Research Methodology & Tools

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MOBHOPE Project Coordination Team
info@mobhope.eu
mobhope.eu

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PARTNERS

Table of Contents

List of Abbreviations 3
List of Tables 3
Executive Summary 3
1. Introduction 5
2. Objective of the Research Framework 5
3. Project Objectives and Scope Lock 6
3.1 Detailed DoA–D2.1–KPI Traceability 6
4. Inception Phase and Scoping 7
5. Evidence Mapping 8
6. Needs Assessment and Stakeholder Consultation 8
7. Research Questions and Methodological Design 9
8. Data Collection Systems and Tools 9
9. Data Analysis, Verification, Monitoring and Synthesis 10
9.1 Quality Control Loop and CAPA Logic 10
10. Development of Options for EU Member States (Service Improvement) 11
10.1 Standardisation Pipeline 12
11. Integration, Validation, and Dissemination 12
11.1 Formal Acceptance Criteria for D2.1 13
12. Ethical Considerations and Data Protection 13
13. Expected Impact of the Research Framework 14
Annex 1. KPI Matrix 15
Annex 2. Minimum REDCap Dataset 16
Mandatory versus Optional Field Logic 16
Minimum REDCap Field Mapping 17
Annex 3. Implementation Timeline and Risk Register 18
Indicative implementation timeline 18
Core risk register 18

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List of Abbreviations

CAPA	Corrective and Preventive Action
D2.1	Deliverable 2.1 “Research Methodology & Tools”
DMP	Data Management Plan
DoA	Description of the Action, Annex 1 in the Project’s Grant Agreement
EU	European Union
GDPR	General Data Protection Regulation (Regulation (EU) 2016/679)
HBV / HCV	Hepatitis B Virus / Hepatitis C Virus
HIV	Human Immunodeficiency Virus
KPI(s)	Key Performance Indicator(s)
M1 – 36	Month 1 – 36 from project start
MASLD	Metabolic Dysfunction-Associated Steatotic Liver Disease
OMOP	Observational Medical Outcomes Partnership
PoC	Point of Care
PREM(s)	Patient-Reported Experience Measure(s)
PROM(s)	Patient-Reported Outcome Measure(s)
REDCap	Research Electronic Data Capture
RDT(s)	Rapid Diagnostic Test(s)
SOP(s)	Standard Operating Procedure(s)
UMC	Mobile Screening Unit – Madrid Positivo (Spain)
WP1 – 5	Work Package 1 – 5

List of Tables

Table 1	Operationalisation of Objectives	Page 6
Table 2	DoA–D2.1–KPI Traceability	Page 6
Table 3	Quality Control	Page 11
Table 4	Standardisation Pipeline	Page 12
Table 5	Acceptance Criteria for D2.1	Page 13
Table 6	KPI Matrix	Page 15
Table 7	Minimum REDCap Dataset	Page 16
Table 8	Mandatory versus Optional Field Logic	Page 16
Table 9	Minimum REDCap Field Mapping	Page 17
Table 10	Implementation Timeline	Page 18
Table 11	Risk Register	Page 18

Executive Summary

The **Research Methodology Framework (D2.1)** establishes a common approach to generating evidence through routine service delivery and translating findings into practical improvements in care. Research is integrated into existing outreach activities, avoiding parallel research structures and minimising disruption to service provision. MOBHOPE combines quantitative monitoring with qualitative and user-centred research

to assess health needs, service performance, and barriers to care. Quantitative data will capture the burden of hepatitis B, hepatitis C, metabolic dysfunction-associated steatotic liver disease (MASLD), and related liver conditions, alongside screening outcomes and service performance. Qualitative research will explore healthcare access, user experiences, social determinants of health, and the effects of stigma and discrimination. A central component is the **cascade of care**, covering outreach, screening, confirmatory assessment, referral, linkage to care, treatment initiation, retention, and follow-up. Monitoring each stage will help identify gaps, reduce losses between screening and treatment, and guide continuous quality improvement. The framework harmonises operational procedures, definitions, minimum data requirements, and key performance indicators across the participating countries. Data will be managed through a shared REDCap platform hosted on secure EU-based infrastructure, supported by appropriate data-quality controls and governance. A common methodological core will enable cross-country comparison while allowing adaptation to national healthcare systems, referral pathways, legislation, and community needs. All research activities will follow applicable ethical and data-protection requirements, including the General Data Protection Regulation (GDPR). Participation in research-related activities will be voluntary and will not affect access to care. Confidentiality, informed consent, dignity, and non-discrimination will guide implementation.

The framework will generate evidence to improve early detection, linkage to care, treatment continuity, and equitable access to liver health services. It will also help identify the operational and social factors influencing service uptake and outcomes among underserved populations, supporting evidence-informed improvements in service delivery. Beyond the participating sites, the findings will inform the development of a **standardised package of mobile liver health services for potential adoption across EU Member States**. This package will encompass service delivery, referral pathways, monitoring indicators, staff training, health promotion, anti-stigma measures, data governance, and guidance for national adaptation.

D2.1 is the methodological deliverable under WP2 – Cascade of Care Development through Mobile Outreach Services. It provides the common research and implementation framework for the participating sites, supports monitoring and quality improvement, and contributes to training and communication (WP1), stigma and user experience (WP3), evidence synthesis and standardisation (WP4), and project coordination and data governance (WP5). **Ultimately, MOBHOPE aims to transform experience gained in Spain, Portugal, and Croatia into an evidence-informed, transferable European model that brings liver health services closer to underserved populations, strengthens the pathway from screening to sustained care, and contributes to reducing health inequalities.**

1. Introduction

This document presents the Research Methodology Framework for optimising mobile liver health services implemented across Spain, Portugal, and Croatia. The framework supports a multi-country initiative designed to improve access to screening, diagnosis, linkage to care, and follow-up for viral hepatitis and related liver diseases among vulnerable populations who face major barriers to conventional healthcare services.

MOBHOPE is implemented through three experienced partners with established community outreach models: the Mobile Screening Unit (UMC) in Spain, the Croatian Society for Liver Diseases *Hepatos* in Croatia, and *Ares do Pinhal* in Portugal. The project works through existing mobile units operating in streets, shelters, harm reduction spots, prisons, and other community settings serving populations at increased risk, including people who inject drugs, migrants, sex workers, men who have sex with men, and people experiencing homelessness.

The methodology is embedded within these existing services. The project does not create a parallel research structure; instead, it integrates evidence generation into routine outreach, testing, counselling, referral, and follow-up. This allows the consortium to utilize data in real-world settings, minimise disruption to care, and use findings immediately to improve service delivery.

The framework follows a mixed-methods operational research approach. Quantitative service and epidemiological data will be combined with qualitative evidence on stigma, barriers to care, service preferences, and user experience. Its final purpose is not only to analyse what happens in the three participating countries, but also to translate findings into a standardised and scalable EU model for mobile liver health services.

2. Objective of the Research Framework

The objective of this framework is to guide the systematic collection, analysis, interpretation, and use of evidence generated by mobile liver health services in Spain, Portugal, and Croatia. The framework is intended to support high-quality service delivery, strengthen the cascade of care, improve comparability across countries, and produce a standard package of mobile liver health services that can be adapted by other EU Member States.

Specifically, the framework is designed to:

- Assess the prevalence of hepatitis B, hepatitis C, Metabolic dysfunction-associated steatotic liver disease (MASLD), and related liver morbidity among populations reached by mobile units.
- Identify bottlenecks in the cascade of care, from screening and diagnosis to referral, treatment initiation, retention, and follow-up.
- Analyse social determinants of health, perceived barriers and enablers to care, and user values and preferences regarding mobile services.
- Evaluate the operational contribution of mobile units to improving linkage to care and reducing drop-out.
- Integrate stigma and discrimination assessment into service monitoring and improvement.
- Generate evidence-based recommendations for a standardised EU package of mobile liver health services.

The framework therefore combines research objectives with ongoing operational objectives. It is intended to function as a methodological guide, an implementation reference, and a monitoring tool for the consortium.

3. Project Objectives and Scope Lock

This framework is aligned to the overall MOBHOPE objective of reducing the burden of viral hepatitis and liver-related morbidity in vulnerable populations through mobile services and operational research. Within that overall logic, the framework directly supports the specific objectives that are most relevant to WP2 and interfaces with WP1, WP3, WP4, and WP5.

For the purposes of implementation, the objectives are operationalised as follows:

Table 1. Operationalisation of Objectives

DoA Objective	Operational Translation	Main Outputs
Objective 1 – prevention, communication and health promotion	Training methodology and educational tools	Training modules, pre/post tools, outreach education indicators
Objective 2 – cascade of care through outreach, RDTs and PoC liver services	Standardised screening, referral, and follow-up pathway	Cascade protocol, linkage indicators, referral SOPs
Objective 3 – operational research on detection, social determinants, barriers, preferences and standard of care	Mixed-methods research design	Quantitative and qualitative tools, analysis plan
Objective 4 – stigma and discrimination assessment	Validated stigma and dignity package	Stigma module, staff training, dissemination tools
Objective 5 – standardisation of mobile liver health services	Translation of evidence into an EU service package	Standard package, country annexes, policy recommendations

The scope of D2.1 is therefore broader than a conventional research protocol. It must define the methodological basis for operational research while also creating the implementation architecture that allows results to be translated into standardised practice.

3.1 Detailed DoA–D2.1–KPI Traceability

The matrix below establishes the minimum traceability between the DoA objectives, the corresponding sections of this D2.1, the operational KPIs used to evidence delivery, and the primary sources that will support periodic monitoring and verification.

Table 2. DoA–D2.1–KPI Traceability

DoA Objective	D2.1 Section(s)	Reference KPI(s)	Primary Data Source	Frequency
Objective 1 – prevention, communication and health promotion	Sections 4, 6, 8; Annex 1	Training sessions delivered; participants with ≥30% knowledge increase; staff trained	Training log, pre/post tools, staff register	Quarterly

Objective 2 – cascade of care through outreach, RDTs and PoC liver services	Sections 7, 8, 9, 12; Annexes 1–3	Cascade protocol implemented; tests/liver exams; prison-based tests; linkage to care; time to specialist evaluation	REDCap, prison logs, referral tracker, date stamps	Monthly / Quarterly
Objective 3 – operational research on detection, social determinants, barriers, preferences and standard of care	Sections 5, 6, 7, 8, 9, 13	Operational research outputs; positivity rates; MASLD/liver disease burden; service preference responses	REDCap, qualitative tools, analysis outputs	Quarterly / Semi-annual
Objective 4 – stigma and discrimination assessment	Sections 7, 8, 11, 13; Annex 1	Participants completing stigma tools; staff trained in dignity/anti-stigma; dissemination sessions	Validated stigma module, training register, dissemination log	Quarterly
Objective 5 – standardisation of mobile liver health services	Sections 10, 11, 13; Annexes 1–3	Draft standard package produced; sites using standard core; policy briefs/recommendations	Standardisation memos, consortium approvals, dissemination outputs	Milestone-based / Semi-annual

This traceability matrix shall be treated as normative for the rest of the deliverable. No methodological section shall be considered complete unless it remains verifiably connected to at least one DoA objective and one measurable implementation indicator.

4. Inception Phase and Scoping

The inception phase covers Months 1–12 and is intended to ensure that research activities are fully integrated into routine mobile services and harmonised across the three implementing countries. This phase will establish governance, finalise tools, align workflows, and prepare the conditions for consistent data collection and monitoring.

The core outputs of the inception phase are:

- Approval of the Research Methodology & Tools framework (D2.1).
- Finalisation of the Data Management Plan and REDCap architecture.
- Agreement on a joint protocol and common operating definitions.
- Development of the SOP framework for screening, referral, consent, data entry, and follow-up.
- Preparation and submission of ethics and institutional approvals where required.
- Training of staff and peers involved in implementation and data collection.
- Establishment of governance, reporting, and quality assurance mechanisms.

Governance during this phase will include:

- Project Manager – overall coordination and deliverable oversight.
- Steering Committee – operational and methodological decision-making.
- External Advisory Board – strategic technical advice and external perspective.
- Public and Patient Involvement – structured user and community input.

- Data Coordinator – REDCap administration, access control, and data quality monitoring.

The scoping exercise will map existing workflows at each site, identify points where research can be embedded without disrupting care, and agree the minimum dataset and monitoring approach used across the consortium.

5. Evidence Mapping

Evidence mapping exercise will be undertaken to inform methodological choices, service design, and standardisation. Its purpose is to identify and describe relevant existing evidence, guidance, and practices, and to translate key findings into practical considerations for the development and implementation of the service model.

The review will focus on four domains:

- Epidemiology of viral hepatitis, MASLD, and advanced liver disease in vulnerable populations.
- Evidence on mobile clinics, outreach-based testing, and point-of-care models.
- Barriers and enablers to screening, diagnosis, referral, treatment initiation, and retention.
- Stigma, discrimination, social determinants, and user preferences relevant to mobile services.

The evidence mapping will generate three concrete outputs:

1. A best-practice matrix for mobile liver health services.
2. A list of standardisable components for the EU service package.
3. A methodological note explaining how the review informed tool selection, variables, and implementation priorities.

6. Needs Assessment and Stakeholder Consultation

A multi-level needs assessment will be conducted to ensure that the framework is grounded in real service conditions. This assessment will include mobile unit staff, hospital referral teams, public health stakeholders, community organisations, peer workers, and representatives of the vulnerable groups targeted by the project.

Stakeholder engagement methods will include:

- Structured interviews with service providers and key informants.
- Workshops with implementing partners and local stakeholders.
- Informal consultations embedded in outreach activity.
- Feedback sessions with peers and community representatives.

The needs assessment will identify operational barriers, resource constraints, contextual differences across countries, service preferences, and opportunities for adaptation. Its outputs will be used to refine research tools, define country-specific annexes, and ensure that the common EU framework remains feasible and culturally appropriate.

7. Research Questions and Methodological Design

The project addresses the following core research questions:

1. What is the prevalence of hepatitis B, hepatitis C, MASLD, and related liver disease among populations reached by mobile units?
2. How effectively do mobile services link individuals to confirmatory diagnosis, treatment, and follow-up care?
3. Which social determinants influence access to mobile liver health services and continuity of care?
4. How do stigma and discrimination affect service uptake, engagement, and retention?
5. What barriers and enablers shape engagement with mobile services from the perspective of users, peers, and providers?
6. Which components of mobile service delivery contribute most strongly to improved outcomes and should therefore be retained in the final standard package?

To answer these questions, MOBHOPE will use a mixed-methods operational research design consisting of four integrated components:

1. Quantitative service and epidemiological monitoring embedded in routine mobile activity.
2. Standardised cascade-of-care analysis, from outreach and screening to linkage, treatment initiation, and follow-up.
3. Qualitative and user-centred research.
4. Benchmarking and standardisation work to compare sites and define a scalable EU package of services.

For implementation purposes, the cascade of care will be defined as:

- Outreach contact and eligibility assessment.
- Testing and/or PoC liver assessment.
- Confirmatory evaluation where required.
- Referral to specialist or appropriate follow-on service.
- Attendance at specialist evaluation / linkage to care.
- Treatment initiation where indicated.
- Retention and documented follow-up.

This standard cascade is essential because the main value of the project lies not only in the number of tests performed, but in the proportion of participants who move successfully from detection to meaningful care.

8. Data Collection Systems and Tools

This project will use secondary data routinely collected by participating mobile service units during standard service delivery. Existing datasets will be harmonised across all participating countries using a common REDCap platform hosted on secure EU-based infrastructure. The platform will allow multilingual entry, role-based access, real-time monitoring, standardised reporting, and continuous quality control.

The minimum quantitative dataset includes:

- Participant profile and service setting.

- Vulnerability indicators and relevant social determinants.
- Test type, result, and related laboratory or PoC details.
- Liver assessment findings, including elastography where available.
- Referral dates, referral destination, and specialist attendance.
- Treatment initiation and follow-up outcomes.
- Service activity counts and staff implementation data.

The qualitative and patient-centred dataset includes:

- Patient-reported experience and satisfaction measures
- Perceived barriers and facilitators to care
- Values and preferences regarding mobile versus standard service models
- Validated stigma and discrimination measures
- Staff and stakeholder reflections on implementation barriers and solutions

All tools will be harmonised at consortium level and adapted locally where necessary. The D2.1 package therefore includes not only the methodological description, but also the principal forms, guides, instruments, and operating definitions to be used across the project.

9. Data Analysis, Verification, Monitoring and Synthesis

Quantitative analysis will focus on prevalence, positivity, liver disease burden, and the operational performance of the cascade of care. Core measures will include test coverage, positivity rate, referral completion, time from diagnosis to specialist evaluation, treatment initiation, and retention/follow-up.

Qualitative analysis will use thematic methods to identify common patterns in barriers, facilitators, stigma, acceptability, service preference, and country-level implementation constraints. Findings will be triangulated with quantitative results to generate service-level recommendations.

Verification and quality assurance will include:

- Predefined SOPs and operating definitions.
- Automated REDCap validation rules and consistency checks.
- Regular audits by a designated data coordinator.
- Cross-site review of indicators and missingness patterns.
- Deviation logs and corrective action procedures.
- Periodic review of operational risks, data risks, and referral bottlenecks.

Monitoring shall be driven by a formal KPI matrix. At minimum, the framework will track the targets already defined in the DoA, including establishment of a cascade-of-care protocol in 3 sites by Month 12, 4,400 tests and/or liver exams in streets and shelters by Month 36, 600 prison-based tests and/or liver exams by Month 36, linkage to care of at least 80%, average time to specialist evaluation below 30 days, and at least 2 operational research outputs or publications.

9.1 Quality Control Loop and CAPA Logic

Quality control shall operate as a closed loop of capture, validation, review, correction, follow-up and learning. The objective is to ensure that data quality, implementation

fidelity and referral performance are checked first at point of capture, then at site level, and finally at consortium level.

Table 3. Quality Control

Step	Control Point	Responsible	Tool / Evidence	Trigger for Action	Output
1 Capture	Field completion at point of service	Site staff / peer / data collector	REDCap forms, consent log, device traceability	Mandatory field missing or inconsistent entry	Clean record or query raised
2 Automated validation	Range, logic and complete-ness checks	REDCap / Data coordinator	Validation rules, branching logic, completeness dashboard	Failed validation rule or duplicate record	Correction request
3 Site review	Weekly / monthly review of site performance	Site lead	Query log, missingness report, referral tracker	Repeated missing fields, bottleneck in referral pathway	Site corrective action
4 Consortium review	Cross-site comparison and escalation	Project manager / Data coordinator	KPI dashboard, audit summary, deviation log	Threshold not met in two consecutive periods	CAPA decision
5 CAPA implementati-on	Corrective and preventive action execution	Assigned owner	CAPA register with root cause and deadline	Open major deviation or unresolved risk	Implemen-ted action with deadline

All CAPA actions shall be documented in a single register containing the date of detection, root cause, responsible person, corrective action, preventive action, deadline and closure verification.

10. Development of Options for EU Member States (Service Improvement)

The evidence generated through this framework must feed directly into the development of a standard package of mobile liver health services for wider EU use. This is a core project objective and must therefore be visible from the methodology stage.

The standard package will include:

- Minimum service components for screening and liver assessment.
- A standardized cascade-of-care pathway and referral model.
- Core monitoring indicators and data definitions (i.e. OMOP).
- Communication and health-promotion requirements.
- Anti-stigma and dignity-promoting elements.
- Integration points for mental health, addiction, and psychosocial support.
- Training requirements and role profiles for mobile teams.
- Country-specific adaptation annexes where legal or system differences require them.

The objective is not to eliminate local flexibility, but to define a common operational core that can be replicated and adapted within different EU health systems.

10.1 Standardisation Pipeline

Standardisation shall not appear only as a final output, but as a traceable process through which implementation evidence is progressively converted into a common EU operational standard. The pipeline below formalises that process and links each stage to specific inputs, methods and decision rules.

Table 4. Standardisation Pipeline

Phase	Timing	Primary Input	Method	Output	Decision Rule
Baseline methodolo-gical package	M1–M12	SOPs, minimum dataset, site readiness, pilot criteria	Internal technical review	Baseline package v1.0	Approval by coordination + WP2 + data/ethics
Pilot learning phase	M7–M12	Feasibility data, incidents, pathway timings, tool acceptability	Descriptive analysis + lessons-learned review	Pilot adjustment memo	Critical CAPA actions closed before scale-up
Interim harmonisa-tion	M13–M24	KPI trends, qualitative findings, country adaptations	Cross-site benchmarking and consensus review	Interim standard core v1.2	No unresolved major deviation affecting comparability
Final synthesis	M25–M30	Full operational dataset, validation feedback, dissemination inputs	Integrated mixed-methods synthesis	Draft EU standard service package	Steering Committee endorsement
Adoption support	M31–M36	Final package, policy and implementati-on lessons	Dissemination, policy translation and uptake support	Final standard package + policy recommen dations	Final consortium approval and release

The final standard package shall contain, at minimum, the minimum care circuit, the mandatory SOP core, the core dataset, the KPI nucleus, minimum data-governance conditions and the minimum criteria for country-level adaptation.

11. Integration, Validation, and Dissemination

Findings arising from the framework will be progressively validated and translated into project outputs through structured consortium review, stakeholder consultation, and integration with later deliverables. Validation is not a single end-stage event; it is a continuous process linked to quality improvement.

Validation mechanisms include:

- Review of interim findings with consortium partners.
- Stakeholder workshops with providers, policymakers, community actors, and peer representatives.
- Revision of tools and operating procedures based on implementation feedback.
- Cross-country comparison and benchmarking to refine the future standard package.

Dissemination outputs include:

- Public reports and summary documents.
- Policy briefs for national and EU-level authorities.
- Scientific publications and conference dissemination.
- Training materials and operational tools for mobile teams.
- Materials designed to support uptake beyond the three participating countries.

11.1 Formal Acceptance Criteria for D2.1

For contractual closure and internal quality control purposes, D2.1 shall be considered formally accepted only when the criteria below are met simultaneously. The purpose of this table is to avoid a purely narrative approval and to establish verifiable closure thresholds.

Table 5. Acceptance Criteria for D2.1

Acceptance Criterion	Verifiable Evidence	Minimum Threshold	Validation Owner	Closure Status
Validated SOP framework	SOPs approved, versioned and assigned	100% of core SOPs approved and available at all sites	Site leads	Open
Operational REDCap setup	Production project, active codebook, configured permissions and validation rules	Core instruments active and testable in production	Data coordinator	Open
Approved KPI matrix	KPI register with definitions, owners and reporting frequency	All core DOA-linked KPIs approved	Project coordinator	Open
Minimum dataset activated	Mandatory fields enabled in all countries	No site removes any mandatory field	Data coordinator	Open
Quality-control loop functioning	Query log, audit routine, CAPA register	Monthly site review and consortium escalation route in place	Project manager / Data coordinator	Open

Closure of D2.1 shall require internal sign-off by the project coordinator and the Steering Committee members. If any criterion remains open, the deliverable may be regarded as operationally usable but not formally closed.

12. Ethical Considerations and Data Protection

All research and service activities will follow the principles of voluntary participation, informed consent, confidentiality, non-discrimination, and respect for vulnerable

populations. Mobile services will remain free of charge and low-threshold, and participation in research-related components will never be a condition for access to care.

The ethical and data protection framework covers:

- Local ethics or institutional approvals where required.
- Participant information and consent procedures adapted to different settings and languages.
- Safeguarding arrangements for urgent social, mental health, or clinical needs.
- Pseudonymisation and role-based access to personal data.
- Local control of re-identification keys for follow-up and clinical purposes.
- A consortium-level Data Management Plan defining storage, retention, access, and quality procedures.
- Training of staff in confidentiality, ethics, GDPR, and secure data handling and best practices.

The REDCap environment and all associated processes must comply with GDPR and national legislation, with clear separation between direct identifiers and analytical data wherever feasible.

13. Expected Impact of the Research Framework

By embedding operational research within routine mobile service delivery, this framework will generate evidence capable of improving early diagnosis, strengthening linkage to care, reducing loss across the care continuum, and lowering inequities in access to liver health services for vulnerable populations.

At project level, the expected impact includes:

- Improved comparability of mobile liver health services across Spain, Portugal, and Croatia.
- More robust evidence on prevalence, barriers to care, and user needs in underserved populations.
- Better operational performance of the cascade of care, particularly for linkage to specialist services.
- Improved understanding and measurement of stigma and discrimination in mobile care contexts
- A standardised and transferable package of mobile liver health services for broader EU use.
- A stronger evidence basis for policy recommendations, scalability, and sustainability.

This framework is therefore both a methodological document and the operational basis for the project’s standardisation agenda.

Annex 1. KPI Matrix

The matrix below consolidates the main indicators that should drive monitoring of implementation, performance, and standardisation.

Table 6. KPI Matrix

Objective	Indicator	Target	Data Source	Frequency
Objective 1	Training sessions delivered	12/year	Training log	Quarterly
Objective 1	Participants with ≥30% knowledge increase	≥30%	Pre/post test	Quarterly
Objective 1	Staff trained in communication and health promotion	50	Training register	Quarterly
Objective 1	Training package developed	Ready by M12	Availability in website	Monthly
Objective 1	Develop educational materials	In 3 languages by M12	Leaflets, brochures, digital content	Quarterly
Objective 1	Education in prisons in Croatia	5 prison staff; 600 inmates	Training register	Annual
Objective 1	Education to mobile unit users	3,000 users	Sites data registry	Annual
Objective 2	Cascade protocol implemented	3 sites by M12	Site readiness checklist	Monthly to M12
Objective 2	Tests and/or liver exams in streets and shelters	4,400 by M36	REDCap encounter module	Quarterly
Objective 2	Prison-based tests and/or liver exams	600 by M36	REDCap + prison logs	Quarterly
Objective 2	Linkage to care for positive cases	≥80%	Referral tracker	Monthly
Objective 2	Average time from diagnosis to specialist evaluation	<30 days	Date stamps	Monthly
Objective 3	Operational research outputs / publications	≥2	Publication tracker	Semi-annual
Objective 3	User preference dataset completed	≥600 responses	Survey module	Quarterly
Objective 3	Prevalence estimates available	By M24	Analysis dataset	Milestone review
Objective 4	Participants completing validated stigma tool	≥600	REDCap stigma module	Quarterly
Objective 4	Reduction in stigma score after staff training delivery	≥20%	Pre/post analysis	Semi-annual
Objective 4	Staff trained in dignity and anti-stigma practice	50	Training register	Quarterly
Objective 5	Standard service package finalised	1 by M30	Controlled document	Milestone review
Objective 5	Sites adopting the standard package	≥3 by M36	Adoption checklist	Quarterly
Objective 5	Policy briefs disseminated	≥2 by M36	Dissemina-tion tracker	Semi-annual

Annex 2. Minimum REDCap Dataset

This is the minimum dataset recommended for harmonised collection across the three implementing countries.

Table 7. Minimum REDCap Dataset

Module	Variable Group	Examples	Frequency	Notes
Encounter	Site and setting	Country, site, street/shelter/prison, date	Per encounter	Mandatory
Participant profile	Demographics	Age group, sex/gender, migrant status	Per participant / encounter	Use coded values
Vulnerability	Social determinants	Homelessness, PWID status, incarceration history, health coverage	Per encounter	Core equity variables
Testing	HBV/HCV/HIV	Test type, lot, result, confirmatory action	Per test	Link to traceability log
Liver assessment	MASLD/advanced liver disease	Elastography category, clinical risk, referral need	Per assessment	Where available
Referral	Cascade variables	Referral date, destination, appointment date, attended Y/N	Per positive / eligible case	Drives linkage KPI
Treatment / follow-up	Care continuation	Treatment initiated, date, follow-up status	Follow-up	As locally feasible
User-centred data	PREM/PROM	Satisfaction, acceptability, perceived quality	Defined schedule	Short tools recommended
Stigma	Validated stigma tool	Item responses, summary score	Baseline / follow-up	WP3 integration
Implementa-tion	Operations	Staff role, duration, stock issue, incident	Per session	Supports quality assurance

Mandatory versus Optional Field Logic

For comparability across countries and for performance monitoring, the project defines a minimum harmonised dataset composed of a mandatory core and an optional block. Mandatory variables shall not be removed in any country; optional variables may be activated by site or sub-sample, provided the same dictionary and coding logic are retained.

Table 8. Mandatory versus Optional Field Logic

Module	Mandatory Variables	Optional Variables
Encounter	country, site, date, setting type, session identifier	exact location, extended operational notes
Participant profile	pseudonymised ID, consent status, age group, sex at birth	gender identity, country of origin, preferred language
Vulnerability and determinants	housing status, PWID status, incarceration history, health coverage	employment, food insecurity, digital access
Testing and liver assessment	test type, result, confirmatory action, elastography category where available	lot number photo, expanded clinical notes

Referral and follow-up	referral date, destination, specialist attendance, treatment initiation	reason for non-attendance, follow-up narrative

Minimum REDCap Field Mapping

Table 9. Minimum REDCap Field Mapping

REDCap Field	Suggested Label	Instrument	Type	Rule	Status
record_id	Record ID	Encounter	Auto-number	Unique per record	Mandatory
country_ code	Country	Encounter	Dropdown	Fixed catalogue	Mandatory
site_code	Site	Encounter	Dropdown	Fixed catalogue	Mandatory
encounter_ date	Encounter date	Encounter	Date	Cannot be future dated	Mandatory
setting_type	Setting type	Encounter	Dropdown	Street / shelter / prison / other	Mandatory
participant_ uid	Pseudonymi-sed participant ID	Participant profile	Text	Unique within country	Mandatory
consent_ status	Consent obtained	Participant profile	Yes/No	Required before data completion	Mandatory
hbv_hcv_ hiv_result	Screening result	Testing	Categorical	Value list controlled	Mandatory where test performed
referral_date	Referral date	Referral	Date	Must be on/after encounter date	Mandatory for positive / eligible cases
specialist_ attended	Attended specialist evaluation	Referral	Yes/No	Required for linkage KPI	Mandatory for referred cases

Annex 3. Implementation Timeline and Risk Register

Indicative implementation timeline

Table 10. Implementation Timeline

Period	Main Activities	Main Outputs
Months 1–12	Framework finalisation, DMP, REDCap setup, SOPs, ethics, training	D2.1, approved tools, governance routines
Months 7–12	Pilot implementation and readiness review	Site-level adjustments, cascade protocol in place
Months 13–24	Full implementation and monitoring	Interim analyses, dashboard review, benchmarking
Months 25–30	Synthesis and standard package drafting	Draft standard service package
Months 31–36	Final analysis, dissemination, adoption support	Final recommendations, policy briefs, publications

Core risk register

Table 11. Risk Register

Risk	Type	Impact	Mitigation
Delay in ethics or local permissions	Regulatory	High	Prepare common template set early and stagger site start-up if needed
Incomplete referral completion	Operational / clinical	High	Case-management workflow, reserved specialist slots, active follow-up
Data inconsistency across sites	Data quality	Medium	Common codebook, REDCap validation, monthly audit review
Device downtime or stock interruption	Operational	Medium	Traceability log, maintenance plan, minimum stock thresholds
Restricted access to prison settings	Operational / contextual	Medium	Country annexes and alternative deployment scheduling
Data breach or device loss	Data protection / cyber	High	Role-based access, encryption, incident response, staff training

Note: The implementation timeline and risk register presented in this annex are indicative and provide a high-level overview of the main implementation phases, expected outputs, key risks, and proposed mitigation measures. These tables are intended as a basic planning framework and will be further elaborated and operationalised within the project's common data-sharing system. The detailed versions will be maintained and regularly reviewed and updated by the Project Manager, in consultation with the relevant project partners, to reflect implementation progress, emerging risks, agreed mitigation actions, and any necessary adjustments to activities, timelines, and responsibilities.