D1.3 Mobilise-D Data Management Plan

Mobilise-D

Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement.

Grant Agreement No. 820820

WP1.3 – Data Management Plan

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Document History

Version	Date	Description
V0.1	30 May 2019	First Draft
V0.2	27 Sep 2019	Comments and feedback from workshop
V1.0	30 Sep 2019	Final Version

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1 Executive Summary

This deliverable provides the first version of the Mobilise-D Data Management Plan (DMP). The project is in its early stages and the studies and data described within this document are still under development and are subject to change. The deliverable outlines the current understanding of how the research data collected or generated will be handled during and after the Mobilise-D project. It further describes which standards and methodologies for data collection and generation will be followed, and how relevant data will be shared.

2 Introduction and aim

The main objectives of Mobilise-D are threefold: to deliver a valid solution (consisting of sensor, algorithms, data analytics, outcomes) for real-world digital mobility assessment; to validate digital outcomes in predicting clinical outcome in chronic obstructive pulmonary disease, Parkinson's disease, multiple sclerosis, proximal femoral fracture recovery and congestive heart failure; and, to obtain key regulatory and health stakeholder approval for digital mobility assessment.

The Mobilise-D project plan includes a DMP and together with the Consortium Agreement provides the general framework regarding data management, data protection, data ownership, accessibility, and sustainability requirements. As the DMP is an evolving document, some of these aspects may be further described and/or updated in later versions of the document.

In summary, the Mobilise-D DMP gives guidance and provides an oversight of general data management, while each evaluation site needs to provide specific data management information for this plan including, but not limited to, data capture systems, data analysis systems, data protection and data privacy measures, including description of de-identification of data sets and access rules. Project partners do not have to ensure access to parts of research data if such access would compromise their legitimate interests. In such cases, the DMP will contain reasons for not providing access.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No. 820820. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme, and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

3 General principles

Mobilise-D is a multi-national, multi-disciplinary research programme that involves over 50 collaborators, divided into seven work-packages:

- WP1 Project Coordination & Oversight
- WP2 Algorithm development and technical validation
- WP3 Database development and data management
- WP4 Definition and validation of digital mobility outcomes against clinical endpoints
- WP5 Regulatory, HTA and payer consensus over operational definitions
- WP6 Statistical analysis, evaluation of results and data availability
- WP7 Stakeholder information and results dissemination and exploitation

- All work-packages are tightly integrated so that data, samples and technical expertise are shared throughout the programme. All data from all sites has to be captured according to local institutional guidelines

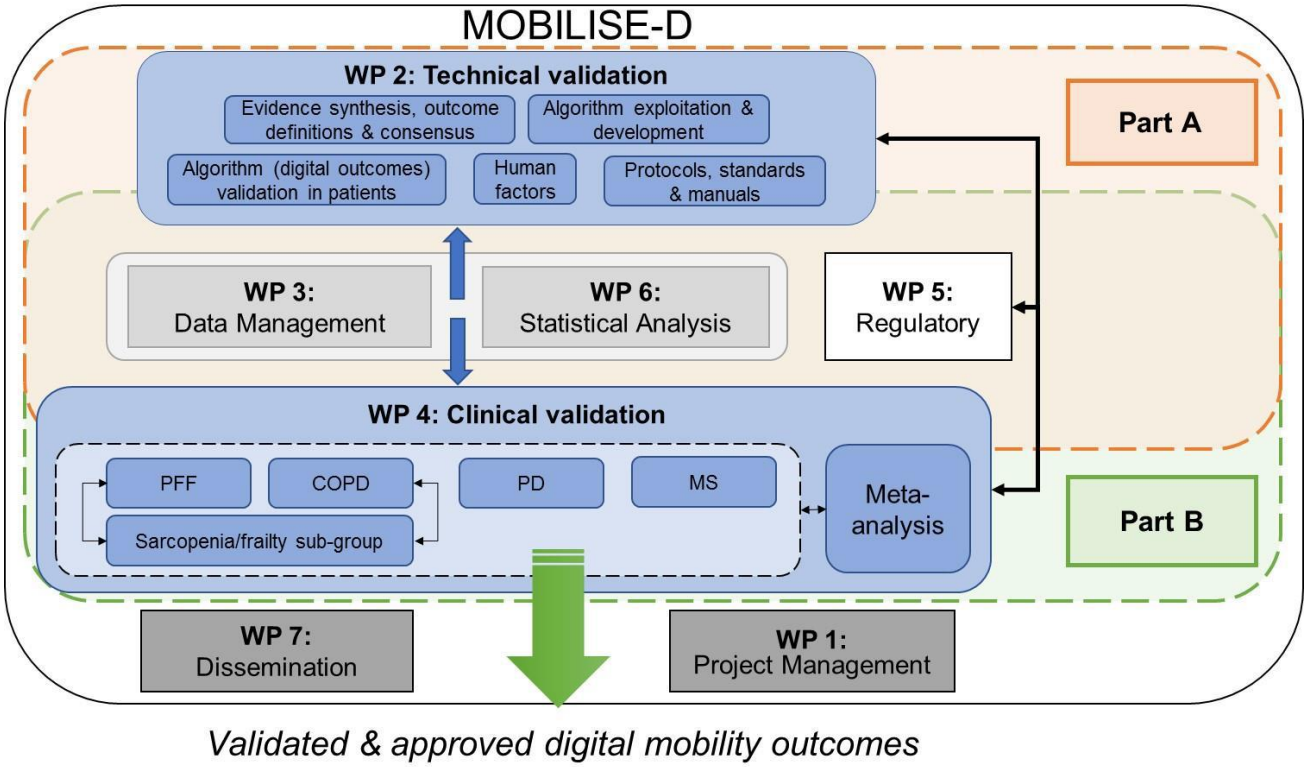

Figure 1: Overview of Mobilise-D Project Structure

Part A - Year 1-2 - Technical validation and qualification advice
Part B - Year 3-5 - Clinical validation and regulatory endorsement

Mobilise-D will generate the following types of data:

- Participant information: anonymised participant demographic and clinical data (such as diagnosis code and disease severity classification)
- Research data: large digital datasets, results from longitudinal cohort studies, results from technical validation studies. This will include wearable motion sensor data, data from ground truth motion capture systems, confounding factor data (e.g. GPS location data), text from semi structured participant interviews, and data from clinical rating and functional assessment scales.
- Evaluation data: results of technical and clinical validation studies; standards (text and spreadsheets)

The DMP follows the principles that research data are findable, accessible, interoperable and reusable (FAIR)[1], as well as being attributable, legible, contemporaneous, original and

accurate (ALCOA)[2]. The general principles on access rules are defined in the Consortium Agreement (Section 8 Intellectual property – Access rights).

4 Compliance with Data Protection Law

By signing the Mobilise-D Consortium Agreement, all member organisations have agreed to comply with all laws, rules, regulations and guidelines applicable to the collection, use, handling, disposal and further Processing of the Personal Data and the Human Samples, in accordance with *Appendix 2: Actions involving Personal Data and/or Human Samples, Consortium Agreement for Mobilise-D*.

Mobilise-D researchers commit to the highest standards of data security and protection in order to preserve the personal rights and interests of study participants. They will adhere to the provisions set out in the:

- General Data Protection Regulation (GDPR)[3]
- Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communication services or of public communications networks[4]
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)[5]
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[6]

Prior to collecting, storing, and processing sensitive personal data, the consortium will seek approval of the applicable local data protection authorities. Consent forms will contain information on how personal data will be managed. To secure the confidentiality, accuracy, and security of data and data management, the following measures will be taken:

- All personal data obtained in Mobilise-D will be available to partners within the consortium only after anonymization. Keys to re-identification will be held confidentially within the respective research units. In situations where re-identification of study participants becomes necessary, for example the collection of additional data, this will be possible only through the research unit and in cases where informed consent for such cases has been given.
- Personal data are entered to secure websites. Data are processed only for the purposes outlined in the patient information and informed consent forms. Use for other purposes will require explicit patient approval. Also, data are not transferred to any places outside the consortium without patient consent.
- None of the personal data will be used for commercial purposes, but the knowledge derived from the research using the personal data may be brought forward to such use as appropriate, and this process will be regulated by the Grant Agreement and the Consortium Agreement, in accordance with any generally valid legislation and regulations.

5 Overview of data managers, data repositories and access rules

The responsible roles for the repositories used in the Mobilise-D project are listed in Table 1 below. The platform “e-Science Central” (e-SC) is used as the data management platform for Mobilise-D members and will be used to upload and receive anonymised datasets, reports and algorithms. The final version of the DMP will have details regarding the long-term storage and preservation of anonymized data particularly after the end of the Mobilise-D project. The relevant committee will determine where it is allowed to store data and under which license(s). Datasets containing personal data in the possession of partners other than the research data owner must be destroyed at the end of the Mobilise-D project. Other non-public and public datasets not containing personal data will be stored for the recommended timeframe from the end of the Mobilise-D project to ensure their long-term availability to future researchers.

Role	Responsibilities	Name	Email	e-Science Central	DW1	DW2
				Access Levels		
Study Volunteer	N/A	Subj ID	N/A	Request personal data as per GDPR	N/A	N/A
Clinical Investigator	Acquire and upload data			RW	-	-
Data Controller (Lead CI)	Data protection and processing at sites			RW	R	R
Platform Manager	Provide administration of and access to platform	HH / DS / HG	HH / DS / HG	All	All	All
Data Analyst	Analyse/interpret data and develop data optimization strategies			R	RW	RW
Statistician	Responsible for implementation of pre-defined statistical analyses on the derived data and results files.			-	-	RW

Table1: Main contacts for e-SC data management

All questions related to data management such as rules for uploading data, requests for access rights should be sent to the platform managers.

The processes and the role description of the platform manager will be developed by project month 12 and explained further in the next version of the DMP. Work package (WP) leads are responsible for informing the platform managers about all generated datasets, in their respective packages.

6 Overview of data generated and collected in Mobilise-D

Mobilise-D members use a SharePoint platform to facilitate collaboration between members, to plan deliverables, to track progress of all tasks, and to store meeting minutes and task reports.

The research data generated and collected during the Mobilise-D project can be divided into two categories;

1. Technical Validation Study (WP2 / WP3)
2. Clinical Study (WP4 / WP6)

Patient data will be generated and processed during the activities planned in WP2, WP3 and WP4. All data will be uploaded to the Mobilise-D platform e-SC hosted on AWS. During the technical validation study some data (CRF/sensor data) may be uploaded manually via a portal provided. All other data will be transferred via API from 3rd party servers. No Personal Identifiable Information (PII) will be uploaded to e-SC. See Figure 2 below;

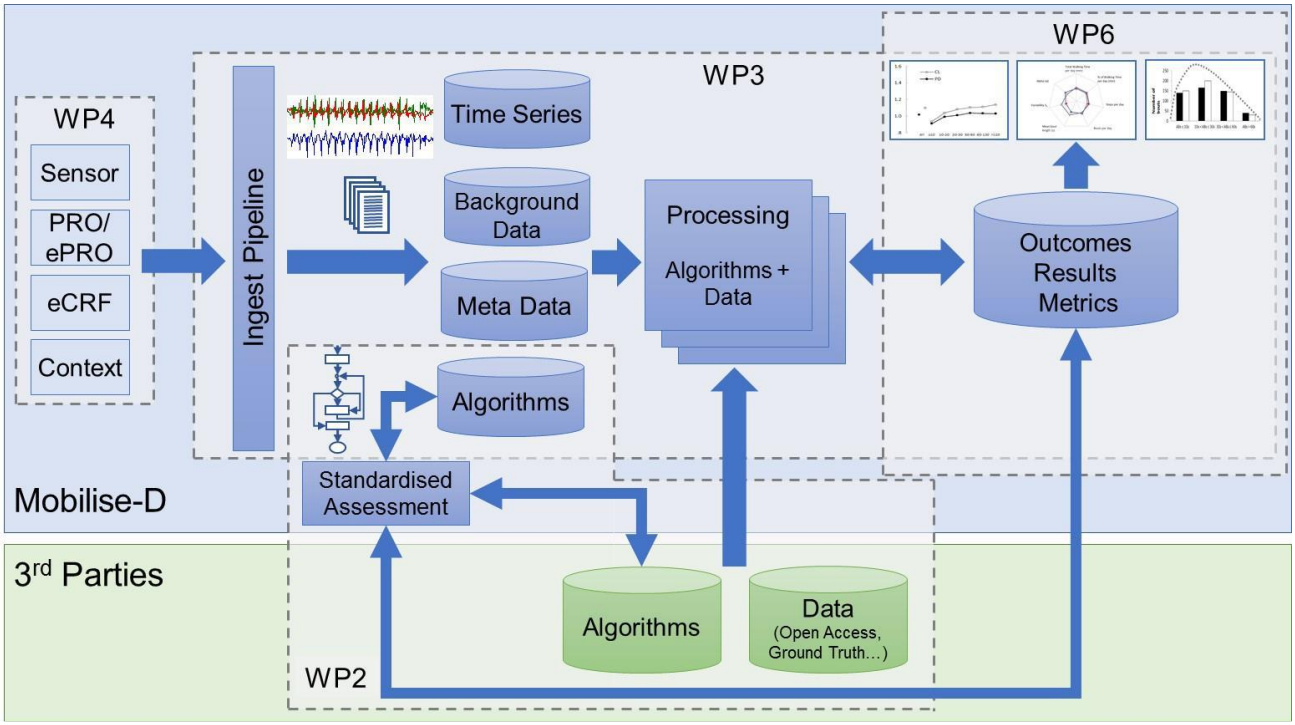

Figure 2: Overview of Mobilise-D Data Management

6.1 Technical Validation Study (WP2/3)

6.1.1 Description of the data

For the technical validation study existing digital mobility data from partners in the consortium will be synthesised into a metadatabase of real-world and laboratory data and algorithms to inform validation. Using the Dynaport Movemonitor+ from technology partner McRoberts, WP2 will produce a validated device-algorithm pair, and associated technical, clinical and patient specific standards for clinical validation. 5 sites will participate in the recruitment and assessment of participants in the technical study. Data will be collected from study volunteers over 9 days using a combination of clinical, laboratory, and home assessments. These activities are illustrated in the flowchart below;

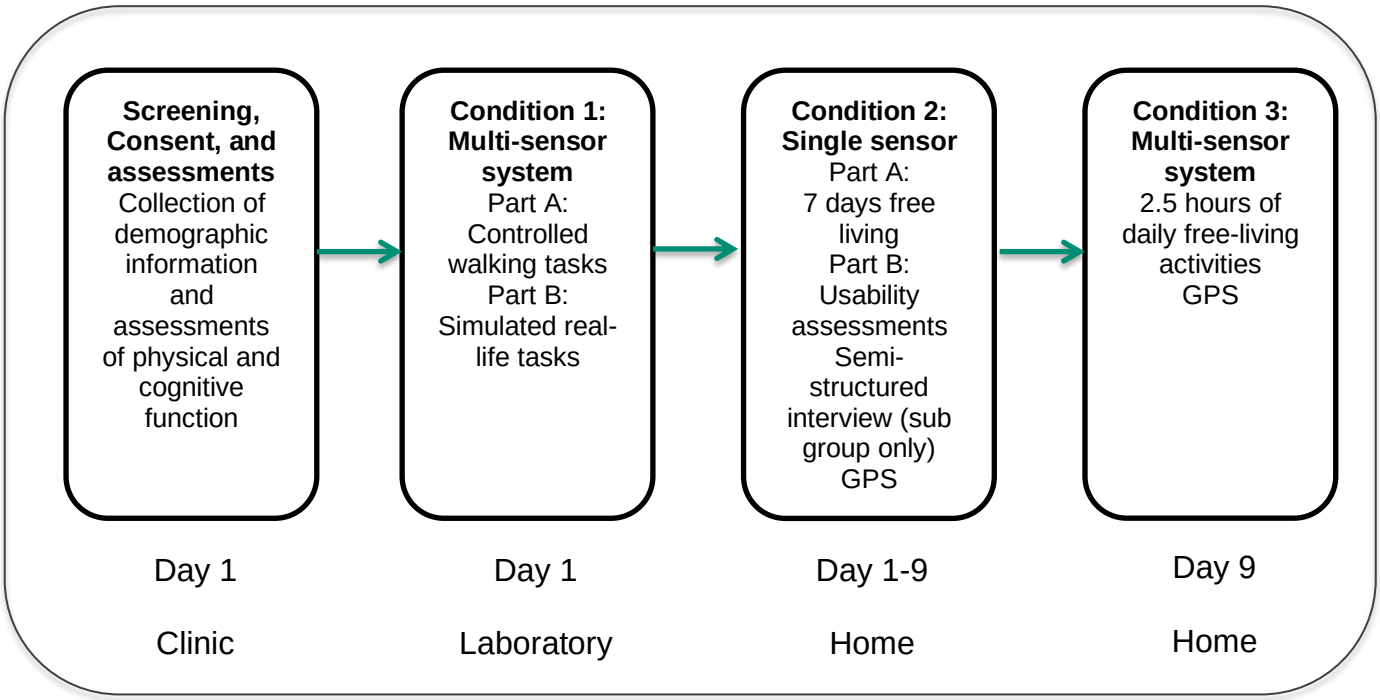

Figure 3. Technical study activities, time points and locations.

Data set reference and name

The broad umbrella term used to describe the data collection comprising multiple datasets in the technical validation study is **Mobilise-D-TVS**. This collection will include the following datasets;

- Demographic, cognitive, physical function
- Multi-sensor-lab data
- Single-sensor data
- Multi-sensor-home data
- Patient Reported Outcomes
- Semi-structured interviews
- GPS annotated data
- Legacy data

6.1.2 Data collection/generation

Day 1: Clinic

Assessment data is collected by clinical practitioners using paper-based and/or eCRFs and collated in e-SC.

Day 1: Lab

Data is collected from a number of sensors as follows;

- **Optolectronic stereo-photogrammetric** systems use cameras to capture the human body motion by tracking the trajectories of spherical retroreflective markers attached to the body. Only the marker-trajectory information is relevant for Mobilise-D. This information will be exported as a .csv file and manually uploaded to the e-SC platform. No video files will be uploaded to e-SC however annotations of those files may be uploaded.

- **INDIP system** includes 4 Magneto-Inertial Measurement Units (MIMU), 2 distance sensors and 2 pressure insoles). Each MIMU has an on-board flash memory and can record at least 5 hours of acquisitions at 100Hz. A Windows-based application is used to manage the INDIP system (including saving data at the end of the assessment). The number of files is dependent on the protocol. If 5 tests then 5 x 4 files (1 for each MIMU for each test). The format of each file is .txt. Each file is manually uploaded to e-SC via the portal provided.

- **DynaPort MM+** (McRoberts MoveMonitor) consists of a small and light casing containing a tri-axial accelerometer, tri-axial gyroscope, rechargeable battery, USB connection and 1GB flash memory. The sensor will be worn at all times (except bathing) and will store 7 days of data. The sensor is then physically connected to a PC and McRoberts software is used to transfer this data to the e-SC platform. Both raw and processed data can be transferred to Mobilise-D.

Day 1-9: Home

This period will include 7 days of free-living activities wearing the Dynaport MM+ sensor, along with a mobile phone (BYOD or provisioned) which will be used to collect patient reported outcomes (ePRO), and GPS data to understand confounding factors. Researchers will visit the study volunteer and reclaim sensor data which will be uploaded as described previously, ePRO data will be uploaded to the ePRO partner (ERT) platform and from there de-identified data will be sent to e-SC via API. GPS coordinates will not be sent to e-SC but de-identified processed data will be sent from GPS server to e-SC via API. This data will be in JSON format. Human factors will be addressed using a combination of quantitative (e.g. deployment of instruments) and qualitative (e.g. semi-structured interviews) techniques in a sub-sample of the users involved in the seven days validation protocol. The audio files from these interviews will be transcribed and transcriptions will be manually uploaded to e-SC. The audio files will be securely retained at each site until project completion after which point they will be destroyed (see Appendix A).

Day 9: Home

This is another series of activities in a free-living environment conducted over a 2.5 hour period. During this time the study volunteer will wear the Dynaport MM+ sensor, the INDIP system, and carry the phone for GPS related information. All data will be transferred as described earlier.

Data Tools used

Mobilise-D will produce different types of software. Algorithms will be developed/refined to process the raw signals from the sensors and extract from them specific quantification of mobility such as average step length, average step cadence, or average walking speed. Source code will use standard programming language format files, depending on the chosen language for the development. All code will be developed using SDLC and hosted on a shared SCM platform. Tools used for data visualization will be determined at a later stage.

6.1.3 Data organisation, documentation and metadata

For version one of the Mobilise-D data processing platform, we will develop a simple data model for the project data sets and deploy a basic website that authorized project members can use to upload, browse and process data. In its initial phases, the Mobilise-D project needs to gather together existing sets of Gold Standard data and make use of a set of published algorithms to analyse them. Data will be organised hierarchically within the data model in order to group together sets of data representing different collections, measurement types etc.

Data for evaluation.

Legacy datasets and algorithms will be provided by Mobilise-D partners. Existing public datasets (e.g. weather) may also be used.

Research data and metadata

Quantitative data will be generated during the technical validation study in clinical, laboratory, and home environments utilizing multiple sensors and a ground truth reference system. Qualitative data will be collected in the form of questionnaires and interviews with end-users who will test the Mobilise-D tools. Data dictionaries will be provided at a later stage describing the variable names/labels etc.

Processed data files

Source code and research data will be accompanied by a readme file including who created or contributed to the data, its title, date of creation and under what conditions it can be accessed. Documentation will also include details on the methodology used, analytical and procedural information, any assumptions made, and the format and file type of the data. In the case of software it may also include installation instructions and usage examples.

Data Format

Semi-structured interview data and system annotations will be collected in text files in DOC, PDF, or TXT format. Spreadsheet data will be collected in CSV format. Key/Value pair data will be collected in JSON format.

Filenaming convention

Files will be named according to their content to ease their identification. Software development will be managed through specific software versioning and revision control systems (SCM) such as git.

Each file will be labelled in standardised format, including information on:

- Centre
- Participant unique ID
- Data source/ modality
- Time point – YYYYmmdd

Example
Centre code_pt ID_time point_source/modality ID
01_001_01_1

E.g.
Centre 01, pt 001, time 01 and McRobert free-living data

6.1.4 Data storage and security

Managing, storing and curating data

During the project both software (algorithms/applications) and data will be stored on the data management platform e-SC built on AWS. Source code however will be managed through a GIT VCS. Data will be encrypted in transit (HTTPS) and at rest. Flat files will be stored in S3 buckets which are encrypted using AES-256 encryption. RDS databases are also encrypted using AES-256. Platform managers will be responsible for the data while in the data management platform. Amazon RDS creates and saves automated backups of the DB instance securely in Amazon S3 for a specified retention period. In addition, we will create daily snapshots which are kept until we explicitly delete them.

The data stored in the Mobilise-D platform is pseudo-anonymised by using a unique identifier for every participant. Technical implementation to combat specific data security issues used within the deployment of the web service are:

1. e-SC runs on virtual servers in AWS. The virtual server platform provides ability to add resources automatically depending on demand (auto-scaling).

3. The webservers are configured using security. All servers are secured using a firewall technology which has automated blocking of non-legitimate access attempts.

4. General shell/admin-level access to webservers is restricted to a primary and backup administrator - there is no general access to project members.

5. Access to the data stored within the PostgreSQL is restricted to the primary and backup administrators only.

6. Access to the website is restricted to a whitelist of staff managed by the platform managers.

7. Access/View/Editing of data records is performed over SSL to ensure the integrity of data from client browser to database record store and is restricted to a number of staff in each partner in the project. Only those authorized as per Table 1 can view records across multiple sites.

6.2 Clinical Study (WP4/6)

6.2.1 Description of the data

The MOBILISE-D clinical study is a longitudinal (non-interventional) observational cohort study conducted in ten different European countries in 16 different partner sites. Participants will have a baseline assessment and follow-ups (every 6 months over a period of 24 months – see Table 2) for a duration of 7 days each using the McRoberts mobility sensor. The device will be placed at each visit and returned for subsequent data download to a local clinic PC. This data is then automatically uploaded to McRoberts platform and raw data will be sent via an API to the e-SC platform developed in WP3. Participants will also complete ePROs available on a mobile phone and this data will be sent automatically to the ERT servers and from there via API to e-SC. Public data and annotations of GPS data will also be uploaded to e-SC to identify confounding factors.

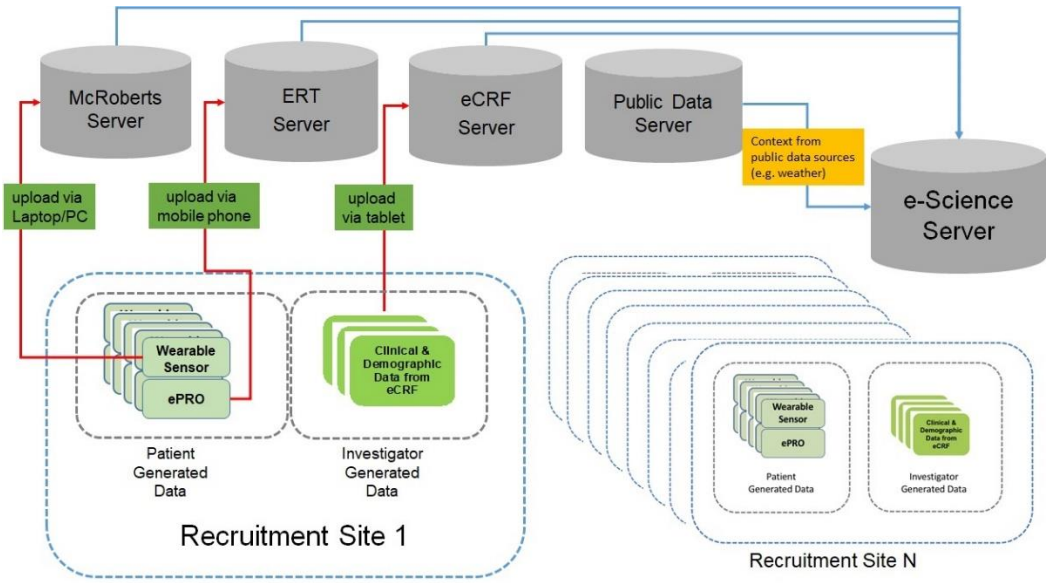

Figure 4. Clinical study data path(s).

Data set reference and name

The broad umbrella term used to describe the data collection comprising multiple datasets in the clinical validation study is **Mobilise-D-CVS**. This collection will include the following datasets;

- Demographic, cognitive, physical function
- Single-sensor data
- Patient Reported Outcomes
- Semi-structured interviews
- GPS annotated data

M1	M6	M12	M18	M24
BL (T1)	FU (T2)	FU (T3)	FU (T4)	FU (T5)
LV	HV	LV	LV	LV

Table 2. Schedule of assessments per patient. BL=baseline; FU=follow-up.

6.2.2 Data collection/generation

T1, T3, T4 and T5 will be performed as in-lab/hospital assessments (LV). T2 will be performed as a home visit (HV). Data will be collected using eCRF at baseline and uploaded to e-SC for data aggregation. Ongoing patient reported outcomes will be collected via ePRO using the ERT platform which will automatically push the data to e-SC. Raw data from McRoberts sensor for the 7-day wear periods will be uploaded to e-SC, along with contextual data from phones/public data services.

6.2.3 Data organisation, documentation and metadata

All data transferred to the e-SC platform from the automated pathways will be stored in S3 on AWS. Pointers to this data will be maintained in a PostgreSQL database. Analysis tools and data storage will be configured to provide access to the derived data. This will be further outlined in the final DMP.

Data for evaluation.

N/A.

Research data and metadata

Quantitative data will be generated during the clinical validation study in clinical, and home environments utilizing a single sensor and ePROs. Qualitative data will be collected in the form of questionnaires and interviews with end-users. Data dictionaries will be provided at a later stage describing the variable names/labels etc.

Processed data files

Source code and research data will be accompanied by a readme file including who created or contributed to the data, its title, date of creation and under what conditions it can be accessed. Documentation will also include details on the methodology used, analytical and procedural information, any assumptions made, and the format and file type of the data. In the case of software it may also include installation instructions and usage examples.

Data Format

Semi-structured interview data and system annotations will be collected in text files in DOC, PDF, or TXT format. Spreadsheet data will be collected in CSV format. Key/Value pair data will be collected in JSON format.

File naming convention

For all manual data collection in the clinical study (interviews) the file naming convention will follow that outlined in the technical validation study. All other data collection is automated and uses the participant ID as the unique identifier.

6.2.4 Data storage and security

Managing, storing and curating data

During the project both software (algorithms/applications) and data will be stored on the data management platform e-SC. Source code however will be managed through a GIT VCS. Data will be encrypted in transit (HTTPS) and at rest. Flat files will be stored in S3 buckets which are encrypted using AES-256 encryption. RDS databases are also encrypted using AES-256. Platform managers will be responsible for the data in the data management platform. Amazon RDS creates and saves automated backups of the DB instance securely in Amazon S3 for a specified retention period. In addition, we will create daily snapshots which are kept until we explicitly delete them.

The additional storage facility (Data Warehouse) for derived data will be fully explored in later versions of the DMP.

7 Data sharing and re-use

The Consortium is aware of the mandate for open access of publications and research data. As previously mentioned the Consortium will choose the appropriate scientific publication and data repository for the project outcomes. The Consortium will ensure that scientific results that will not be protected and can be useful for the research community will be duly and timely deposited in the scientific results repository. This will include;

- Electronic copies of the final version or final peer-reviewed manuscript accepted for publication.
- Project public presentations and any other kind of dissemination material.
- Research data needed to validate the results presented in the deposited publications

7.1 Procedures for making data findable

The information collected and updated via Appendix A will be available to the Mobilise-D consortium through e-SC during the project and the public through a public repository determined at a later stage of the DMP. The datasets will receive unique identifiers as a result of uploading to the relevant repository. This will enable the easy identification of datasets available and identify the data owner.

7.2 Re-use of Mobilise-D results by third parties

For those external individuals/institutions wanting to use Mobilise-D generated or collected data during the course of Mobilise-D, the Data Management Team should be contacted (Table 1). Access rules for the time after Mobilise-D termination will be worked out and described in the final DMP.

8 Ethical aspects

Patient Information and informed consent procedures will be approved by the relevant local ethics boards. Data collectors collecting personal data will inform the study participants about the project in an appropriate manner, including:

- the identity of the data controller
- the voluntariness of the collection of data
- the purposes of the processing
- the nature of the processed data, including its type (identifiable, coded, anonymised)
- the handling of the data
- the existence of the right of access to, and the right to rectify the data concerning themselves
- the sharing of data across research groups
- that consent may be withdrawn and how this is done

There are no other ethics issues currently identified beyond those discussed above. Any potential issues that arise during the project duration will be presented to the Ethics and Data Monitoring Committee who will ensure they are addressed by taking the appropriate organisational, legal, and regulatory steps.

9 List of abbreviations

ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Application Programming Interface
AWS	Amazon Web Services
CA	Consortium Agreement
DMP	Data Management Plan
EU	European Union

ePRO	Electronic Patient Reported Outcome
eCRF	Electronic case report form
EFPIA	European Federation of Pharmaceutical Industries and Associations
FAIR	Findable, accessible, interoperable and reusable
e-SC	e-Science Central
GDPR	General Data Protection Regulation
GPS	Global Positioning System
IMI	Innovative Medicines Initiative
SDLC	Software Development Life Cycle
SCM	Software Configuration Management
WP	Work Package

10 Conclusions

A robust Data Management Plan improves the understanding of the data to be generated within a project, and of the requirements of securing and archiving that data. It also highlights the data publication potential of a project – data sets which can be released are identified early and appropriate steps can be taken to ensure that sharing happens in a timely and efficient manner. This document describes the development of just such a DMP for the MOBILISE-D project. This plan is a key element in maximising the impact of MOBILISE-D. The data management plan is not a static document, but will continue to undergo review and formal revisions as MOBILISE-D progresses.

11 References

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[2]: Guidance for Industry, Electronic Source Data in Clinical Investigations. U.S. Department of Health and Human Services Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH); 2013 [cited 15 February 2017]. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

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[6]: Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data; 1995 [cited 15 February 2017]. Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=en.

Appendix A Data Table

Collected or Created	Title	Description	Category	Type	Format	Size	Owner	Privacy	Storage / Storage for public access	Backup frequency	Destroyed at end of project	Duration of preservation (in years)	Work Package
	Mobilise-D-TVS-Clinic-Base												
	Mobilise-D-TVS-Lab-SP												
	Mobilise-D-TVS-Lab-INDIP												
	Mobilise-D-TVS-Lab-DMM												
	Mobilise-D-CVS-Home1-DMM												
	Mobilise-D-CVS-Home1-GPS												
	Mobilise-D-CVS-Home1-ePRO												