviceRequest Immuni...
status	Σ ?! 1..1	code Binding
category	0..*	CodeableConcept Binding
code	Σ 1..1	CodeableConcept
subject	Σ I 0..1	Reference(Patient Group Device Location)
context	I 0..1	Reference(Encounter EpisodeOfCare)
effective[x]	Σ 0..1	
issued	Σ 0..1	instant
performer	Σ I 0..*	Reference(Practitioner Organization Patient ...
value[x]	Σ I 0..1	
dataAbsentReason	I 0..1	CodeableConcept Binding
interpretation	0..1	CodeableConcept Binding
comment	0..1	string
bodySite	0..1	CodeableConcept
method	0..1	CodeableConcept
specimen	I 0..1	Reference(Specimen)
device	I 0..1	Reference(Device DeviceMetric)
referenceRange	I 0..*	BackboneElement
related	Σ 0..*	BackboneElement
component	Σ 0..*	BackboneElement



Observation	I	Observation
identifier	Σ 0..*	Identifier
status	Σ ?! 1..1	code Binding
code	Σ 1..1	CodeableConcept
subject	Σ I 1..1	Reference(IMMERSE_ResearchSubject)
effective[x]	Σ 1..1	
component	Σ 4..*	BackboneElement
(All Slices)		
latitude	Σ 0..1	BackboneElement
code	Σ 1..1	CodeableConcept
value[x]	Σ 1..1	
valueQuantity		Quantity
longitude	Σ 0..1	BackboneElement
altitude	Σ 0..1	BackboneElement
accuracy	Σ 0..1	BackboneElement



Task 3.2: Interoperable Data Structures (6)



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Task 3.3: Implementation & Operation of Central IT (1)



- **Based on Implementation Guide (Task 3.2) and Privacy Threat Analysis (Task 3.1)**
- **Scope:**
 - ID- & Consent Management
 - integration of medXteam eCRF
 - Research Database
- **Interfaces for data import**
 - Movisens platform
 - medXteam eCRF data
- **Interfaces for data use**
 - data provision for analysis, including execution (optional) of analysis code
 - data deposition to longterm archiving
- **Provision/Maintenance of platform in 3 releases throughout project**



Task 3.3: Implementation & Operation of Central IT (2)



- **Interactions with other WPs:**
 - WP 2: import interface to Movisens platform
 - WP 4: export interface for data analysis access
 - WP 6: implementation of privacy requirements in the platform
 - WP 7: import interface for medXteam eCRF, semantic mapping of ESM forms/eCRF questionnaires



Task 3.3: Implementation & Operation of Central IT (3)



- **Next steps for year 2**
 - set up & configure components of the central IT infrastructure
 - ID-Management (Mainzelliste)
 - FHIR Store
 - Compute area
 - implement interfaces between components
 - import & transformation of ESM forms data from MoMent App
 - import & transformation of movisensXS sensor data
 - import & transformation of eCRF data
 - TBD: interface ID-Management => MoMent Dashboard



WP3 – Deliverables & Milestones



- **Deliverables**
 - **D3.1: Data Management Plan (M6)**
 - **D3.2: Implementation Guide for interoperable data structures and interfaces (M12)**
 - **D3.3: Implementation report for 3rd platform release (M36)**
- **Milestones**
 - **MS9: First central IT platform release (M18)**
 - **MS17: Second central IT platform release (M30)**
 - **MS25: Third central IT platform release (M42)**

