WP3 Data Management, Data Security and Interoperability

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Steering Board Meeting Leuven, 18.11.2022

This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

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**

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Task 3.1: FAIR Data Management (3)

- **Current status & ongoing work**
  - data management aspects were contributed to the requirements specification document & clinical investigation plan
  - second release of DMP in preparation
    - addition of DataCite metadata schema for annotation of datasets
    - addition of phase II data capture aspects
    - extension of inventory with phase II datasets

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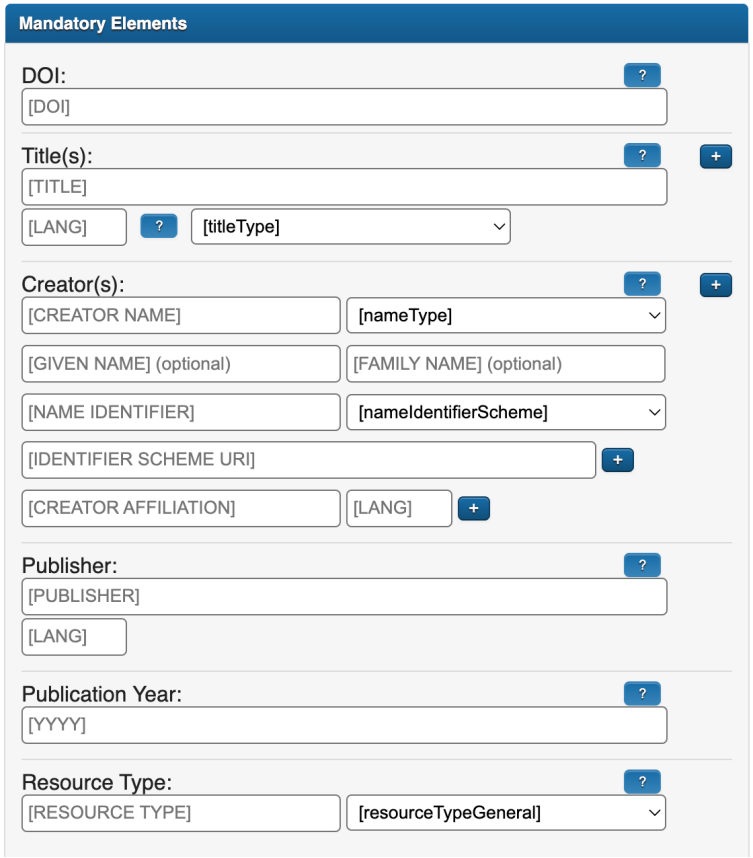
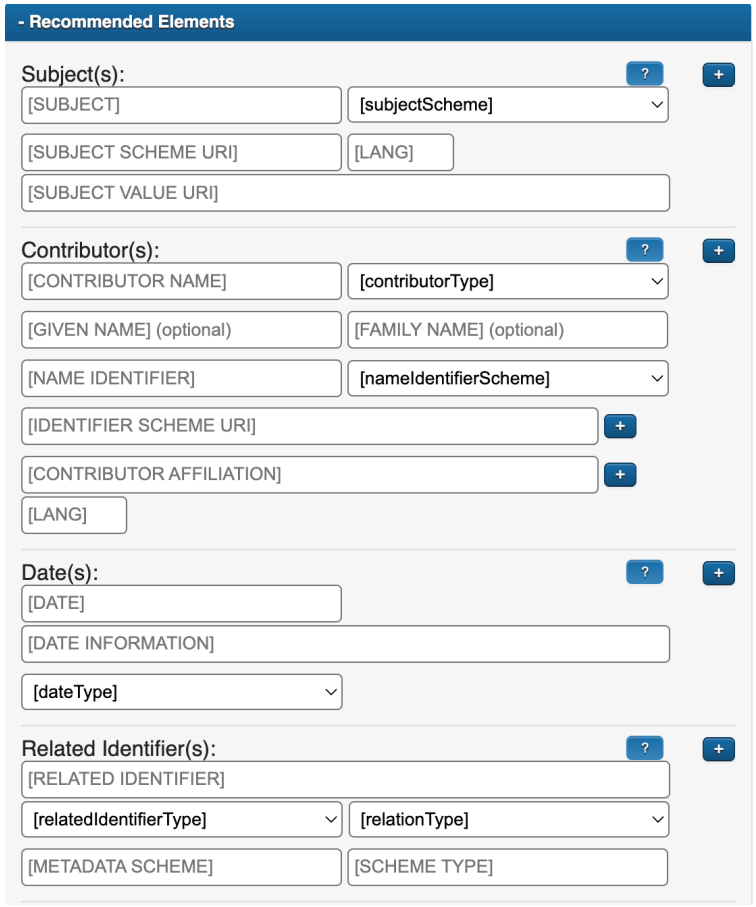
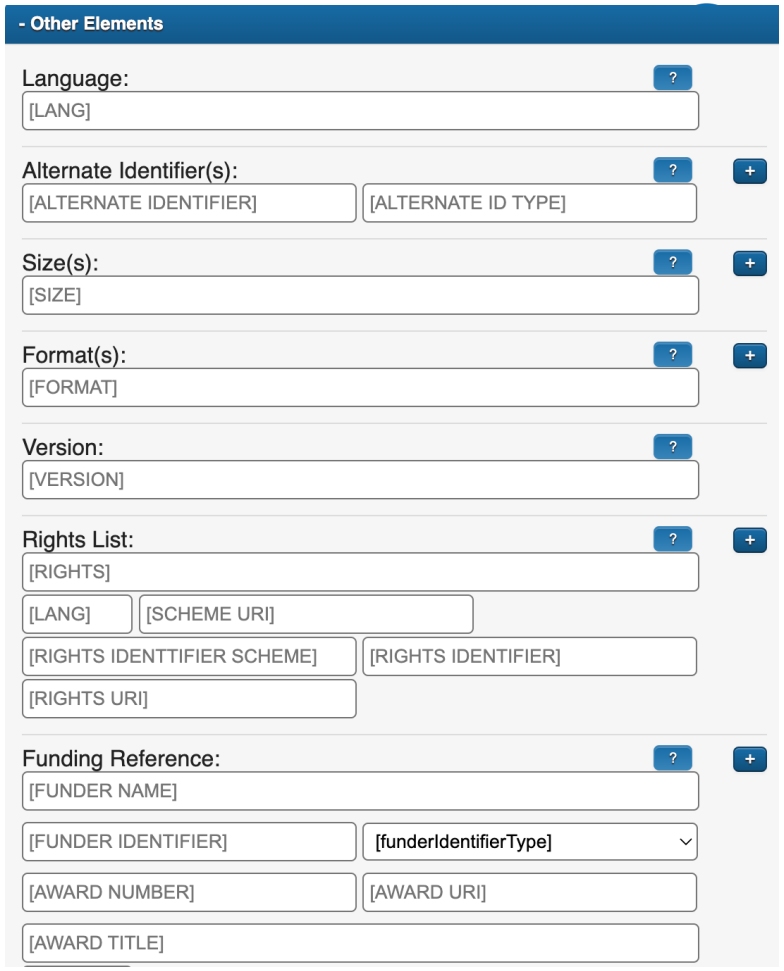
Task 3.1: FAIR Data Management (4)

- **Metadata annotation**
  - proposal to use DataCite schema







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Task 3.1: FAIR Data Management (5)

- **Metadata annotation with DataCite**
  - requires assigning names to each dataset
    - including a single „Creator“ (organization or individual)
    - and several contributors
  - encourages ORCID identifiers for contributors

- **For discussion:**
  - **should we assign „IMMERSE Consortium“ as creator & include associated team members as contributors?**
  - **do all team members have ORCID identifiers?**

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Task 3.1: FAIR Data Management (6)

- **Long-term archiving options**
- Services available at FAU Erlangen
  - FAU DataCloud: storage of not publicly available datasets, assignment of PIDs or (optionally) DOIs, registration of datasets in CRIS research information system of FAU
  - FAU RADAR: storage of publicly available datasets, assignment of DOIs, registration in catalog of FAU library
- Services available indendently of FAU
  - Zenodo: storage & catalog of publicly available datasets, assignment of DOIs

- **For discussion:**
  - **which datasets could/should be made available publicly?**

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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**

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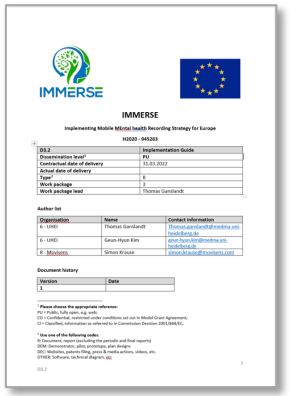
Task 3.2: Interoperable Data Structures (3)

- **Current status & ongoing work**
  - Implementation Guide deliverable released
  - covers architecture, questionnaires (from eCRF, movisensXS and MoMent) & sensor data
  - started version 2 adressing changes to architecture during implementation, semantic annotation of questionnaires
  - added coding of items & responses in Maganamed eCRFs
  - after completion of eCRFs, semantic annotation of questionnaire items and valuesets has started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Implementing Mobile Mental health Recording Strategy for Europe

H2020 - 945263

D3.2	Implementation Guide
Dissemination level	PU
Contractual date of delivery	31.03.2022
Actual date of delivery	
Type	R
Work package	3
Work package lead	Thomas Ganslandt

Author list

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Document history

Version	Date
1	

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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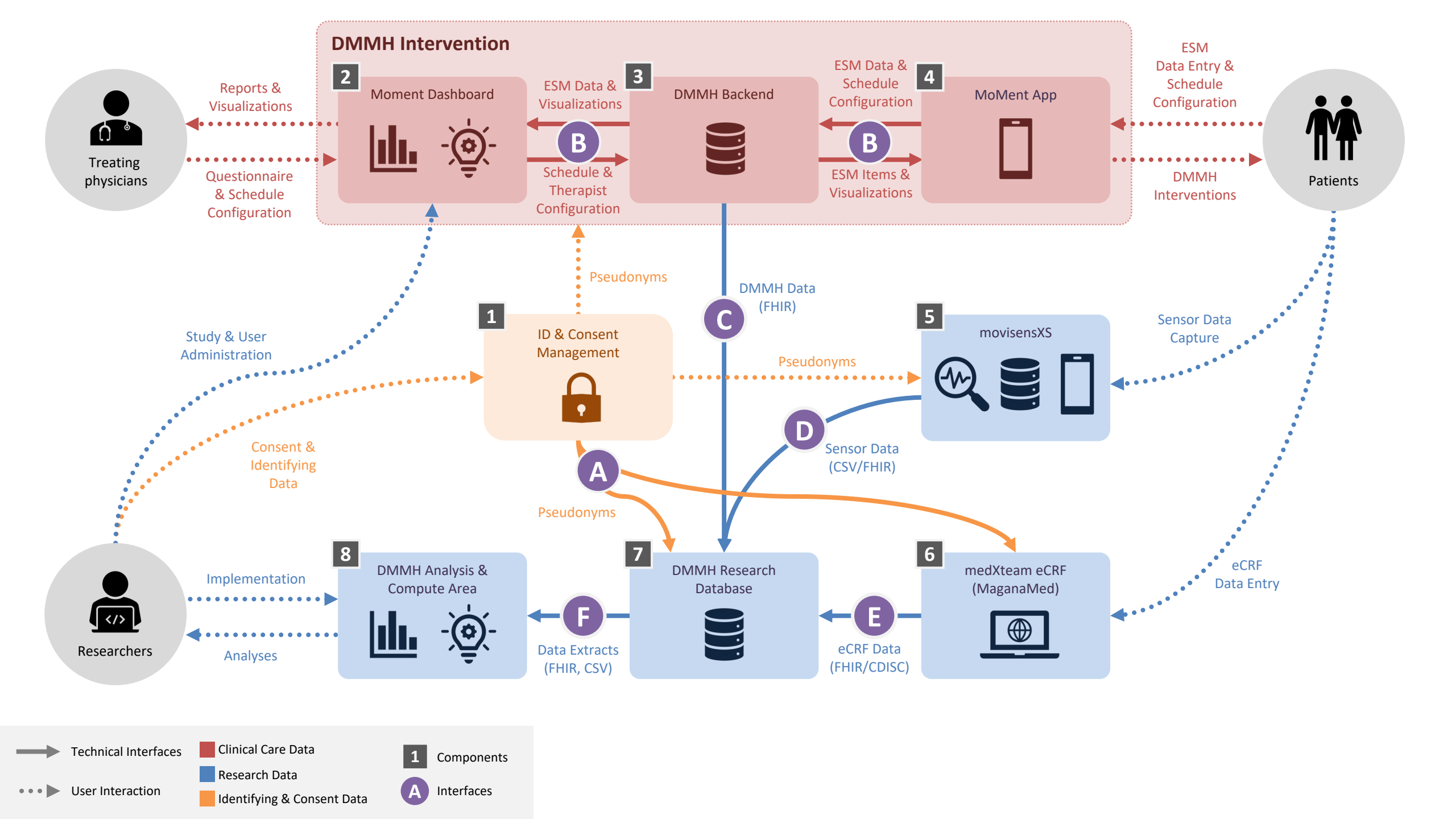
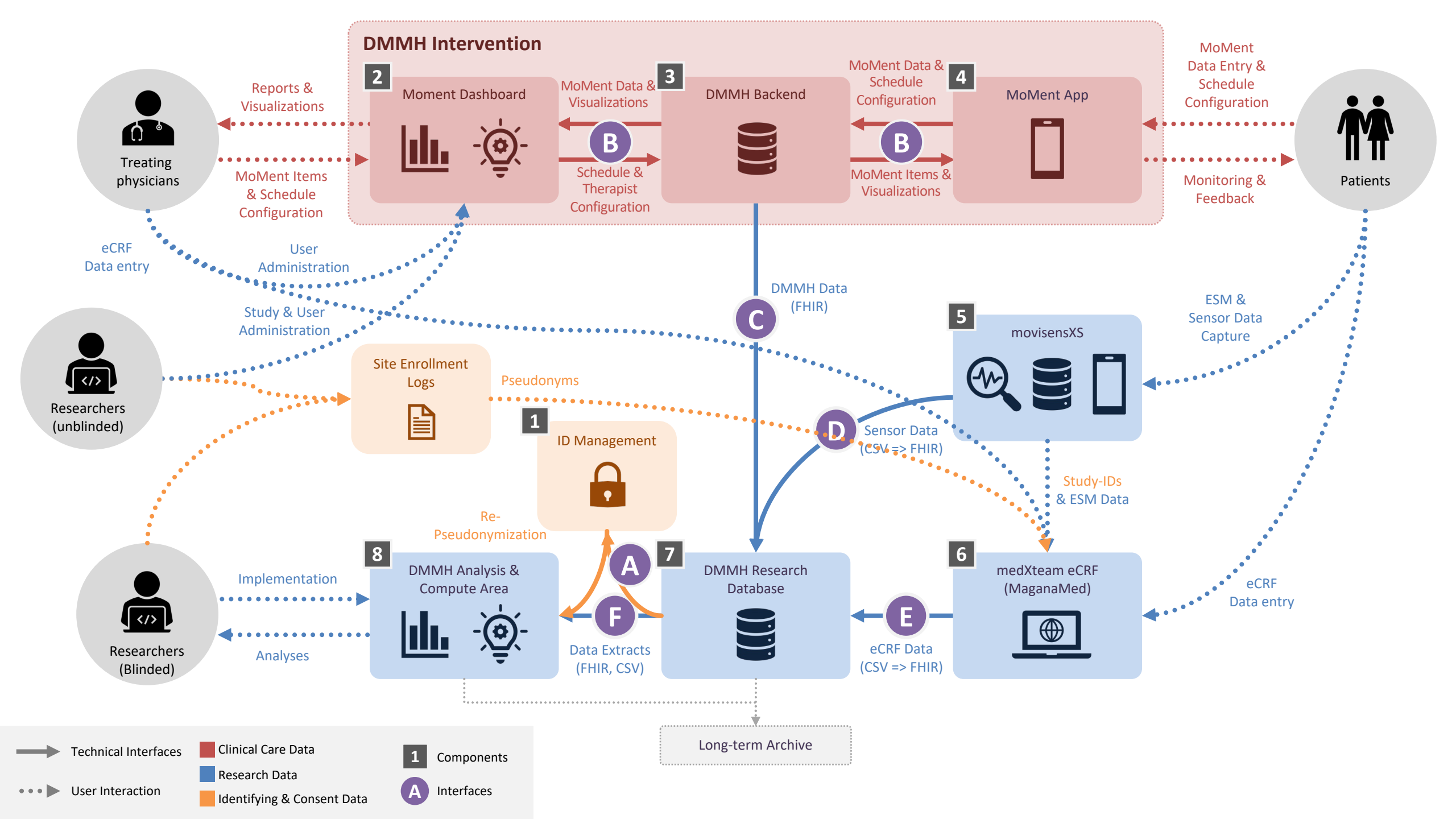

DMMH Intervention
2
Moment Dashboard
3
DMMH Backend
4
MoMent App
Reports & Visualizations
Questionnaire & Schedule Configuration
ESM Data & Visualizations
Schedule & Therapist Configuration
ESM Data & Schedule Configuration
ESM Items & Visualizations
ESM Data Entry & Schedule Configuration
DMMH Interventions
Treating physicians
Patients
B
B
C
DMMH Data (FHIR)
Pseudonyms
1
ID & Consent Management
5
movisensXS
Sensor Data Capture
Study & User Administration
Consent & Identifying Data
Pseudonyms
D
Sensor Data (CSV/FHIR)
A
Pseudonyms
8
DMMH Analysis & Compute Area
7
DMMH Research Database
6
medXteam eCRF (MaganaMed)
eCRF Data Entry
Implementation
Analyses
F
Data Extracts (FHIR, CSV)
E
eCRF Data (FHIR/CDISC)
Researchers
Technical Interfaces
User Interaction
Clinical Care Data
Research Data
Identifying & Consent Data
1
Components
A
Interfaces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MoMent Data & Schedule Configuration
MoMent Items & Visualizations
MoMent Data Entry & Schedule Configuration
Monitoring & Feedback
Treating physicians
Patients
eCRF Data entry
User Administration
Study & User Administration
DMMH Data (FHIR)
ESM & Sensor Data Capture
5
movisensXS
Researchers (unblinded)
Site Enrollment Logs
Pseudonyms
1
ID Management
Sensor Data (CSV => FHIR)
Study-IDs & ESM Data
Re-Pseudonymization
8
DMMH Analysis & Compute Area
7
DMMH Research Database
6
medXteam eCRF (MaganaMed)
Implementation
Analyses
Data Extracts (FHIR, CSV)
eCRF Data (CSV => FHIR)
eCRF Data entry
Researchers (Blinded)
Long-term Archive
A
B
C
D
E
F
Technical Interfaces
User Interaction
Clinical Care Data
Research Data
Identifying & Consent Data
Components
Interfaces

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
  - Research Database
- **Interfaces for data import**
  - Maganamed eCRF data
  - movisensXS
  - MoMent App
- **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**

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

- **Current status & ongoing work**
  - changes from original approach
    - switch from automated ID management to paper-based approach (site enrollment logs)
      - ID-management used only for re-pseudonymization of exported datasets
    - operation of REDCap instance for randomization
    - capture of organizational data through movisensXS
  - set up & configure components of the central IT infrastructure
    - ID-Management (switched from Mainzelliste to gPAS)
    - REDCap instances at UKER
      - productive: randomization (instance for each site)
    - Shared network drive for provision of datasets
  - implement interfaces between components

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Task 3.3: Implementation & Operation of Central IT (4)

- **Current status & ongoing work (cont'd)**
  - implement interfaces between components
    - automated extraction of movisensXS data
    - anomymization of geolocation data
    - automated upload of datasets to UKERCloud shared network drive
    - extraction of Maganamed eCRF data: parsing of codebook completed
  - next steps
    - interface to MoMent App backend
    - parsing of eCRF data conent
    - implementation of data entry dashboard
    - setup of FHIR server & transformation of raw data as it becomes available
    - metadata annotation & deposition of phase I datasets & artifacts
    - interface to extract DROPS abstract submission content from Leuven REDCap
    - for discussion: implement dummy datasets?

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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)

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