Data Management Plan
(DMP)

EU4health
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List of Abbreviations

CC BY 4.0	Creative Commons Attribution 4.0 International
CSV	Comma-Separated Values
DPIA	Data Protection Impact Assessment
DMP	Data Management Plan
DOCX	Microsoft Word Open XML Document Format
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
FIBHGM	Fundación para la Investigación Biomédica del Hospital Gregorio Marañón
GDPR	General Data Protection Regulation
ICD-10	International Classification of Diseases, 10th Revision
IHME	Institute for Health Metrics and Evaluation
ISO	International Organization for Standardization
LOINC	Logical Observation Identifiers Names and Codes
MASLD	Metabolic Dysfunction-Associated Steatotic Liver Disease
NUTS	Nomenclature of Territorial Units for Statistics
OMOP	Observational Medical Outcomes Partnership
PDF	Portable Document Format
PDF/A	Portable Document Format for Long-Term Archiving
PPTX	PowerPoint Open XML Presentation Format
PWID	People Who Inject Drugs
QC	Quality Control
RDT	Rapid Diagnostic Test
REDCap	Research Electronic Data Capture
SNOMED CT	Systematized Nomenclature of Medicine — Clinical Terms
TXT	Plain Text File
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
WP1 – 5	Work Package 1 – 5
XLSX	Microsoft Excel Open XML Spreadsheet Format
XML	Extensible Markup Language

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Executive Summary

The MOBHOPE Data Management Plan (DMP) establishes the framework for the responsible management, protection, sharing, and preservation of data and research outputs generated throughout the 36-month project. Supporting MOBHOPE's objectives in viral hepatitis prevention, liver health, access to care, operational research, and stigma reduction, the plan promotes high-quality, interoperable, and reusable evidence to inform scientific research, public health policy, and the wider adoption of mobile liver health services across the European Union.

The project anticipates testing or enrolling approximately 5,000 individuals across three mobile units. Data will include clinical and epidemiological information, rapid diagnostic test and elastography results, stigma and discrimination survey responses, training and health promotion records, qualitative research materials, and project management documentation. The four beneficiaries—Ares do Pinhal, Hepatos, FIBHGM, and Madrid Positivo—will collaborate through two designated platforms: REDCap for the anonymous ECDC stigma assessment survey and FIBHGM SharePoint for non-confidential project documents and approved shared materials. Confidential or identifiable source records will remain under the responsibility of the relevant beneficiary and will not be included in these shared environments under the arrangements described in the DMP. MOBHOPE will implement the FAIR principles (Findability, Accessibility, Interoperability, and Reusability) proportionately to the nature of each dataset and applicable ethical, legal, and confidentiality requirements. Data dictionaries, metadata, standard formats, consistent terminology, documented quality-control procedures, and clear licensing arrangements will support data interpretation, interoperability, and responsible reuse. Publicly available outputs will include the standardized mobile liver health service package, training materials, policy briefs, scientific publications, and other eligible research outputs. Participant-level health data, qualitative transcripts, and other restricted materials will remain subject to controlled access, with external requests assessed according to established governance procedures and applicable requirements. Data protection, information security, and research ethics are central to the plan. The beneficiaries will apply appropriate access controls, security safeguards, quality-assurance procedures, and incident-reporting arrangements, in compliance with the General Data Protection Regulation (GDPR), relevant national legislation, ethical approvals, and the EU4Health Grant Agreement. Particular attention will be given to anonymity, confidentiality, indirect identification risks, voluntary participation, and the prevention of stigma and discrimination. Each beneficiary remains responsible for the data it collects and manages locally, while FIBHGM coordinates the overall DMP, shared platform administration, and project-level data management. The consortium will use existing institutional infrastructure and allocated project resources to support data management, quality assurance, open-access dissemination, and long-term preservation. Public outputs will be disseminated through the project website and the EU Funding & Tenders Portal, as applicable, with retention and post-project responsibilities confirmed against the relevant contractual and institutional requirements. The DMP will be reviewed at Months 12, 24, and 36, and updated whenever significant changes arise.

Overall, this DMP provides a coordinated and proportionate approach to ensuring that MOBHOPE data and research outputs are reliable, secure, ethically managed, appropriately accessible, and useful beyond the project's lifetime, while protecting participants' rights and supporting the sustainable uptake of evidence-based mobile liver health services across Europe.

1. Data Summary

1.1 Purpose and Relation to Project Objectives

MOBHOPE will generate, collect, and manage project data in support of its five specific objectives: (1) improving primary and secondary prevention through health promotion; (2) developing a cascade of care for viral hepatitis and liver diseases; (3) conducting operational research on detection rates, social determinants, and barriers to care; (4) assessing stigma and discrimination; and (5) standardizing mobile liver health service packages for broader adoption across the European Union.

Data will support both scientific objectives, including prevalence estimation, cascade-of-care analysis, and stigma assessment, and operational objectives, including monitoring project activities, informing implementation improvements, and supporting policy development. The resulting evidence will inform scientific publications, policy briefs, project reports, and the standardized mobile liver health service package intended for dissemination across EU Member States.

For the purposes of this Data Management Plan (DMP), project data refers to data and information made available for sharing among the four MOBHOPE beneficiaries through the project's designated collaborative platforms: REDCap and FIBHGM SharePoint. These materials support joint project implementation, monitoring, analysis, reporting, and dissemination.

The DMP primarily addresses the management of these shared project data and associated research outputs. It does not replace the individual responsibilities of partners for any separate local records, confidential information, or personal data that are not shared through these platforms. Such records remain subject to the applicable legal, ethical, institutional, and contractual requirements.

1.2 Types and Formats of Data

MOBHOPE will generate or collect the following categories of project data and research outputs.

Table 1. Data Formats and Sources

Dataset	Type / Format	Source / WP
DS1 – Clinical-epidemiological records	Structured numerical & categorical data (REDCap / CSV / XLSX)	All mobile units
DS2 – Rapid diagnostic test (RDT) & elastography results	Structured numerical data (REDCap / CSV)	All mobile units
DS3 – Stigma & discrimination survey data	Questionnaire responses (REDCap / CSV), validated tool (World Hepatitis Alliance/ECDC)	All mobile units
DS4 – Training & health promotion records	Attendance sheets, pre/post assessment scores (REDCap / CSV / PDF)	All mobile units
DS5 – Operational research & qualitative data	Interview transcripts, focus group notes (TXT / DOCX / PDF), field notes	All mobile units
DS6 – Standard service package documentation	Protocols, guidelines, policy briefs (PDF / DOCX)	WP4 – All partners

DS7 – Project management & coordination records	Reports, financial statements, meeting minutes (PDF / DOCX / XLSX)	WP5 – FIBHGM (COO)

The four MOBHOPE beneficiaries are Ares do Pinhal, Hepatos, FIBHGM, and Madrid Positivo. The precise contribution of each beneficiary to the individual datasets will be documented as the project's data collection and reporting arrangements are implemented.

REDCap is used for the ECDC stigma assessment survey, which is designed to collect anonymous questionnaire responses without direct participant identifiers. All four beneficiaries have access to the project REDCap environment for the agreed survey data-entry activities. The implementation will continue to avoid unnecessary identifiers and will be reviewed for risks arising from combinations of responses or small subgroups.

FIBHGM SharePoint is used for collaborative work on project documents and other materials approved for access by all beneficiaries. It is not intended to serve as a repository for confidential or identifiable participant information. Only materials suitable for shared project access will be uploaded.

Data generated locally by individual partners, including clinical records, identifiable research records, and confidential qualitative source materials, are not automatically included in the shared project data. Their handling remains the responsibility of the relevant partner under applicable requirements. Only information approved for sharing under the project's arrangements will be made available through REDCap or SharePoint.

Tabular research data will be maintained in non-proprietary, machine-readable formats such as CSV wherever practicable. XLSX may be used for working documents and analyses. Narrative documentation will generally be maintained in widely supported formats, including PDF/A for long-term document preservation where appropriate, PDF for dissemination, and TXT or DOCX for text-based materials. Relevant metadata and data dictionaries will accompany structured datasets where applicable.

Where qualitative research involves audio recordings, these will be treated as separate source materials and handled in accordance with the approved research protocol, participant information, and applicable retention procedures. Recordings will not be placed in the shared project platforms unless their inclusion has been explicitly approved and the applicable safeguards have been established.

1.3 Re-use of Existing Data

MOBHOPE may use existing data sources and research resources to inform operational research, support interpretation of findings, and contextualize results. These may include:

- Existing datasets held by beneficiary partners from previous mobile outreach activities, where their use is permitted by the original collection conditions, applicable legal requirements, and any relevant agreements.
- Publicly available European Centre for Disease Prevention and Control (ECDC) data on hepatitis B and C epidemiology in EU/EEA Member States.

- WHO Global Hepatitis Report data and Institute for Health Metrics and Evaluation (IHME) burden-of-disease estimates.
- Relevant stigma assessment instruments developed or made available by ECDC and the World Hepatitis Alliance, subject to verification of the applicable terms of use.
- Published literature and research outputs from previous EU-funded initiatives involving mobile hepatitis services, including HepCare Europe and EuroTEST, where relevant and accessible through appropriate repositories or publications.

For each reused source, the project will document its origin, version or publication date, access date where relevant, and applicable licence or reuse conditions. Where necessary, the project will verify whether additional permissions or data-sharing agreements are required before reuse.

Existing data held by a partner will not automatically become shared project data merely because it is relevant to MOBHOPE. Its inclusion in shared project activities will depend on the applicable permissions, ethical conditions, and agreed data-sharing arrangements.

1.4 Expected Data Volume

MOBHOPE anticipates that approximately 5,000 individuals will be tested or enrolled across the three mobile units over the 36-month project period.

The estimated volume of structured quantitative data is expected to remain relatively small. Assuming approximately 5,000 records with an average size below 5 KB per record, the resulting volume would be approximately 25 MB for those records. The total volume may be higher because individuals may have multiple visits or assessments and because additional datasets, metadata, exports, and supporting documentation will be generated. Qualitative transcripts and field notes may add an estimated 200–500 MB, depending on the number and length of interviews, focus groups, and other activities. This estimate will be refined as the research instruments and data collection requirements are finalized. Temporary audio recordings, where applicable, will be accounted for separately.

The project REDCap environment and FIBHGM SharePoint are expected to accommodate the anticipated shared project data volumes within their existing provisioned capacity. Storage requirements and any associated costs will be reviewed as implementation progresses.

1.5 Data Utility Beyond the Project

The shared project data and research outputs generated by MOBHOPE may be useful to:

- Public health authorities and ministries of health in EU Member States seeking evidence on mobile outreach effectiveness and access to hepatitis services.
- Researchers working on viral hepatitis elimination, cascade-of-care optimization, stigma reduction, and health equity.

- NGOs and civil society organizations operating mobile health services for vulnerable populations.
- EU institutions and agencies, including ECDC, the European Medicines Agency, and relevant European Commission services, where the outputs are pertinent to their mandates.
- International organizations, including WHO and UNAIDS, and other public health organizations interested in comparable evidence and good practices.
- Mobile unit staff, participating organizations, and other stakeholders involved in the implementation and improvement of outreach services.
- The wider public and interested organizations seeking access to public project outputs, protocols, training materials, policy briefs, and appropriately prepared research data.

Access to and reuse of project materials will depend on their nature, applicable licensing conditions, participant information and consent arrangements where relevant, ethical approvals, confidentiality requirements, and applicable legal obligations. The public dissemination of project findings will not imply unrestricted access to locally held clinical records or other confidential source materials.

2. FAIR Data

MOBHOPE will apply the FAIR principles (Findability, Accessibility, Interoperability, and Reusability) to its shared project data and research outputs, taking into account the nature of each dataset, its intended use, and any applicable ethical, legal, confidentiality, and contractual requirements. The FAIR principles will be implemented proportionately and will not require the public release of information that is confidential, restricted, or unsuitable for disclosure. For this DMP, shared project data are the materials made available to the four MOBHOPE beneficiaries through the designated project platforms: REDCap and FIBHGM SharePoint. Data retained locally by individual beneficiaries and not shared through these platforms remain subject to the applicable requirements of the responsible organization.

2.1 Making Data Findable: Metadata and Identifiers

MOBHOPE will ensure that shared project data and research outputs are adequately described and can be located by authorized project participants and, where applicable, external users.

Persistent Identifiers

Project deliverables submitted through the EU Funding & Tenders Portal will be identified using the relevant grant and deliverable references. These administrative references will be recorded where appropriate but will not be treated as substitutes for repository-issued persistent identifiers. Public project deliverables and eligible research outputs will be made available through the project website and the EU Funding & Tenders Portal, in accordance with the applicable grant requirements. The project will not rely on a separate public research data repository under the current dissemination arrangements. The use of additional repositories or persistent identifiers may be considered if required by the Grant Agreement or agreed by the consortium.

Metadata and Documentation

Structured datasets shared through REDCap will be accompanied by relevant metadata, a README file, and a data dictionary or codebook, as appropriate. Documentation will describe variable names, definitions, response categories, units of measurement, coding conventions, missing-value conventions, and relevant methodological information. Project documents shared through FIBHGM SharePoint will include appropriate descriptive information, such as document title, version, date, responsible beneficiary, and relevant work package or project activity. Metadata and documentation prepared for public dissemination will be reviewed to ensure that they do not disclose confidential information or contain unnecessary personal data.

Search Keywords

Metadata for relevant datasets and research outputs will include descriptive keywords appropriate to their subject matter. These may include: viral hepatitis, hepatitis B, hepatitis C, mobile health services, vulnerable populations, people who inject drugs (PWID), harm reduction, cascade of care, liver health, metabolic dysfunction-associated steatotic liver disease (MASLD), stigma, discrimination, operational research, public health, Spain, Croatia, Portugal, and the European Union. Keywords will be selected according to the content of each output rather than applied indiscriminately to every dataset. Where appropriate, established controlled vocabularies and subject classifications will be used to improve discoverability and consistency.

Metadata Availability

Documentation and metadata will be maintained alongside the relevant shared project materials. Where datasets or research outputs are deposited in a public repository, their metadata will be made available in accordance with the repository's functionality and applicable restrictions, even when access to the underlying data is restricted. Metadata published externally will be reviewed to avoid disclosure of personal data, confidential information, or details that could create a risk of participant re-identification.

2.2 Making Data Accessible

MOBHOPE will make project outputs accessible to the intended users through clearly defined access arrangements. Access will depend on the type of material, its intended purpose, and any applicable ethical, legal, confidentiality, licensing, and contractual requirements.

Access Platforms and Dissemination

FIBHGM SharePoint is the consortium's collaborative environment for sharing non-confidential project documents and other materials approved for access by all four beneficiaries. The FIBHGM project manager coordinates administration of the shared workspace and access arrangements. The project REDCap environment, administered by the FIBHGM data coordinator in the role of Global Project Coordinator, is used for the ECDC stigma assessment survey. All four beneficiaries have access to the environment for the agreed survey data-entry activities. The survey is designed to collect anonymous

responses without direct identifiers, and the project has assessed the responses as not reasonably linkable to individual participants. Public project deliverables and other eligible outputs will be disseminated through the project website and the EU Funding & Tenders Portal, as applicable. The project website supports public dissemination, while SharePoint supports collaboration among authorized project partners. SharePoint is not intended to serve as a public research data repository.

Open and Restricted Data

The intended access arrangements for the principal datasets and outputs are summarized in Table 2. These arrangements distinguish shared consortium materials from locally retained source records and from outputs intended for public dissemination.

Table 2. Access Rights

Dataset	Availability	Rationale
DS1 – Clinical-epidemiological records (raw)	Restricted / Consortium only	Contains personal health data. Pseudonymized aggregated summaries will be made public.
DS2 – Rapid diagnostic test (RDT) & elastography results (raw)	Restricted / Consortium only	Personal health data. Aggregated results published in reports and papers.
DS3 – Stigma & discrimination survey data (raw)	Restricted / Consortium only	Anonymised datasets. Only aggregated results will be made public under corresponding reports.
DS4 – Training & health promotion records (aggregated)	Public	No personal identifiers. Training effectiveness summaries will be openly available.
DS5 – Operational research & qualitative data (transcripts)	Restricted / Consortium only	Participants have not consented to public release of transcript content.
DS6 – Standard service package documentation	Public	Core output intended for EU-wide dissemination. No personal data.
DS7 – Project management & coordination records	Restricted / EU Commission access	Financial and contractual information; accessible to the EC as per Grant Agreement.

The classification of materials as public, internally shared, or restricted will be reviewed where their content or intended use changes. Inclusion in a project platform does not automatically authorize publication or unrestricted reuse. The public release of research data will be considered separately from the sharing of project documents among beneficiaries. Where participant-level data are not suitable for public release, MOBHOPE will seek to make relevant findings, documentation, and appropriately aggregated results available instead.

Access Protocol

Restricted datasets held within REDCap are accessible only to authorized consortium members using role-based credentials managed by the administrator (the Global Project Coordinator). Third-party researchers wishing to access restricted data after project completion may submit a Data Access Request to the lead beneficiary, which will be evaluated by the Steering Committee within 30 days. Access to REDCap and SharePoint will be limited to authorized project personnel according to the requirements of their roles. Access permissions will be managed by the relevant platform administrator and reviewed when project responsibilities change or access is no longer required. Requests from

external researchers for access to non-public project data will be assessed on a case-by-case basis. Where a dataset is eligible for controlled access, the requester will be asked to specify the intended purpose, proposed data use, and any relevant safeguards. Requests will be reviewed by the designated project governance body in coordination with the responsible beneficiary and, where necessary, the relevant data protection or ethics representatives. No external access will be granted where the proposed disclosure would conflict with applicable legal requirements, ethical approvals, participant information or consent arrangements, third-party rights, or the conditions under which the data were collected. The project will document the outcome and rationale for relevant access decisions.

Data Storage and Collaborative Access

MOBHOPE uses two designated platforms for shared project activities:

- **REDCap:** administered by the FIBHGM data coordinator for the anonymous ECDC stigma assessment survey and associated project data-entry activities.
- **FIBHGM SharePoint:** administered by the FIBHGM project manager for non-confidential project documents and other materials approved for access by all four beneficiaries.

The platforms have distinct functions and are not intended to replace the local data-management systems of the participating organizations. Confidential or identifiable participant information will not be placed in these shared environments under the arrangements described in this DMP. Each beneficiary remains responsible for ensuring that materials uploaded to or entered into the shared platforms are appropriate for their intended use and do not contain information that should remain restricted. Before sharing or publishing outputs, the responsible partner will consider the risk of re-identification arising from small numbers, rare characteristics, combinations of variables, free-text content, or other indirect identifiers. The hosting arrangements, access controls, and applicable technical safeguards for each platform will be documented and verified as part of the project's data security procedures.

Embargoes

Where justified by publication preparation or other documented requirements, an embargo may be applied to eligible outputs for a specified period. The justification, start date, duration, and approving authority will be documented. Any embargo will remain subject to the applicable Grant Agreement requirements and other legal or contractual obligations.

2.3 Making Data Interoperable

MOBHOPE will promote interoperability by using consistent variable definitions, documented data structures, standard formats, and established terminology systems where appropriate and feasible. The consortium will aim to harmonize relevant data definitions and coding conventions across the four beneficiaries so that project findings can be compared across participating countries and interpreted consistently. The following measures will be applied as appropriate to the datasets and analytical requirements:

- **Clinical and diagnostic terminology:** ICD-10 may be used for relevant disease classifications. Other clinical terminologies, including SNOMED CT, will be considered where they are suitable for the variables being collected and their implementation is feasible.
- **Laboratory and diagnostic results:** Units of measurement, test-result categories, and interpretation rules will be documented consistently. Where appropriate, established laboratory terminology and coding systems, such as LOINC, may be used.
- **Core monitoring indicators:** Common indicator definitions, calculation methods, denominators, and reporting periods will be documented to support cross-country comparison. Any implementation of the OMOP Common Data Model or other formal data models will be specified separately if adopted.
- **Stigma assessment instruments:** The agreed ECDC stigma assessment instrument will be used consistently, preserving the relevant question wording, response options, and scoring rules, subject to the approved instrument and any applicable terms of use.
- **Data dictionaries:** REDCap data dictionaries and relevant variable documentation will be retained in machine-readable formats, including CSV where appropriate, to support interpretation and potential migration.
- **Geographic information:** Country identifiers may use ISO 3166 codes, and regional information may use NUTS classifications where appropriate. Geographic detail will be limited in externally shared data where necessary to protect confidentiality and reduce re-identification risk.
- **Project-specific codes:** Where common terminology is unavailable or unsuitable, project-specific categories will be documented. Mapping tables or crosswalks will be produced where needed to support comparison across partners and alignment with established standards.
- **Data formats and conventions:** The consortium will document date formats, missing-value codes, units, category labels, and relevant language or translation conventions to support consistent interpretation.

The standards selected for implementation will reflect the project's actual technical capabilities and requirements. The use of a terminology or data model will not be claimed unless it is implemented or a specific implementation plan has been agreed.

2.4 Increasing Data Re-use

MOBHOPE will support responsible reuse of eligible project data and research outputs by providing clear documentation, appropriate licensing, information about data provenance, and transparent quality-control procedures.

Documentation

Where applicable, shared datasets and research outputs will be accompanied by:

- A README file describing the context, purpose, data collection methods, relevant limitations, and instructions for interpreting the material.
- A data dictionary or codebook describing variable names, definitions, response categories, units, and coding conventions.

- Relevant data collection instruments, questionnaires, and REDCap forms in an appropriate format, subject to applicable copyright, licensing, confidentiality, and ethical restrictions.
- Information on the relevant research protocol and ethics approval, where appropriate and permissible to disclose.
- Details of the dataset version, responsible beneficiary, date of preparation, and any relevant changes made during data cleaning or processing.
- References to related publications, reports, analytical scripts, and other outputs where available.

Documentation will be prepared so that intended users can understand the data and their limitations without relying on undocumented knowledge held by the original data collectors.

Licensing

Licences will be assigned according to the nature of each output and the rights held by the consortium. Eligible public documentation, including protocols, training materials, and policy briefs, may be released under the Creative Commons Attribution 4.0 International (CC BY 4.0) licence where the consortium holds the necessary rights and the content is suitable for unrestricted reuse. Research datasets will be assessed individually before release. The choice of licence or access conditions will take account of the dataset's content, disclosure risk, participant information and consent arrangements, third-party restrictions, and applicable legal requirements. CC BY 4.0 will not be applied automatically to every dataset. Metadata may be released under a permissive arrangement such as CC0 where appropriate and legally permissible. Software and analytical scripts will be distributed under a clearly identified open-source licence where the consortium holds the necessary rights and publication is appropriate. The selected code repository and licence will be documented when the dissemination arrangements are finalized. The application of a licence does not remove legal obligations relating to personal data, confidentiality, or third-party rights.

Provenance and Quality Assurance

The consortium will apply documented quality-assurance procedures to the data it collects and manages. For data entered through REDCap, validation rules and other available system features will be used where appropriate to support completeness, consistency, and accuracy. Field staff and other relevant personnel will receive instructions on data entry, coding conventions, and applicable quality-control procedures. The FIBHGM data coordinator will coordinate quality monitoring for the project REDCap environment, including checks for completeness, inconsistent values, duplicate entries, and other potential data-quality issues, as supported by the system and agreed procedures. The frequency and scope of these checks will be documented. Beneficiaries remain responsible for the quality and accuracy of materials they prepare and contribute to shared project activities. Corrections and relevant changes to shared data will be documented so that the reasons for changes and their effects on subsequent analyses can be understood. REDCap audit-trail features will be used where available and enabled, in accordance with the platform configuration and applicable requirements. Before external publication or repository deposit, the responsible beneficiary will review the relevant material for quality, consistency, documentation, confidentiality, and

suitability for release. Any necessary transformations, exclusions, aggregations, or de-identification steps will be documented where appropriate.

Re-use After Project End

Public research outputs and eligible datasets will remain accessible for the period required by the applicable EU4Health Grant Agreement and the project's agreed preservation arrangements. Where a minimum retention period applies, the consortium will document the applicable start date, duration, responsible organization, and preservation method. FIBHGM will coordinate the preservation of eligible shared project outputs and the identification of an appropriate institutional or repository contact for post-project enquiries, subject to the responsibilities and resources agreed by the consortium. The continued availability of public outputs will be supported through suitable storage or repository arrangements, version documentation, and the preservation of associated metadata. Access to restricted or non-public materials after project completion will remain subject to the applicable legal, ethical, contractual, and access-control requirements. The preservation and retention of data held locally by beneficiaries, including any confidential source records not shared through the project platforms, remain the responsibility of the relevant organization under applicable law, institutional procedures, research protocols, and contractual requirements.

3. Other Research Outputs

In addition to the shared project data described in Sections 1 and 2, MOBHOPE will produce research outputs and supporting materials that require appropriate documentation, access arrangements, licensing, and preservation. These outputs will support project implementation, dissemination, knowledge transfer, and the wider adoption of mobile liver health services.

Table 3. Other Research Outputs

Output	Type	Management Approach
Standard mobile clinic service package	Protocol / Guideline (PDF, DOCX)	Published openly via project website, and disseminated to EU health authorities. CC BY 4.0 licence.
Culturally adapted training materials	Educational resources (PDF, PPTX, video)	Deposited on project website with CC BY 4.0. Versions in Spanish, Croatian, and Portuguese.
Policy briefs	Short documents (PDF)	Distributed to national health ministries and EU institutions. Posted on project website. CC BY 4.0.
Peer-reviewed scientific publications	Journal articles (PDF)	Open access as per Grant Agreement Article 17.
Conference presentations	Slides, posters (PDF, PPTX)	Linked to project page.
REDCap data collection instruments	XML / PDF	Linked to project page.
Data analysis scripts	Code files	Deposited on the project’s website under open-source licence (if any).

The consortium will distinguish between materials intended for public dissemination and materials intended solely for internal project collaboration. Public release will be subject to appropriate quality checks, intellectual property considerations, confidentiality requirements, and any applicable ethical or legal restrictions. Where outputs include information derived from research participants, the responsible beneficiary will ensure that the material is suitable for its intended audience and does not disclose personal or confidential information. Physical materials, including printed training resources and demonstration consumables, are not treated as research datasets under this DMP. Their management will follow the project's operational procedures and any applicable safety or procurement requirements. The availability of research outputs will be reviewed during the project's reporting milestones and at project closure. The consortium will document the location, version, access conditions, and applicable licence of eligible public outputs.

4. Allocation of Resources

4.1 Costs for FAIR Data Management

MOBHOPE will use existing institutional infrastructure and staff resources wherever practicable to manage shared project data and research outputs in accordance with the FAIR principles. The principal anticipated costs and funding arrangements are summarized in Table 4. The estimates below are planning assumptions and will be confirmed against the approved project budget, the Grant Agreement, and the actual infrastructure and staffing arrangements.

Table 4. Data Management Costs

Activity	Estimated Cost	Funding Source
REDCap hosting and maintenance	Covered by institutional infrastructure	N/A
Website maintenance (public datasets, deliverables)	Free of charge	N/A
Open-access publication fees	~€1,500–3,000 per article	EU4Health grant (eligible cost)
Staff time for data management, QC, DMP updates	~0.5 FTE equivalent across project lifetime	EU4Health grant (personnel costs)
Data stewardship post-project (5 years)	FIBHGM institutional commitment	FIBHGM institutional budget

The project will review data-management resource requirements throughout implementation. Any material changes in infrastructure costs, staffing needs, or preservation requirements will be considered in subsequent DMP updates.

4.2 Responsibilities for Data Management

Data management is a shared responsibility of the four MOBHOPE beneficiaries: Ares do Pinhal, Hepatos, FIBHGM, and Madrid Positivo. Specific operational responsibilities are assigned according to the activity and platform involved.

Table 5. Responsible Parties

Role	Responsible Party	Funding Source
DMP Owner	Project Manager (FIBHGM)	Overall DMP oversight, DMP updates, GDPR compliance oversight, Data Protection Impact Assessment.
Project Data Manager (Data Governance Lead)	Data Coordinator	REDCap administration, quality audits, handling of data subject rights requests.
Site Data Coordinators	Ares do Pinhal, Hepatos, Madrid Positivo (one per partner)	Local data entry, completeness monitoring, liaison with central Data Manager, compliance with national data protection regulations.
Steering Committee	All partners (WP1-5)	Decisions on data sharing, embargo periods, third-party data access requests, and DMP revisions.
Support	External Advisory Board	Consultation: does not manage data, but can have access to aggregated results.

Each beneficiary remains responsible for the data and documents it contributes to the project and for ensuring that these materials may appropriately be shared through the designated platforms. The roles described in this section concern project coordination and data management. They do not, by themselves, determine the legal status of any beneficiary as a data controller, joint controller, or processor under the GDPR. Such roles will be documented separately where relevant.

4.3 Long-term Preservation

Eligible public project outputs will be preserved in accordance with the applicable EU4Health Grant Agreement, relevant institutional requirements, and the project's agreed dissemination and preservation arrangements. The project website and EU Funding & Tenders Portal will be used for public dissemination, as applicable. The consortium will review which outputs should remain available after project completion and will document their locations, versions, responsible contacts, and applicable access conditions. The exact retention periods, starting dates, and categories of records covered will be verified against the applicable Grant Agreement and any relevant institutional or legal requirements before the final DMP is approved. The consortium will not assume that the same retention period necessarily applies to every type of record. FIBHGM will coordinate the identification of a responsible institutional contact for eligible shared project outputs and post-project enquiries, subject to the arrangements agreed by the beneficiaries. Shared materials in REDCap and SharePoint will be reviewed at project closure. The consortium will determine which materials must be retained, exported, transferred to an appropriate institutional environment, or securely deleted, taking account of the platform's purpose and the applicable requirements. Data held locally by beneficiaries but not shared through the project platforms will remain under the responsibility of the relevant organization. Their preservation or deletion will follow applicable legislation, institutional procedures, approved research protocols, and contractual requirements. The preservation plan will be updated when the applicable retention periods and post-project responsibilities have been confirmed.

5. Data Security and Protection

MOBHOPE will apply appropriate technical and organizational measures to protect the confidentiality, integrity, and availability of project data throughout collection, storage, use, sharing, dissemination, and preservation. The security arrangements described in this section primarily concern the shared project data managed through REDCap and FIBHGM SharePoint. They do not replace the individual responsibilities of beneficiaries for local records, confidential source materials, or personal data maintained outside these platforms. The measures applied will be proportionate to the nature of the data, the potential risks to individuals and organizations, the intended uses of the information, and applicable legal, ethical, institutional, and contractual requirements.

5.1 Data Storage and Sharing

MOBHOPE uses two designated platforms for shared project activities.

REDCap is administered by the FIBHGM data coordinator, acting as Global Project Coordinator, and is used for the ECDC stigma assessment survey. All four beneficiaries have access for the agreed data-entry activities. The survey is designed to collect anonymous responses without direct identifiers, and the project has assessed that the responses cannot reasonably be linked to individual participants.

FIBHGM SharePoint is administered by the FIBHGM project manager and is used for collaborative work on non-confidential project documents and materials approved for access by all four beneficiaries.

The platforms are not intended to store confidential or identifiable participant information under the arrangements described in this DMP. Beneficiaries will ensure that materials uploaded to SharePoint or entered into REDCap are appropriate for their intended purpose and do not contain information that should remain restricted. Before sharing research summaries or other outputs externally, the responsible beneficiary will consider whether the information could identify individuals indirectly, particularly through small numbers, rare characteristics, combinations of variables, or detailed geographic information. Each beneficiary remains responsible for the security of its own local data-management systems and records. The sharing of information through the project platforms will not transfer or remove those responsibilities.

5.2 REDCap Management and Security

The project REDCap environment is administered by the FIBHGM data coordinator in the role of Global Project Coordinator. Responsibilities include user access management, coordination of data-entry procedures, and oversight of data quality and auditability for the project survey. The REDCap environment is reported to be hosted on servers located within the European Union, associated with biomad.es, the training platform established by HEALTH4OL in Madrid, Spain. The precise hosting arrangement, the relationship between the relevant organizations, and the applicable security and service responsibilities will be documented and verified with the relevant service provider. Access will be restricted to authorized project personnel using individual user accounts and appropriate permissions. Access rights will be managed according to the agreed project responsibilities and reviewed when personnel or responsibilities change.

Technical security arrangements, including authentication, encryption in transit and at rest, backups, audit logging, and recovery procedures, will be documented according to the actual system configuration and verified capabilities. The DMP will not be interpreted as confirmation that a particular technical control is active until its implementation has been verified. Where available and enabled, REDCap audit-trail functionality will support traceability of data entries and modifications. These records may be used for data-quality monitoring and investigation of suspected unauthorized access or data manipulation. The project will periodically review the suitability of the REDCap configuration and access arrangements for the intended processing activities. Any material change in hosting, functionality, or data collected will be considered in subsequent DMP updates.

5.3 Anonymity and Confidentiality

The ECDC stigma assessment survey is designed to collect anonymous responses without direct participant identifiers. Based on the project's current assessment, the responses cannot reasonably be linked to individual participants. The survey will not intentionally collect names or other direct identifiers. The consortium will also avoid collecting unnecessary information that could create a risk of indirect identification. The design and configuration of the questionnaire will be reviewed if new variables, free-text fields, or additional data-linkage arrangements are introduced. The project will distinguish between anonymous information and pseudonymized personal data. Information is not considered anonymous merely because names and direct identifiers have been removed; the possibility of identification through combinations of remaining information must also be considered. If a beneficiary holds separate local records containing personal or confidential information, those records remain subject to the applicable confidentiality and data protection requirements. They will not be included in the shared project platforms unless a specific processing and sharing arrangement has been assessed and approved. Access to any locally held records, linkage keys, consent forms, or other identifying documentation will remain restricted to personnel authorized by the responsible organization. Such materials will be stored separately from research datasets where required by the applicable research protocol and security procedures.

5.4 Technical and Organizational Safeguards

The beneficiaries will apply appropriate security measures to the project systems and materials for which they are responsible. Measures will be selected according to the nature of the information, the applicable risks, and the capabilities of the relevant institutional infrastructure. These measures will include, as appropriate:

- Restricting platform access to authorized personnel and reviewing permissions periodically.
- Using individual user accounts and appropriate authentication measures.
- Protecting devices used for data collection and processing against unauthorized access.
- Using approved channels for transferring project materials.
- Maintaining appropriate backup, recovery, and continuity arrangements.
- Protecting paper records and other physical documentation against unauthorized access, loss, or damage.
- Revoking access when personnel leave the project or no longer require it.

- Applying appropriate retention and secure deletion procedures.
- Documenting hosting arrangements, storage locations, access responsibilities, and relevant security controls.

The project manager and data coordinator will coordinate the review of the respective SharePoint and REDCap arrangements. Each beneficiary will remain responsible for implementing the necessary measures within its own organizational environment. Security arrangements will be reviewed periodically and when significant changes occur in the data collected, project infrastructure, participating organizations, or applicable requirements.

5.5 Personal Data Breach Management

Each beneficiary will promptly report suspected or confirmed security incidents affecting project data through the agreed consortium incident-reporting procedure. Where an incident involves personal data, the relevant controller or joint controllers will assess the incident, document the facts and response, and determine whether notification to the competent supervisory authority or communication to affected individuals is required under GDPR Articles 33 and 34. Where a processor is involved, it will notify the relevant controller without undue delay in accordance with the applicable contractual arrangements and GDPR requirements. The beneficiaries will cooperate in investigating incidents, implementing corrective measures, and documenting relevant decisions. Responsibilities and communication arrangements will be specified in the applicable governance and data-processing documentation. The consortium will also consider incidents affecting the availability, integrity, or confidentiality of shared project documents, even where no personal data are involved, and will implement proportionate corrective measures.

5.6 End-of-Project Data Management

At project closure, the beneficiaries will review the shared materials held in REDCap and FIBHGM SharePoint and determine which materials should be retained, exported, transferred, or securely deleted. The review will take account of the applicable Grant Agreement, project reporting and audit requirements, institutional policies, ethical approvals, intellectual property rights, and any relevant legal obligations. Access to project systems and collaborative workspaces will be reviewed and adjusted or revoked as appropriate. The responsible administrators will document relevant decisions concerning continued access, transfer of responsibilities, and preservation of eligible project outputs. Public outputs will remain available through the project website and EU Funding & Tenders Portal, as applicable, in accordance with the preservation arrangements described in Section 4.3. The end-of-project review will not automatically authorize the deletion of records subject to mandatory retention requirements. Equally, records will not be retained indefinitely without an applicable justification. The relevant retention periods and responsibilities will be confirmed before the final DMP is approved.

6. Ethics

6.1 Ethical and Legal Framework

MOBHOPE addresses viral hepatitis, liver health, stigma, and access to healthcare among populations that may experience social exclusion or discrimination. Research activities may involve sensitive topics, including health status, substance use, migration, imprisonment history, and sexual behaviour, depending on the specific protocol and instruments used. Ethical considerations are therefore integral to the design, collection, analysis, sharing, and dissemination of project data. The project will respect participants' dignity, privacy, autonomy, and right to receive services without discrimination. The following provisions apply:

- **Ethics approval:** FIBHGM has obtained ethical approval for the project protocol entitled MOBHOPE-Research. The approval reference, date, approved version, and relevant conditions will be recorded in the project's documentation. Any additional approvals required for activities conducted by other beneficiaries will be obtained before the relevant activities begin. The need for amendments or additional approvals will be assessed whenever the protocol or data-processing activities change.
- **Data protection legislation:** The project will comply with Regulation (EU) 2016/679 (General Data Protection Regulation, GDPR) and applicable national legislation. Each beneficiary will identify the relevant organizational responsibilities and contacts for data protection matters.
- **Data Protection Impact Assessment:** The consortium will assess whether a Data Protection Impact Assessment (DPIA) is required for the relevant processing activities under GDPR Article 35. Given the project's research context and the potential sensitivity of the information involved in local activities, the need for and scope of a DPIA will be documented before any relevant high-risk processing begins. Any required DPIA will be maintained and updated as appropriate.
- **Lawful basis for processing:** Where personal data are processed, the responsible organization will document the applicable lawful basis under GDPR Article 6 and, where special categories of personal data are involved, the applicable condition under Article 9. The relevant basis will be determined for each processing activity, taking account of national law and the approved protocol. Participant consent to take part in research and the GDPR lawful basis for processing personal data will be addressed as distinct but related matters.
- **Participant information and consent:** Where required by the approved protocol and applicable law, participants will receive appropriate information before participating. Information and consent materials will be provided in a language and format that participants can understand, taking account of the project's operating countries and the needs of relevant communities.
- **Data subject rights:** Where personal data are processed, participants will be informed of the rights applicable to their circumstances and the appropriate contact point for enquiries. The handling of requests will take account of applicable legal provisions and any lawful limitations or research-related derogations.
- **International transfers:** The project does not currently anticipate transferring personal data outside the European Economic Area (EEA). Any proposed transfer will be assessed before it occurs and will comply with GDPR Chapter V

and other applicable requirements. Appropriate safeguards will be implemented where required.

- **Qualitative research:** Interviews, focus groups, recordings, transcripts, and field notes will be handled according to the relevant approved protocol and participant information. Identifying details will be minimized or removed where appropriate, and source materials will not be shared through the project platforms unless the sharing arrangement has been assessed and authorized.
- **Voluntary participation and non-discrimination:** Participation in research activities will not be a condition for receiving healthcare or other services. Research procedures will be designed to minimize unnecessary burden and avoid stigmatizing or discriminatory practices.

The project will maintain documentation of relevant ethical approvals, participant information materials, consent procedures where applicable, and decisions concerning data use and sharing. Documents containing confidential or identifying information will be stored and accessed in accordance with the applicable requirements rather than uploaded to the shared project platforms.

6.2 Controllership, Processing Roles, and Inter-Partner Data Agreements

MOBHOPE involves four legally distinct beneficiary organizations: Ares do Pinhal, Hepatos, FIBHGM, and Madrid Positivo. The legal roles of the beneficiaries will be determined according to the actual purposes and means of each processing activity. Where two or more beneficiaries jointly determine the purposes and essential means of a particular processing activity involving personal data, they may qualify as joint controllers under GDPR Article 26. Where one organization processes personal data on behalf of another, a processor relationship may arise under Article 28. These roles will not be assumed solely from the fact that the beneficiaries collaborate or share project platforms. The shared project REDCap environment is administered by the FIBHGM data coordinator for the anonymous ECDC stigma assessment survey. FIBHGM SharePoint is administered by the FIBHGM project manager for the sharing of non-confidential project documents and materials among the beneficiaries. Under the current arrangements described in this DMP, the project platforms are not intended to contain confidential or identifiable participant information. The use of these platforms does not, by itself, establish a joint controllership or processor relationship. The consortium will assess whether any personal data are processed in connection with platform administration, user management, technical support, or other activities and will document any resulting obligations where applicable. Each beneficiary remains responsible for determining and documenting its obligations for personal data processed within its own activities and organizational environment. Where a joint controllership arrangement is required, the relevant beneficiaries will formalize their respective responsibilities under GDPR Article 26. The arrangement will address, as applicable, transparency and participant information, the exercise of data subject rights, security measures, incident response, retention, and contact arrangements. The essence of the arrangement will be made available to data subjects where required. Where a processor arrangement is required, the relevant parties will document the processing operations and responsibilities in an agreement meeting the requirements of GDPR Article 28. The consortium will also document the responsibilities associated with hosting and administering the REDCap environment and SharePoint workspace, including the relevant service-provider arrangements where applicable. Any changes to the

processing activities or platform configuration that affect the parties' legal roles will be reviewed and reflected in the relevant documentation and DMP updates.

6.3 Stigma and Dignity Considerations

Given MOBHOPE's focus on stigma and discrimination, particular attention will be paid to participants' dignity, autonomy, and the risk of reinforcing existing barriers to healthcare. The following safeguards will apply:

- Participation in stigma assessment activities will be voluntary and separate from access to mobile health services.
- Staff involved in administering the ECDC stigma assessment instrument will receive appropriate guidance on respectful, trauma-informed, and non-stigmatizing communication.
- The survey will be designed and implemented without direct participant identifiers, and the project will avoid unnecessary information that could permit indirect identification.
- Public reporting will focus on aggregate findings and will avoid presenting small groups or distinctive combinations of characteristics in a way that could expose individuals or reinforce stereotypes.
- The wording and interpretation of results will be reviewed to avoid stigmatizing descriptions of populations or attributing blame to participants.
- Any future change to the survey instrument or its data collection arrangements will be assessed for potential ethical and confidentiality implications before implementation.

These safeguards support the project's commitment to equitable access to care and responsible dissemination of findings.

7. Other Issues

7.1 National and Institutional Procedures

In addition to the EU-level requirements described in this DMP, MOBHOPE beneficiaries will comply with applicable national legislation, institutional procedures, and contractual obligations governing research, data management, and information security. The following frameworks and arrangements are relevant to the project:

- **Spain:** Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales (LOPDGDD), which supplements the GDPR in Spanish law. FIBHGM will follow its applicable institutional procedures for research governance, ethics, information security, and data management. Any additional institutional procedures applicable to participating clinical services will also be followed. Madrid Positivo will comply with the applicable Spanish data protection legislation and its relevant internal procedures for research activities, project documentation, and information security.
- **Croatia:** Act on the Implementation of the General Data Protection Regulation (Official Gazette, NN 42/2018), together with other applicable national and institutional requirements. Hepatos will follow the procedures relevant to its research and public health activities.

- **Portugal:** Lei n.º 58/2019, which ensures the implementation of the GDPR in Portuguese law, together with applicable national and institutional requirements. Ares do Pinhal will follow the procedures relevant to its activities and organizational responsibilities.
- **REDCap and SharePoint:** Use of the project platforms will follow the applicable institutional policies, service arrangements, access controls, and responsibilities established for the respective environments. Relevant hosting and platform-management arrangements will be documented and verified.
- **EU4Health Grant Agreement:** This DMP will be maintained in accordance with the applicable Grant Agreement, including relevant requirements concerning research outputs, data management, dissemination, access, and preservation. The applicable provisions will be checked against the signed agreement and incorporated into subsequent DMP updates where necessary.

The consortium will review the applicability of these requirements as the project evolves. Any material change in participating organizations, data-processing activities, or applicable legal obligations will be considered in the DMP review process.

7.2 DMP Update Schedule

This DMP is a living document and will be updated as necessary to reflect the project's actual data-management arrangements, research activities, and applicable requirements. The planned review milestones are:

- **Month 12:** First formal DMP submission, reflecting the planned data landscape, agreed responsibilities, and initial data-management arrangements.
- **Month 24:** Review and update to reflect ongoing data collections, platform use, research outputs, changes in data-sharing arrangements, and any relevant ethical or legal developments.
- **Month 36 (project end):** Final review documenting the completed data landscape, public outputs, preservation arrangements, outstanding access commitments, and post-project responsibilities.
- **Ad hoc updates:** Additional revisions when significant changes occur, including new data collection activities, changes in consortium composition, modifications to the survey or platform configuration, new sharing arrangements, material security incidents, or relevant changes in legal, ethical, or contractual requirements.

Each version will record its version number, date, and a summary of material changes. The designated DMP owner at FIBHGM will coordinate revisions in consultation with the project data coordinator, the project manager, and the other beneficiaries. Where a change affects data protection, ethics approvals, platform security, or contractual obligations, the relevant beneficiary will assess whether additional review, documentation, or approval is required before the change is implemented. The updated DMP will be circulated to the beneficiaries for review in accordance with the project's governance arrangements and submitted through the applicable EU project reporting channels where required.