Liveration
UNRAVELLING THE IMPACT OF RADIOFREQUENCY IN LIVER SURGERY

# Unravelling the impact of radiofrequency in liver surgery

## D1.3: Data Management Plan

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## Partners

| Participant organisation name and country | Participant abbreviation |
|---|---|
| Consorcio Mar Parc de Salut / INSTITUT HOSPITAL DEL MAR, SPAIN | IMIM |
| FUNDACIO INSTITUT HOSPITAL DEL MAR, SPAIN | FIMIM |
| Vecmedical, SPAIN | VECMEDICAL |
| Sociedad para el Avance Científico, SPAIN | SACSIS |
| SHINE 2Europe, Lda, PORTUGAL | SHINE |
| European Liver Patient Association, BELGIUM | ELPA |
| Avedis Donabedian Research Institute, SPAIN | FAD |
| University of Ioannina, GREECE | UOI |
| ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK, FRANCE | ECRIN |

**Disclaimer:**

## Executive summary

This deliverable outlines the consortium's data management plan (DMP), and it provides detailed consideration to data management within the clinical trial and the data collection of other activities in the project (Patient Reported Outcome Measures, Patient Reported Experience Measure, Living Labs, Chapter on the Diagnosis and treatment cluster, Data collected for intervention evaluation and monitoring, Multi stakeholder group, Cost data, and Systematic review). This deliverable is a living document as is intended to evolve over the course of the project. Initial preparation began at month 3 but it will be updated during the project, with the final version at month 60.

**TABLE OF CONTENT:**

## SYMBOLS, DEFINITIONS, ABBREVIATIONS, AND ACRONYMS

| Abbreviation/Acronym | Meaning |
|---|---|
| CRLM | Colorectal cancer Liver Metastasis |
| HCC | HepatoCellular Carcinoma |
| CTU | Clinical Trial Unit |
| EC | European Commission |
| DEC | Dissemination, Exploitation and Communication |
| KPI | Key performance indicators |
| QoL | Quality of Life |
| OA | Open Access |
| WP | Working Package |
| GA | Grant Agreement |
| IMIM | Institut Hospital del Mar d'Investigacions Mèdiques, SPAIN |
| FIMIM | FUNDACIO INSTITUT HOSPITAL DEL MAR, SPAIN |
| VECMEDICAL | Vecmedical, SPAIN |
| SACSIS | Sociedad para el Avance Científico, SPAIN |
| SHINE | SHINE 2Europe, Lda, PORTUGAL |
| ELPA | European Liver Patient Association, BELGIUM |
| FAD | Avedis Donabedian Research Institute, SPAIN |
| UOI | University of Ioannina, GREECE |
| ECRIN | ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK, FRANCE |

# 1. INTRODUCTION

The DMP is a live document, which will vary during the course of the project. This document will define how the data will be managed, described, treated and stored, during and after the end of the project. In addition, the mechanisms to use the results at the end of the project, will be described to share and preserve the data.

This Data Management plan (DMP) is the initial document for establishing the plan to satisfy the expectations for data management, like:

- Detail the clinical trial data management plan.
- Explain how the data will be shared, and the level of access to be provided (and why).
- Use a repository service to deposit the data and where possible make it and the underlying metadata accessible to third parties, free of charge.
- Arrange backup and storage procedures which are most suited to the partners and nature of the project.

This is a critical point in any project but even more in a project that is going to obtain data from a pragmatic clinical trial. The primary objective of the trial is to evaluate the impact of an additional coagulation of the margin with a radiofrequency device in liver surgery in terms of decreasing local recurrence, overall and disease free survival.

A description of the existing data relevant to the project and a discussion about the data's integration will be provided, together with the description of the metadata to be provided, related to the subject of the project.

## 1.1 RELATION TO OTHER PROJECT DOCUMENTS

In the event of discrepancy between documents, this Data Management Plan is overruled by the Grant Agreement including its Annexes and the Consortium Agreement.

# 2. DATA

## 2.1. CLINICAL TRIAL DMP (WP2 & WP3)

### 2.1.1. Plan Objective

The Data Management Plan (DMP) describes all the necessary steps in the data transfer process from the list of variables or data dictionary to a final transfer for the analysis, describing all the data management system procedures.

This document is created by the Data Manager (DM) responsible for the study and will be reviewed and approved, at least, by the following people:

Chief Investigator: Patricia Sánchez Velázquez, Hospital del Mar, Barcelona, Spain
Clinical Data Manager: María Teresa García, Hospital Universitario La Paz, Madrid, Spain
Project Manager: Paloma Moraga / Belén Ortiz (Hospital Universitario La Paz, Madrid, Spain) and Carlos Fusté (Hospital del Mar, Barcelona, Spain)
Biostatistician: Dimitris Mavridis, University of Ioannina. Greece.

A copy of the signed DMP and appendixes will be filed in the study documentation by the Data Manager. Any changes performed in the Data Management Plan during its development should be identified by a new version number and the date of change.

A copy of the new document will be sent to the study team for its review and approval.

### 2.1.2. Study Characteristics

Short description of the study: This is a multicenter single-blind, randomised, with 2 parallel groups, controlled clinical trial including a total of 720 patients scheduled for either conventional or additional margin coagulation of liver transection in order to assess oncological outcomes. Main primary end-points will be the incidence of local recurrence. Secondary end-points will be overall survival, Disease Free Survival (DFS), Cancer Specific Survival (CSS) and surgical complications as well as Quality of Life.

Register: Clinicaltrials.gov ID: NCT05492136

Number of subjects: A total of 720 patients will be scheduled for either conventional or additional margin coagulation of liver transection in order to assess oncological outcomes.
Participating countries: It is expected to recruit patients from seven countries in a total of twenty four (24) centres.
Participating centres:

SPAIN

Hospital del Mar (Barcelona)
Hospital Clínico de Valencia
Hospital Reina Sofía (Córdoba)
Hospital de Sanchinarro (Madrid)
Hospital Josep Trueta (Girona)

FRANCE
Hôpital de Beaujon (Paris)
Hôpital Paul Brousse (Paris)
Hôpital de Strasbourg.

ITALY
Hospital Tor Vergata (Roma)
Hospital San Raffaele (Milan)
Ospedales Miulli, Acquaviva delle Fonti
Instituto Tumori Napoli
San Camilo Forlanini

SLOVENIA
University Hospital of Lujbljana

POLAND
Zielona Góra University
Uniwersytecki Szpital Kliniczny Lodz
Medical university of Warsaw
Medical University in Katowice

SWITZERLAND
Kantonspital Winterthur

GREECE
General Hospital of Athens "Laiko"
Agios Savvas Hospital, Athens
Metaxa Anticancer Hospital
General University Hospital of Larissa
General Hospital of Athens "Ippokrateio"

### 2.1.3. Timelines

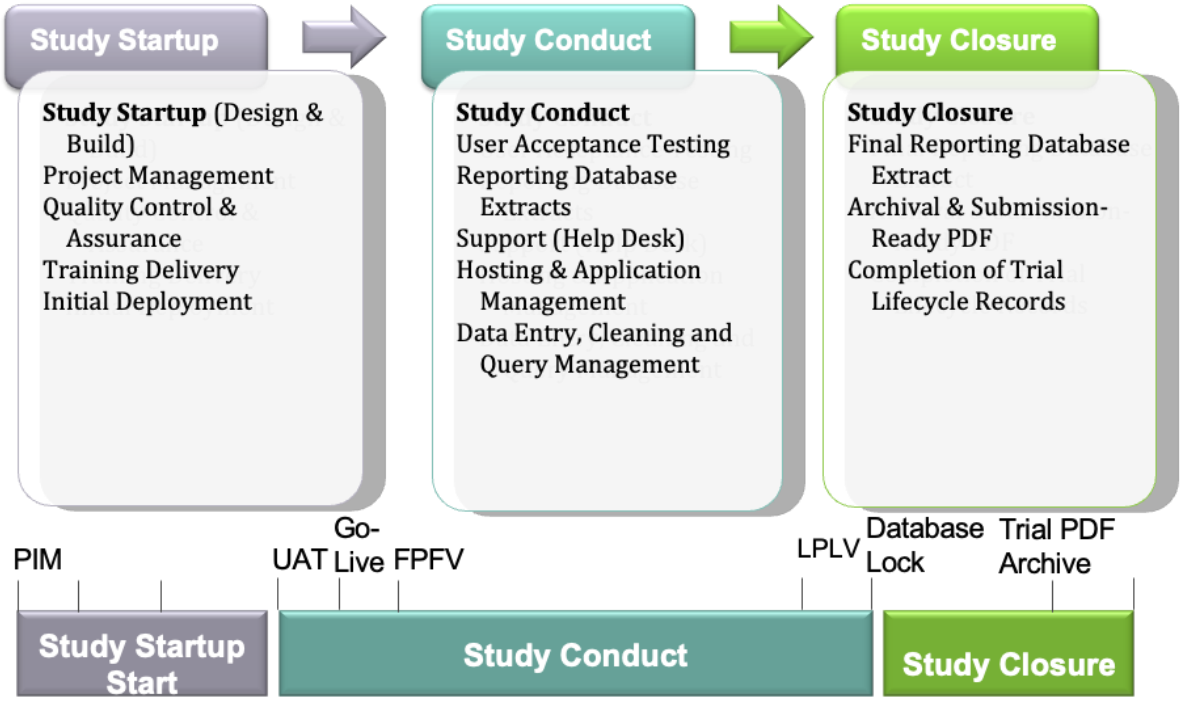
Timelines and assignments will be reviewed by the project team and will be discussed at regular team meetings. Frequency schedule is determined by task. It is essential that modifications to activities, such as responsibilities and timings, are communicated as soon as there is a possibility of change.

The preliminary timelines are as follows:

- First team meeting, that establishes time “0” week as a starting point for accomplishment of the scheduled timeline once the protocol has been approved.
- List of variables or data dictionary creation and approval: 2 weeks after the first team meeting.
- Data Entry Screens creation and approval: 2 weeks after list of variables or data dictionary is approved.
- Edit Checks Specifications: 2 weeks after data entry screens are approved.
- Edit Checks Programming: 2 weeks after edit checks specifications are approved.
- User acceptance Testing (UAT) and approval: 1 week after edit checks programming.
- Go Live: 1 day after UAT approval.
- Manual Data Review/Validation: depending on recruitment, can be established along the study when 25%-50%-75% and finally 100% of the subjects are recruited.
- Serious Adverse Events (SAE) Reconciliation: depending on the number of serious adverse events occurred.
- Database closure: 1 week after the last query is resolved
- Database lock: 1 week after database closure.

### 2.1.4. Workflow

The following workflow shows the data (eCRF and Query) process:



### 2.1.5. Randomization and Blinding procedures

The study protocol defines the randomization and blinding procedures.The Data Manager is responsible for preparing and checking the randomised code list. A copy of the randomised code list will be distributed in electronic or paper copies to the Chief Investigator and Project Manager. The original randomised code list is stored by the Data Manager and the following persons have access to it:

Chief Investigator: Patricia Sánchez Velázquez, Hospital del Mar, Barcelona, Spain
Data Manager: María Teresa García, Hospital Universitario La Paz, Madrid, Spain
Project Manager: Paloma Moraga / Belén Ortiz (Hospital Universitario La Paz, Madrid, Spain) and Carlos Fusté (Hospital del Mar, Barcelona, Spain)
Biostatistician: Dimitris Mavridis, University of Ioannina. Greece.

The Data Manager will review the account for the randomised code list at the end of the trial. The randomization schedule for each investigator, or other unit of randomization, should be checked to determine that it has been followed. The Data Manager checks whether code numbers have been allocated in chronological order. An emergency access to the code for individual patients is explained in the study protocol. The circumstances for breaking the code are clearly described in the study protocol.

### 2.1.6. Generation of the database

The program uses the MACRO system version 4.8 for the database creation.
A detailed description of the information to be captured in the database will be documented in an Annotated CRF. The Annotated CRF details the input object names on the CRF with the name, format and type of variables to be used during the data entry process. The database should be tested for both false positive and false negative results in all fields and functions.

Test data will be used to validate all components of the database including data entry screens and validation specifications (Data Validation Plan). Testing should be performed at each step of development and integrated testing should be performed to ensure all parts work together correctly once the database is completed.

In general:

- The database must capture all items included in the list of variables or data dictionary.
- The variables will be defined with the appropriate format, length and type.
- Database validation testing will help to identify key records management issues, i.e. the database will not accept entry of duplicate records and primary key variables will be appropriately assigned and managed by the definition of the database's structure.

Validation procedures will be described in the Data Validation section. There are different levels of validation procedures:

- Mandatory variables: fields that need to be completed.

- Automatic queries: automatic discrepancies are launched/ fired by the system during the data entry process.
- Manual queries: obtained from the manual review of listings.

All these procedures must be validated using test data. The purpose of these data is entering both valid and invalid data values to ensure that the checks catch all errors. Once the checks are executed, errors are generated for each subject. These errors will be reviewed for any potential programming errors that will be fixed prior to moving the eCRF to production mode.

Validation documentation for the database will be stored with the study documentation and is available for review.

If any edit checks are added or reviewed during the course of a study, the steps followed for creating the edit checks at the beginning of the study should be tracked/repeated.

A key part of the database setup is the definition of users and their roles. A complete list of users and their roles must be created before the eCRF is in production.

The following roles must be assigned:

- Principal Investigator (PI): enrolls subjects, enters data, answers/solves queries, signs the case book.
- Data Entry (DE): enrolls subjects, enters data, answers/solves queries. Basically the same permissions as Principal Investigator except for signing the case book.
- Project Manager (PM): Views data, executes reports.
- Clinical Research Associate (CRA/Monitor): Views data, Source Data Verification (SDV) reviews, creates queries, closes queries, and executes reports.
- Data Manager (DM): Views data, creates and closes queries, opens and locks case book, executes reports, manages database/CRF change requests.

When the database and validation procedures have been fully tested, the Data Manager will request to switch the eCRF to production. All the site users must be trained in the eCRF by certified personnel. Necessary training sessions will be conducted. As users pass the training session, the final eCRF link, the username and the password to access to the CRF in production are provided to them.

#### 2.1.7. Data Entry of Patient Diaries/Questionnaires (if applicable)

Quality of Life and patient experience questionnaires will be completed in the eCRF by the Principal Investigator.

#### 2.1.8. Data Validation

After entry, data will undergo systematic validation procedures. This review will include checks to ensure key clinical data are accurate, reliable and consistent. Edit check specifications will be

carefully designed to ensure checks are in place for critical data fields such as efficacy and safety variables.
The aim of data validation is to check the completeness, consistency and plausibility of the study data. The Data Validation Plan (DVP) will include automatic checks for:

- Missing values: If checks are not applied to all data fields, at least, they should be used for critical variables such as subject identification, primary safety and efficacy variables.
- Range checks: these checks are intended to identify values that may be the result of an entry error or that may be indicative of a value outside of those expected for the subject population.
- Duplicates: these checks are intended to negate the potential for the same data to be entered into the database more than once.
- Logical inconsistencies across a single CRF: e.g. a CRF indicating that the subject is pregnant, but also indicating that the subject is male.
- Inconsistencies across CRF pages or modules: edit checks can also be programmed to identify discrepant data across CRF pages or modules.
- External data: programmed edit checks may also be applied to external data.
- Protocol violations: these checks are designed to identify specific data that may be indicative of protocol violations, as date ranges or inclusion / exclusion criteria.

All edit checks will be performed electronically unless otherwise specified. The Data Manager will evaluate if edit checks are manual or electronic; sometimes the edit checks can be more feasible or efficient with a manual review (e.g. visual review of data for adverse events, medical history, physical examination, comments for spelling, etc.)

Data will be reviewed on a regular basis to identify trends in CRF completion. Any trend found will be documented and communicated to the project team in an effort to increase the cleanliness of future data received.The purpose of the cleaning process is to obtain all the forms completed, with no queries (or the minimum ones).

Mandatory fields: Periodically the Data Manager will review the mandatory fields and will contact the CRA/Investigator to remind them to complete the missing information.

When automatic edit checks specified in the Validation Plan are fired, Investigators have two options: to change the data or to keep the data as they are and provide an explanation. If the data are changed and the discrepancy is solved, the query is closed automatically by the system. In case the Investigator keeps the data, the answer must be reviewed by the Data Manager, who will decide if the query must be closed or resent to the Investigator.

Periodically, as established in the Data Management Plan and depending on recruitment percentage, the manual listings specified in the Validation Plan are executed and reviewed. The discrepancies found are entered in the system as manual queries so the Investigator can answer them. The responses of these queries follow the same procedure as with the automatic queries.

### 2.1.9. Data Coding

The data points to be coded and dictionaries to be used are listed as follows:

| CRF Title: | Field Name: | Own Dictionary based on |
|---|---|---|
| Past Medical History and Current Medical Conditions | Condition | MedDRA |
| Adverse Events | AE term | MedDRA |
| Concomitant Medication | Medication name | ATC |

Coding will be performed at the end of the data collection stage or on a periodical basis as data are verified, at the Data Manager's discretion. Every unique medication name is coded by the Data Manager. The coding list will be sent to the Chief Investigator for review and approval.
If, during the course of the trial, new versions of the dictionaries are released, the Chief Investigator will be notified and actions to be implemented will be discussed.

### 2.1.10. External Data Handling (if applicable)

Not applicable

### 2.1.11. Serious Adverse Event (SAE) Reconciliation

The standard for SAE reconciliation will be to reconcile CRF data with the SAE database listings. A scheduled communication timeline between the Data Manager and the Pharmacovigilance node will be established depending on the number of serious adverse events occurred, in order to perform the SAE reconciliation along the study, as it is important to verify the follow up of these events and always before the database closure.

The Pharmacovigilance node will send, in the accorded scheduled time, a report of the SAE included in their SAE database to the Data Manager, in order to carry out their reconciliation.
Data Management will verify the following variables to either an exact match (data should be exactly the same) or consistency of data (data should have the same meaning but may be stated in different words):

1. Project code (exact match)
2. Investigator number (exact match)

3. Subject Identifier Information (exact match)
4. Patient details (Gender, Age and Date of Birth, Race)
5. Event Start/End Dates (consistent)
6. Reported Term for the Adverse Event (consistent)
7. Study Drug Action Taken (exact match)
8. Causality to Study Medication (consistent)
9. Outcome (exact match)
10. MedDRA term (consistent)
11. Date of death, if applicable (exact match)

Discrepancies found between SAE Listing will be clarified with the safety contact, in the following way:

1. If the result of the comparison indicates that more SAEs have been entered into the clinical database than have been entered into the safety database, the DM will contact the safety database contact to obtain the missing SAE information for the safety database.
2. If the result of the comparison indicates that more SAEs have been entered into the safety database than have been entered into the clinical database, the DM issues a query to the Investigator requesting the missing SAE information.
3. If the result of the comparison indicates a difference in a specific value entered the two databases, the DM and the safety database contact determine if a data entry error has occurred:
    - If no data entry error has occurred, the DM will issue a query to the Investigator.
    - If the Investigator indicates that the clinical database contains the correct data, the DM will communicate this to the safety database contact.
    - If the Investigator indicates that the information entered in the clinical database is not correct, the DM will ask the Investigator to update that information in the clinical database.

#### 2.1.12. Data Management Quality Control (only for studies with paper CRF)

Not applicable

#### 2.1.13. Data Management Reports

The Data Manager will prepare a set of management reports that will provide information about the progress of the study.

#### 2.1.14. Data Transfers

At the beginning of the study the Data transfer specifications will be defined between the Data Manager and the expected recipients and/or senders of data. A particular Data transfer specifications document will be defined with every sender/recipient. Then a data quality control and transfer test should be developed to verify the proper performance of the transfer.

Data will be always encrypted and transferred in a password protected zip archive including a Data acknowledgement of receipt (to be signed by the recipient) and a Transfer query report (to be completed in case a discrepancy in the transfer is found).

While the study is in production, every data transfer request should be communicated to the sender in writing. The recipient will then receive a transfer with data from real patients in the selected program datasets according to the annotated CRF and should review data and confirm they have been correctly received or notify any discrepancy. The sender will correct any eventual error in the transfer process until the data are properly sent. The Data Manager will register the transferred datasets in the study directory accompanied by all the related documentation.

The data for a final statistical analysis will be transferred only once the database is locked. Data transfer will be repeated if any change in the database is needed after database locking.
Written confirmation of receipt must be obtained at each transfer from the recipient for archiving purposes (including test transfers) normally by email using the template SOP-PMBGD12/03.1 Data transfer acknowledgment of receipt.

#### 2.1.15. Database lock

When validation, SAE reconciliation and all coding activities have been completed and the database has been checked by the Biostatistics department, the database will be locked.
Study database must be soft and hard locked to ensure their integrity for the generation of results, analysis and submissions.

Database soft lock should be performed before any interim analysis or report from which trial or regulatory decisions may be made. The study soft lock will start once all eCRF forms, queries, or applicable documents to the subjects are correctly processed following the Data Management Plan and the corresponding Standard Operating Procedures, which also means that all subjects are declared clean and the correct actions have been taken. The Data Manager will complete the Data Handling Report and will distribute it for its review/revision. All study books will be locked in the eCRF. Database hard lock will be performed at study completion and when the Data Handling Report has been signed by the Sponsor. When all tasks are completed and approval signatures are obtained from all the appropriate personnel the database will be locked.

The Lock form of the database will be distributed to the Biostatistician, the Project Manager and the Chief Investigator.

#### 2.1.16. Archive Specifications and CRF submission

Once the database has been locked, the Data Manager will produce an Adobe® Portable Document Format (PDF) of the electronic Case Report Forms (eCRFs) to send to the sites and Sponsor.

The Data Manager will perform a final inventory of all data management documentation and return all study documentation and study databases within 30 days after the acceptance of the final

analysis by the Chief Investigator/Sponsor. All study documents will be returned to the Sponsor with acknowledgment of receipt once the inventory is complete.

Once the study has been closed, all the information is kept in the data management files until the return of all documentation and no copy of it will be stored, therefore whatever request related to the study will have to be done during this period. After this period the responsibility of data safekeeping corresponds exclusively to the Sponsor of the study.

## 2.2. Common Chapter on Data Management Plans (DMPs) For Projects In The Cancer Mission Cluster in Diagnosis And Treatment:

During the cluster meetings the dedicated common data management plan group discussions the common chapter text was formulated:

In this pivotal chapter, we delineate the unified approach for DMPs across all projects within the Cancer Mission Cluster on Diagnosis and Treatment. Central to our DMP is the commitment on how to standardize the management of data similarly across all projects with utmost rigor and precision, yet keeping data separate for each project. This is a foundational element that enhances the quality and accessibility of our research outcomes, thereby impacting the field of cancer diagnostics and treatment significantly without jeopardizing the privacy and patients' fundamental rights.

The DMP for each project serves as a formal working document, guiding how datasets can be harmonized and handled during the active research phase and beyond project completion. In light of the growing emphasis on DMPs in research grant proposals, our approach is proactive, ensuring compliance from the earliest stages of the research lifecycle and to ensure compliance with applicable data protection regulations. The diverse range of Research and development (R&D) activities within projects in the Diagnostics and Treatment Cluster will yield a vast array of data, including large datasets, Standard Operating Procedures (SOPs), and guidelines. These data, generated by various project partners, form the backbone of our research endeavors.

The core of the collaboration on data between projects in the Cluster on Diagnosis and Treatment this common chapter will be to establish focus on a two-pronged framework: Firstly, coordination and exchange of experience between projects while tackling the technical and scientific challenges in data collection, aggregation, and anonymization for public database releases. Secondly, fostering the exchange of best practices and common standards among cluster members, aiming to develop a "cluster best practice protocol". This framework encompasses several key areas: mapping diverse project data (encompassing tissue genomics, liquid biopsy, clinical, imaging, Quality of Life, health costs data, etc.), identifying uniformities and diversities in data standards, validation, protection, and anonymization, mapping the legal frameworks

associated with each project's data, and establishing a minimum standard for FAIR data management in compliance with applicable data protection regulation.

We advocate for a collaborative approach where cluster members, upon agreeing on aims and topics, can form subgroups to work on these areas under a common framework securing both scientific, legal, and ethical aspects of data management. The culmination of these efforts could be a comprehensive 'white paper' that not only benefits our cluster but also serves as a valuable resource for other EU Clusters. Concurrently, in line with our Data Management Plan (DMP), we will establish a working group under Working Group 1 (WG1), as outlined in our Initial Cluster Scientific Work Plan. This group's mandate includes developing comprehensive data management standards, including data standards setting, validation, protection, and exchange processes. These initiatives, both the subgroup collaborations and the focused efforts of WG1, are designed to integrate seamlessly into our broader research activities, enhancing the overall effectiveness of our data management strategies and culminating in producing a 'white paper'. This document will serve our cluster and offer valuable insights for other EU Clusters.

Finally, it is important to emphasize that our DMPs shall be considered as 'living documents'. The DMPs will evolve and be updated throughout the project's lifespan of the cluster project, ensuring their relevance as an instrument for managing and processing of data and to support effectiveness as part of reporting and dissemination of activity. This chapter represents the initial version of how to process with the development of the DMPs and by doing this , laying the groundwork for our collective efforts in advancing cancer diagnosis and treatment research.

# 3. FAIR DATA

The data generated under this project and information supporting information preservation and reuse will be deposited in CORA– Research Data Repository (RdR) (https://dataverse.csuc.cat/). CORA It's a multidisciplinary data repository that allows Catalan Hospitals and Universities to publish research datasets in FAIR mode and following the EOSC guidelines. This repository is designed to collect, disseminate, and provide persistent and reliable, long-term open access to the data. This data repository will allow and facilitate sharing information within the different members of the cluster. The CORA– Research Data Repository (RdR) assigns DOIs for persistent identification and identifiability of the dataset.

The CORA – Research Data Repository (RdR) uses to describe the dataset the Data Documentation Initiative (DDI) standard and is compliant with the Dublin Core Metadata Terms and DataCite. The CORA – Research Data Repository (RdR) provides specific metadata keywords to optimize possibilities of reuse. It's possible to specify if any controlled vocabulary is used.
These data will be preserved and made publicly accessible for at least 10 years. Because of the small scale of these experiments, there is no need for a data access committee.

The CORA – Research Data Repository (RdR) (https://dataverse.csuc.cat) assigns a CC0 licence by default, but other custom licences are allowed.

The activities outlined in the DEC (Dissemination, Exploitation, and Communication) Plan (deliverable 5.1) are designed to adhere to the European FAIR principles, which emphasise making data Findable, Accessible, Interoperable, and Reusable. These principles guide the project in ensuring that the data generated and disseminated throughout the plan are aligned with best practices in data management and sharing.

**Findable:** The DEC Plan focuses on making project data and information easily discoverable by relevant stakeholders. This is achieved through the creation of a comprehensive project website that acts as a centralised hub for disseminating project outcomes, objectives, and news.

**Accessible:** The plan ensures that project data are accessible to both internal and external stakeholders. By utilizing platforms such as Google Drive for internal data sharing, the project makes data available to authorized team members while maintaining necessary security and access controls. For external stakeholders, the project employs multiple communication channels, such as social media accounts and newsletters, to share information in a manner that is easily accessible to a diverse audience.

**Interoperable:** The DEC Plan promotes the interoperability of data. The use of widely accepted formats for dissemination materials, scientific manuscripts, and communication materials ensures that data can be easily understood and integrated into various contexts. This interoperability enhances collaboration and allows stakeholders to seamlessly integrate project findings into their own research or practices.

**Reusable:** The plan prioritises making project data reusable by both project team members and the broader scientific community. The creation of a shared repository, coupled with the commitment to open access publication, allows data and results to be reused for future research endeavours. Moreover, the development of policy recommendation guides and scientific manuscripts provides well-documented insights that can be cited, built upon, and incorporated into policy discussions and further research.

# 4. DATA SECURITY

Data collected from the research group for the Project will be digitised and stored on the CORA which is subject to regular back-up that is controlled by the Consorci de Serveis Universitaris de Catalunya (CSUC), whose tax identification is Q5856253I, having its headquarters at:

C. Gran Capità, 2 (Nexus building) 08034 Barcelona.

The IT department of the CSUC performs operations by type: mission-critical (user data, virtual machines,scientific results, etc.) and static (scientific data sets, intermediate files, etc.). Content will be checked regularly to preserve its integrity, security, and durability.

These procedures are designed, set and applied in order to fully comply with personal data as ruled by Directive 95/46/EC (General Data Protection Regulation) and other current national

legislation and institutional regulations. Research team members will have an appropriate access level according to their role in the project.

The activities outlined in the DEC Plan are designed to fully align with the General Data Protection Regulation (GDPR) and other current national legislation, as well as institutional regulations related to data protection and privacy. For instance, the project's communication channels, such as the website and social media accounts, are used to disseminate information in a way that avoids sharing patient-specific data. Patient engagement efforts, like the contact form on the website, explicitly advise against sharing patient information.
In terms of data storage and sharing, the project employs secure platforms that comply with GDPR and relevant regulations. For instance, the selection of Google Drive as the internal shared drive is based on its compliance with European data protection regulations. This ensures that any data shared or stored on this platform adheres to strict data protection and security standards.

# **5.** ETHICS

All the activities carried out under the project comply with ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights.
The tasks for the project only concern basic research activities and the project does not involve humans, animals or cells.
Due to the fact that the main domain of the project activity is related to materials science with the focus on refractory materials, the risk of having ethics issues during the project is extremely limited.

All activities outlined in the DEC Plan are meticulously designed to align with ethical principles and adhere to a comprehensive framework of relevant national, EU, and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights.

The activities within the DEC Plan are structured to prioritise privacy and data protection in accordance with European regulations such as the General Data Protection Regulation (GDPR). This ensures that any data collection, storage, and dissemination safeguard the rights and confidentiality of individuals, particularly in the context of patient data. It emphasises that patient engagement activities, like the contact form on the project website, refrain from collecting sensitive patient data and offer secure and approved means of communication through clinical sites.

The DEC Plan also places significant emphasis on transparency and accountability. It incorporates measures to provide accurate and comprehensible information to the public and stakeholders, aligning with ethical principles of integrity and accountability. Communication channels such as social media platforms and the project website are used to disseminate

information transparently, and regular updates and publications are shared to ensure the public is informed about project progress without infringing upon privacy or data protection regulations.

Moreover, the DEC Plan upholds the principle of equal treatment and accessibility. It is designed to ensure that communication and dissemination activities are accessible to all stakeholders, irrespective of demographic characteristics or affiliations. The plan specifically highlights that the project website will be designed for accessibility, adhering to web accessibility standards to accommodate diverse audiences.

# **6.** CONCLUSION

This document presents the consortium strategy for LIVERATION. It outlines the consortium's data management plan (DMP), and it provides detailed consideration to data management within the clinical trial and the data collection of other activities in the project (Patient Reported Outcome Measures, Patient Reported Experience Measure, Living Labs, chapter on the Diagnosis and treatment cluster, as data collected for intervention evaluation and monitoring, multi stakeholder group, cost data, and systematic review). This deliverable is a living document as is intended to evolve over the course of the project. Initial preparation began at month 3 but it will be updated during the project, with the final version at month 60.