D9.1 – EXPLOITATION PLAN

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Project acronym: *ARTEMIs*
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Disclaimer

The opinions stated in this report reflect the opinion of the authors and not the opinion of the European Commission.

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Table of Contents

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Table of Figures

Table of Tables

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INTRODUCTION

The global objective of ARTEMIs Project is the development and the Proof of Concept evaluation of a clinical decision support system (CDSS) for application in the clinical management of metabolic dysfunction-associated steatotic liver disease (MASLD is the new nomenclature, previously MAFLD). The CDSS is aimed to provide clinically meaningful information to clinicians, for a more personalised management of MASLD patients.

The aim of this deliverable is to define the plan for the development of the exploitation strategy for the ARTEMIs CDSS. This deliverable will define the roadmap to be followed by tasks 9.1 - *IPR management* and 9.2 - *Exploitation planning for novel tools and methodologies* as part of WP9 - *Exploitation and Sustainability*, with the goal of promoting and accelerating the commercial uptake of the ARTEMIs project results.

This plan will define an exploitation strategy coherent with Horizon Europe beneficiaries' obligation to make their best efforts to exploit the project results.[1]

1. PLAN FOR THE DEVELOPMENT OF THE EXPLOITATION STRATEGY

The exploitation plan will be implemented during the course of the project to assist partners in implementing a strategy for exploiting the new results generated by the ARTEMIs project. The exploitation strategy will ensure that project results are exploited to their maximum potential through pertinent business models and the engagement of the relevant stakeholders. The exploitation strategy will be supervised and coordinated by Matical Innovation. A strong exploitation positioning of the project will be promoted by monitoring all generated Intellectual Property (IP) and collaborating with the owner beneficiary to guarantee appropriate knowledge protection.

1.1. Holistic vision of the project results´ exploitation

The concept of “exploitation” covers all the different routes that may be useful to ensure a societal impact on the achieved results. This includes both commercial and non-commercial exploitation, as summarised in Table 1.

[1] “*Beneficiaries which have received funding under the grant must — up to four years after the end of the action (see Data Sheet, Point 1) — use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing*” in the Annex 5 of the Grant Agreement.

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Table 1 - Types of exploitation routes

Non-commercial routes	Commercial routes
Scientific reuse: new research by the scientific community **Training and education:** new programmes for professionals and/or students **Standards:** contribution to international standardisation efforts **Policy-making:** for regulators to implement evidence-based changes in policies	**Sales of new products and/or services:** bringing new technologies, methodologies, or solutions to market to address specific needs or opportunities **IP licensing:** selling to third parties the access right to results for commercial uses **Start-ups or spin offs:** establishing new companies to commercialise the results as products and/or services **Joint ventures:** entering into a collaboration partnership for joint commercialisation

A holistic vision of exploitation of the results, considering the different routes relevant for a given result and feasible and of interest to the results´ owner(s), will guide the works undertaken in this project.

1.2. Key actors for the project results´ exploitation

The plan of the exploitation strategy implies the need to consider different key actors as parties involved in the exploitation processes in different ways.

Project partners

The ARTEMIs consortium entitles 21 entities comprising 3 enterprises, 1 association, and 17 research institutions (universities, health research institutes and university hospitals). Modellers with over 10 years of working together in advancing the development of liver virtual twins (VTs) will work together with major university hospitals and medical research institutes selected for their expertise in MASLD management, their past implications in research projects, their ability to provide data and evaluate the virtual twins and CDSS in their own clinical practice. Some clinical entities bring relevant experience in AI-model development and evaluation, mainly in medical imaging. Their main role and most relevant areas of expertise are summarised in Table 2.

Table 2 - ARTEMIs project partners

Partner	Description	Clinical research	Model developer	Other
1-MAT	Matical Innovation is the Coordinator, experts in results´ sustainability and exploitation			✓ (exploitation)
2-ICAN	ICAN foundation is a world class research institution in metabolic disorders	✓		
3-AP-HP	Greater Paris University Hospitals	✓		
4-JUH	Jena University Hospital	✓		
5-VHIR	Research institute of the Vall d´Hebron hospital	✓		
6-UKHD	Heidelberg University Hospital	✓		

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Partner	Description	Clinical research	Model developer	Other
7-CUSL	Cliniques universitaires Saint-Luc, the largest hospital of Brussels	✓		
8-SHEBA	Sheba medical centre	✓		
9-HULAFE	Research institute of La Fe university hospital in Valencia	✓	✓ AI	
10-CHARITÉ	Charité university hospital of Berlin	✓	✓ AI	
11-ULS	University Hospital of La Sapienza in Rome	✓	✓ AI	
12-MUV	Medical University of Vienna	✓	✓ AI	
13-INRIA	National Institute for Research in Digital Science and Technology in Paris		✓ (liver & heart VT)	
14-DKFZ	German Cancer Research Center		✓ (liver VT)	
15-ALU-FR	University of Freiburg		✓ (liver VT)	
16-ULEI	University of Leipzig		✓ (liver VT/AI)	
17-MEDEX	BC Platforms (previously Medexprim) a high-tech SME specialised on RWD valorisation for research			✓ (legal, data platform)
18-ELPA	The European Liver Patients´ Association			✓ (patient engagement)
19-BETT	Betthera, a SME specialised in regulatory affairs and health economics			✓ (regulatory & HTA)
20-BU	Bournemouth University		✓ (AI)	✓ (data platform)
21-IMPERIAL	Imperial College London	✓	✓ (AIs)	

All project partners except Sheba and ELPA participate in WP9 as contributors to the IPR management and exploitation planning works. The partners who own or co-own results will actively contribute to describing the key results and identifying the most suitable exploitation routes.

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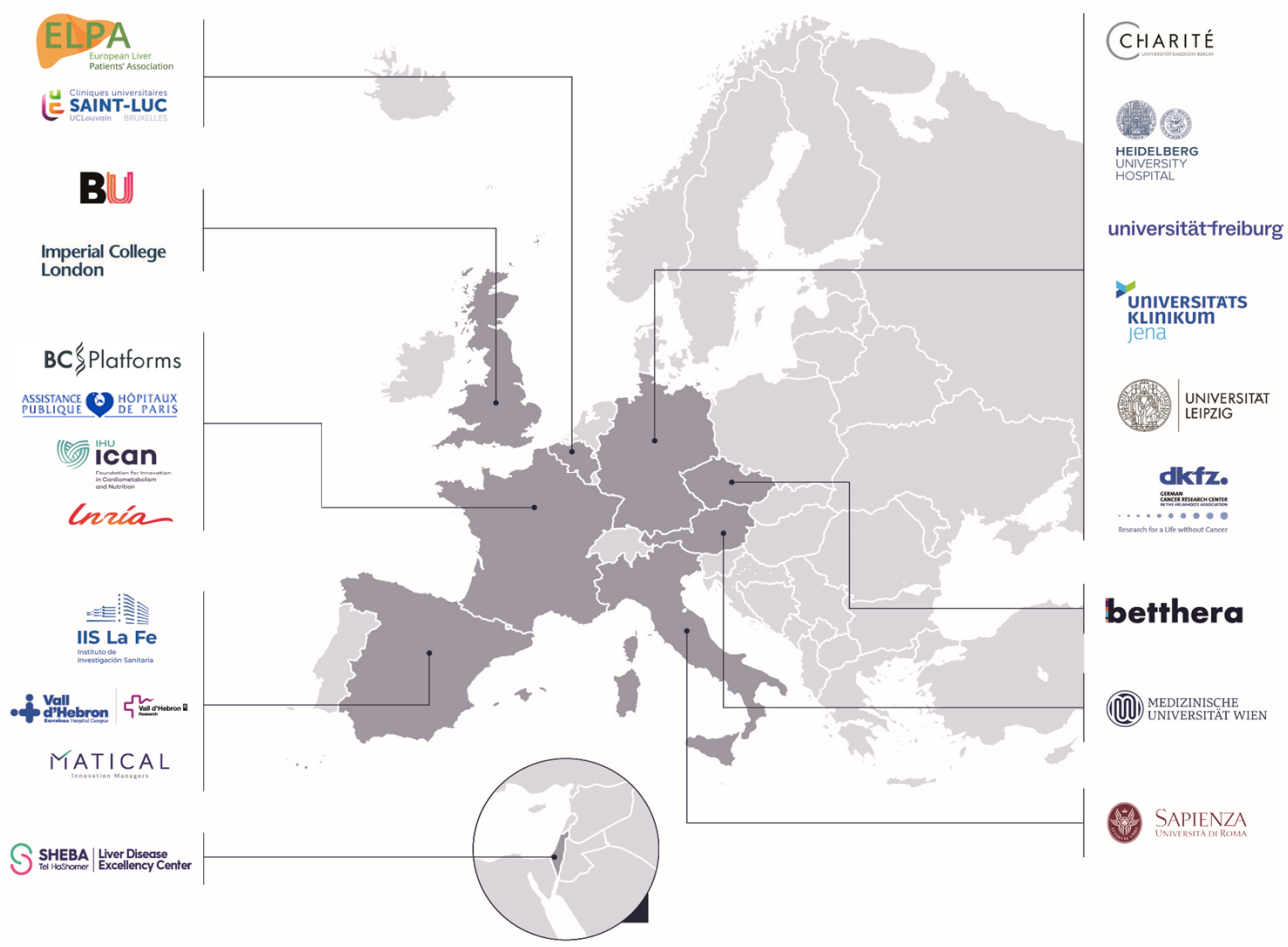

Figure 1 - ARTEMIs partners

External stakeholders

Table 3 - ARTEMIs main stakeholders

Stakeholder	Description	Represented by
MASLD research community	ARTEMIS project brings together specialist in MASLD from 13 clinical and medical research centres in 8 nations, including Key Opinion Leaders, participant in flagship European projects such as LITMUS and LiverScreen, and international consensus initiatives such as Delphi and Baveno. They have an extensive network of collaborator researchers across European hospitals and health research institutes.	ICAN, APHP, JUH, VHIR, UKHD, CUSL, CHA, ULS, MUV, HULAFE, SHEBA, IMPERIAL
VT research community	ARTEMIs partners have developed a set of **heart** and of **liver computational models** (under the Virtual Liver network, LiSyM and LiSyM-Cancer projects). Some partners are participants in EDITH project and members of the Virtual Physiological Human Institute. ARTEMIs will align with EDITH, supporting the development of ecosystems for Digital Twins in healthcare in Europe. ARTEMIs will follow EDITH interoperability guidance and the integrated liver model will be federated in the repository.	INRIA, DKFZ, ALU-FR, ULEI

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Stakeholder	Description	Represented by
Patients	MASLD is presently the most common chronic liver disease worldwide, accounting for a global prevalence of 25%[2]. The involvement of patients is nowadays crucial in any healthcare development, to support a patient-centric vision.	ELPA
MedTech industry	The involvement of the MedTech industry is pivotal in translating research results into technological solutions that can effectively penetrate the market and positively impact the targeted end-user community. Within ARTEMIS, this MedTech sector is represented by a SME, and the engagement from additional players will be sought, such as larger enterprises with resources for scaling up production, distribution networks, and marketing capabilities.	MEDEX (BC Platforms)
Pharma / Biotech industry	The pharma and biotech have a strong interest in addressing MASLD, considering its global prevalence. These industries are key stakeholders as potential buyers of the ARTEMIS CDSS, as it can assist in optimizing clinical trial designs, identifying patient populations most likely to benefit from novel therapies, and enhancing post-market surveillance efforts.	None
Healthcare services	An appropriate management of the MASLD population, with an appropriate risk stratification which enables timely interventions is a major concern for the European public health authorities. Their role is as potential buyers of the system.	APHP, JUH, CUSL, CHA, MUV, SHEBA
Regulatory bodies	The European regulatory approval procedure for ARTEMIs CDSS will need to contemplate the new medical devices regulation for software applications, and the regulation for high-risk AI systems, such as those for healthcare (AI Act proposal). The regulatory bodies will play a crucial role in the post-project time to market phase.	BETT
Private investors / Funding bodies	To reach market maturity, additional funding will be needed. The engagement with potential private investors and public funding bodies is essential, to identify accessible opportunities.	EC

[2] Yuan Q. et al , International Journal of Environmental Research and Public Health (2022). DOI:10.3390/ijerph19042096

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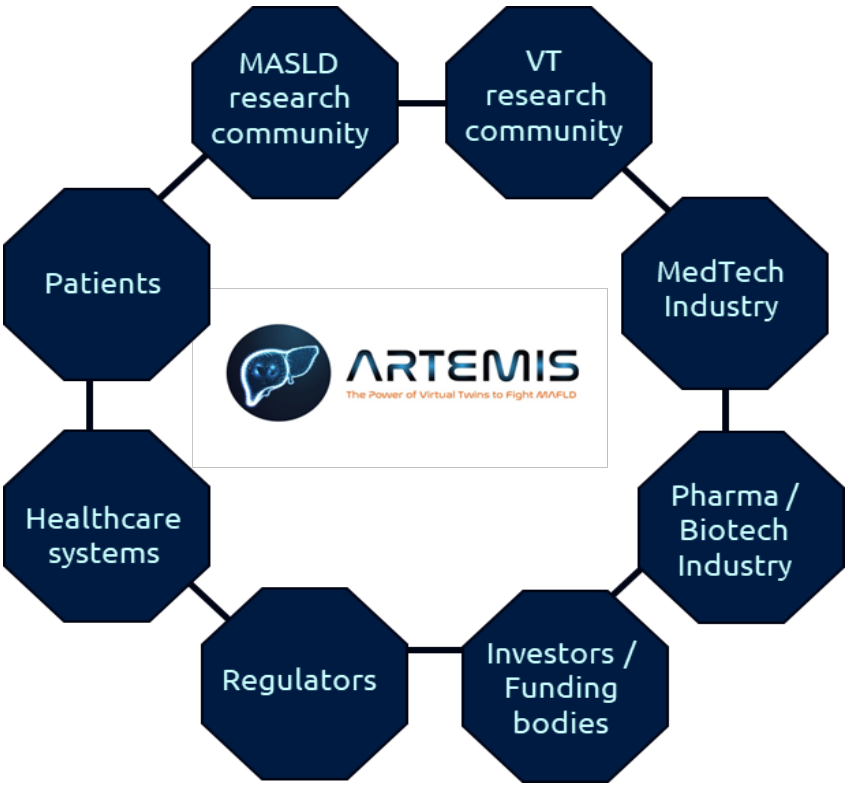

Figure 2 - ARTEMIs stakeholders

Support services of the European Commission

This project will make use of the following free-of-charge services offered by the European Commission:

European IPR helpdesk[3]: This support service on IPR-related issues for EU-funded research projects is relevant, mostly in relation to their online training sessions. Their seminars on areas such as AI-based innovations are of particular interest[4].

Horizon results platform[5]: This is a web platform specific for showcasing the results achieved by European R&D projects, facilitating the identification of possible collaborators with subsequent stages in the time-to-market phase, as well as collaborators for non-commercial exploitation routes, such as further research and educational activities. ARTEMIs plans using the Horizon results platform in project year 3 once a complete description for all the Key Exploitable Results has been documented and each owner(s) has identified their preferential exploitation routes.

Innovation Radar: The innovation radar platform features high-potential innovations developed under European projects and helps them to be in the spotlight for investors and policymakers. ARTEMIs would be proud to be featured in the Innovation radar, to increase the outreach of our innovations. At the 2nd reporting period, we will ask the Project Officer to include the Innovation Radar in the review meeting, in order to become eligible.

Horizon results booster[6]: The team at Matical Innovation responsible for coordinating the ARTEMIs exploitation strategy, have benefited from these services (Service Module C - Assisting

[3] https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk_en
[4] https://intellectual-property-helpdesk.ec.europa.eu/news-events/upcoming-events/eu-webinar-ip-and-artificial-intelligence-advanced-2024-04-23_en
[5] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/horizon-results-platform
[6] https://www.horizonresultsbooster.eu/

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projects to improve their existing exploitation strategy), in the framework of previous projects, with valuable access to these methodologies.

Other support services

Each participant may also seek additional support at their local, regional or national level. Depending on the type of exploitation route they select, different public or not-for-profit entities may offer free-of-charge services in their geographic area. For instance, if establishing a start-up is contemplated, entities such as the European Business and Innovation Centre have regional nodes to support different types of services.

1.3. Methodology

The exploitation strategy development plan is divided into two main blocks: IP Management and Results Exploitation. The main steps and methodologies to support each of these are described below.

Block 1: IP management

The IP Management will follow a professional and procedural approach to ensure that the new knowledge generated in the ARTEMIs project is efficiently protected to promote its use beyond this project. The following subphases are included:

- **Agreement on the IP strategy**: The IP strategy is defined and agreed upon in the GA and CA documents, which are finalised at the time of submission of this deliverable. The conditions of ownership of the results and access to the results for implementation and exploitation activities, as well as the relevant pre-existing knowledge (Background) by each partner, have been documented.
- **KERs identification and assessment**: A methodology for identifying and assessing any tangible or intangible results from the ARTEMIs project is defined (see section 2).
- **IPR Protection**: Support for the KER owner in selecting and implementing the optimal IPR protection means (as a function of the innovation's nature, targeted exploitation route, and business model). These actions are accompanied by IPR surveillance to map existing patents and innovations and address any possible conflicts.

Figure 3 – Main steps of the IP Management methodology

Block 2: Results exploitation

For the global result of the Project, the ARTEMIS CDSS, a complete exploitation strategy will be documented. The following key steps are needed:

- **Stakeholder mapping and value proposition**: The map of the relevant stakeholders will be documented early in the project based on the expected features of the ARTEMIS CDSS

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(see section 3). A questionnaire will be prepared to learn the key aspects of the ARTEMIs CDSS for each stakeholder group. An interview with at least two representatives of each group is planned, they may be internal or external to the consortium. The conclusions from this exercise will be documented in the deliverable D9.2 - ARTEMIs value proposition for the different target groups *learnt from interviews and questionnaires*, due in Month 12.

- **Market analysis**: This assessment includes not only the documentation of the market size and trends for the global and European CDSS market but also the identification of the top global players (main competitors) in CDSS and a specific analysis of emerging innovations, patents, R&D projects in the specific segment of CDSS for hepatic diseases. The assessment of the CDSS market and key players will use standard search engines and publicly accessible sections of market research studies. On the contrary, the analysis targeted to CDSS innovations in the area of hepatic diseases will require the use of specialised sources such as Espacenet Worldwide and Google Patents (patent search), CORDIS (European projects), Innovation radar (emerging innovations and start-ups) and aggregated engines such as Linknovate Premium Version which searches in both academic (scientific publications, conference proceedings, grants) and industrial (patents, trademarks, news and web monitoring) sources. Finally, the gathered information will be used to generate a SWOT analysis[7], showing the main conclusions of considering internal and external aspects of the ARTEMIs CDSS in the market context.

- **Business model**: The definition of the business model will follow a collaborative approach based on the use of the Business Model Canvas (BMC)[8]. This is planned in a target session at the Consortium Meeting of year 2. The BMC will define the basis of the model, which will be further elaborated by the Leader of WP9. The results of this exercise will be documented in the deliverable *D9.3 - Preliminary KER exploitation and data sustainability strategy*, due in Month 24.

- **Complete exploitation strategy**: The analysis undertaken in the previous steps will need to be revised as the scientific and technological (S/T) WPs advance in the development, prototyping and evaluation of the CDSS to include any adjustment needed given the actual features of the developed system. An iterative process will be followed to reach a final and complete exploitation strategy for the ARTEMIs CDSS, including a preliminary estimation of the costs required to reach market maturity and potential public and private financing mechanisms. The complete strategy will be documented in the deliverable *D9.4 - Final strategy for KER exploitation, including a preliminary business plan, and for data sustainability* due in Month 48, revised and approved by the Executive Board.

Figure 4 – Main steps of the Exploitation Strategy development

[7] https://en.wikipedia.org/wiki/SWOT_analysis
[8] https://en.wikipedia.org/wiki/Business_Model_Canvas

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Collaborative participation

Matical Innovation is the Leader of WP9 and responsible for all the deliverables. The inputs from the rest of partners are important, different types of interactions are planned to gather the inputs required from them in the most effective manner, in order to get the most out of the PM effort allocation to WP9, shown in Table 4.

Table 4 - Partners´ PM allocation to WP9

Partner	1-MAT	2-ICAN	3-AP-HP	4-JUH	5-VHIR	6-UKHD	7-CUSL	8-SHEBA	9-HULAFE	10-CHARITÉ	11-ULS
PMs in WP9	26	0.5	0.2	0.2	0.2	0.2	0.2	0	0.5	0.2	0.2

Partner	12-MUV	13-INRIA	14-DKFZ	15-ALU-FR	16-ULEI	17-MEDEX	18-ELPA	19-BETT	20-BU	21-IMPERIA	TOTAL
PMs in WP9	0.2	0.5	0.5	0.5	0.5	2	0	0.5	0.5	0.5	34.1

The following types of interactions are planned:

- **Forms**: Forms (e.g. the result identification form) will be requested via email; the possibility of a remote meeting to guide them through the form, if needed, will be offered in all cases. The filled forms will be stored in the Project's internal archive. Periodic revisions and updates may be requested.
- **Questionnaires:** The Matical team will either email or use the questionnaires as a guide for remote interviews with a selection of representatives of different stakeholders, internal and/or external to the Project. The questionnaire results will be stored in the Project's internal archive. An example of a questionnaire is the one planned to determine the ARTEMIs CDDS´ unique value proposition for different targets.
- **WP meetings:** The WPL will call meetings when joint discussions are needed. One-to-one meetings to address issues related to specific results will be prioritised. WP meetings may be called to present conclusions from analysis prior to the submission of deliverables and period reports.

2. KEY EXPLOITABLE RESULTS (KERs)

2.1 Monitoring of the KERs

The Key Exploitable Results (KERs) of the Project are the results with the highest potential to be further used by the consortium members and by other stakeholders such as the scientific community, industry, regulators, healthcare services and patients.

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The expected KERs from ARTEMIs project are identified (see Table 5). The WPs related to each KER show the needed interrelations between WP9 and the technical WPs.

Table 5 - Expected KERs

KER description	Owner(s)	WPs
KER1: Processing pipelines for omics and digital imaging data, for the extraction of quantitative metrics as inputs to the multiscale models (joint result or set of individual results)	HULAFE, IMPERIAL, VHIR, DKFZ, ULEI	**WP3**
KER2: Multi-modal clustering of patients and pattern identification	BU	**WP4**
KER3: Multiorgan Multiscale Multilevel model of liver-heart axis for MAFLD -Virtual Twin models (joint result or set of individual results)	INRIA, DKFZ, ALU-FR, ULEI, MUV	**WP5-6**
KER4: MAFLD patient multimodal data visualisation module of ARTEMIs CDSS	MEDEX	**WP7**
KER5: ARTEMIs CDSS	MEDEX, BU, INRIA, DKFZ, ALU-FR, ULEI, MUV	**WP7-8**
KER6: Federated data exploitation infrastructure with variables processed to the common data model	MEDEX, APHP, JUH, VHIR, UKHD, CUSL, HULAFE, CHA, ULS, MUV, SHEBA, BU	**WP2**
KER7: Set of methodologies for assessment of trustworthiness (accuracy, robustness, reproducibility, explainability) in the models´ performance.	INRIA, ALU-FR, ULEI, MUV, BU	**WP8**

The level of achievement of the KERs will be monitored during the project through the participation of the leaders of Exploitation Strategy in the periodic Scientific and Technical meetings, where advancement is reported per WP. The monitoring also incorporates other relevant results that might not have been foreseen.

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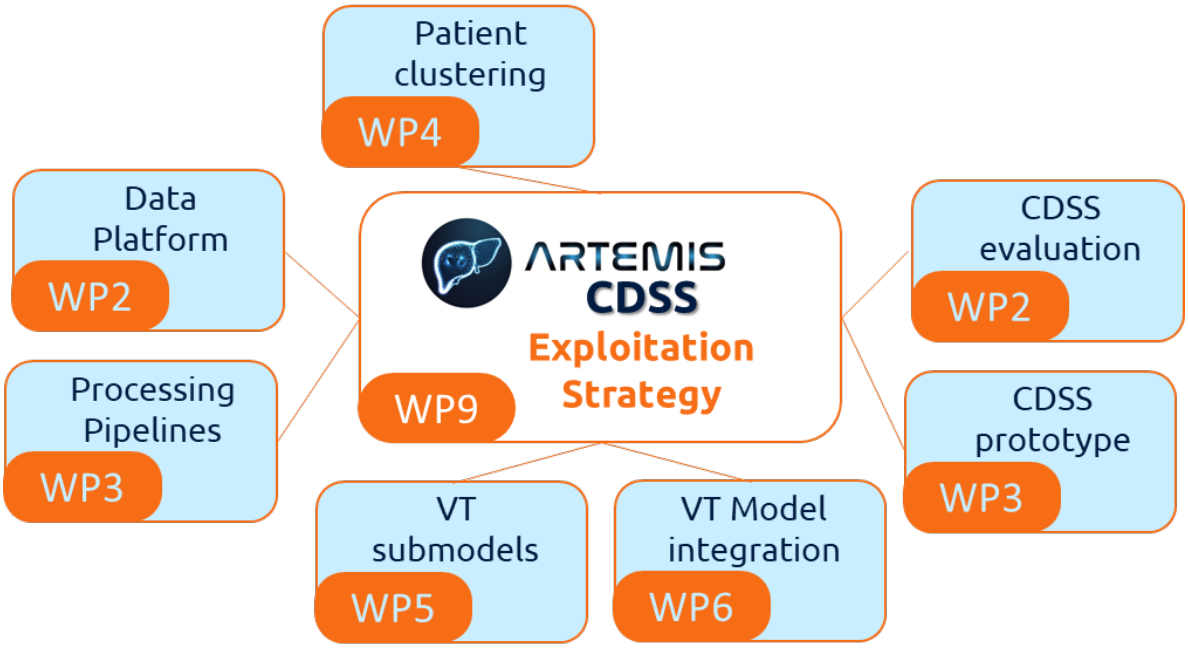

Figure 5 – WP9 relationship with the S/T WPs

2.2 IPR protection strategy

The KER owner(s) are responsible for determining their preferred protection means. Different types of means of protection for the IPR are described as follows:

- **Copyright.** Copyright does not need to be registered. It automatically exists when a work is created. It protects any original, creative expression, such as software source code.
- **Secret know-how.** Secret know-how consists of confidential information that provides an entity with a competitive edge. Contrary to other IP figures, secret know-how is protected without any procedural formalities; consequently, they can be protected for unlimited time. Secret know-how must have been subjected to reasonable steps by the rightful holder of the information to keep it secret (i.e., non-disclosure agreements with employees and business partners and measures to prevent industrial espionage). In this context, non-disclosure agreements (NDAs) allow the holder of confidential information to share it with a third party. The third party is then obligated to keep the information confidential and not use it unless allowed by the owner of the information.
- **Patents.** Patents are granted for technical inventions. Applications for patents are examined by the patent office they are filed with in order to determine whether they meet the stringent requirements for a patent to be granted. Patents generally last for a maximum of 20 years from the filing date.
- **Utility models.** Offer simpler protection for a shorter period of time but are usually registered and published much more quickly than patents. The idea of harmonising laws on utility models across EU countries was abandoned as no agreement could be reached.

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- **Software license.** Software licenses play a crucial role in safeguarding the IPR of software creators by governing the terms of use, distribution, and modification of their works. There are different types of software licenses, offering different levels of protection and flexibility of use. Some of the existing options are:
  - Licenses for Open-Source distribution: some of the most popular correspond to Creative Commons Licenses (developers can choose the level of openness they desire from a range of possible permissions and restrictions) and GNU General Public License (GPL is a widely used open-source license that ensures that software derived from the original source code remains open-source as well).
  - Proprietary Commercial License: The traditional Closed-Source license where the users are granted specific rights based on the terms of the license agreement. These terms can be:
    - Per-User License: This type of license grants the right to use the software to a specified number of users. It is often used for enterprise-level software.
    - Subscription License: Users pay a recurring fee to use the software for a specified period. This can include updates and support during the subscription period.
    - Freemium License: The software is free with limited features or usage, and users can upgrade to a paid version with additional features or capabilities.
- **Sui Generis protection rights for Databases.** The ARTEMIs Cohort should be considered a Database containing the de-identified Data under the DIRECTIVE 96/9/EC of The European Parliament and of The Council of 11 March 1996 on the legal protection of databases. Sui Generis Database Rights means rights other than copyright resulting from this Directive. The Database protection may use Copyright and/or Sui generis rights. The Data Transfer /Sharing Agreements to be implemented in this Project will determine the Consortium´s right to use, sublicense, or modify the information relating to the Database containing the de-identified datasets.

The leader of WP9 will support them by providing information, if needed, on potential means of protection, depending on the nature of the results and the intended exploitation route. The adequate protection of results is of exclusive competence and responsibility of each partner. All partners are aware of the need to coordinate any dissemination action with the protection strategy, in order to prevent any potential conflict that compromises the novelty of the results as well as inventive steps in an eventual patent filing process.

2.3 Detailed description by KER owner(s)

To facilitate monitoring the results with potential for exploitation beyond this project, WP9 participants will be requested to complete a form specifically designed for this purpose (see Figure 6). This form is designed to gather the essential information needed by the Leader of WP9 to identify the most important outcomes, including a brief description of the result, its main application fields and its positioning compared to existing solutions for similar uses (if any). We also note if the project is owned by a sole partner or it corresponds to a joint ownership, and the

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preliminary intentions to protect their IPR. Finally, the developers are asked about their preferred routes to use the result, which may depend on their institution's interests and capabilities.

The ARTEMIS Results Identification Form will be requested first by the project partners in Month 18. This timing is planned to enable enough time for scientific and technological developments and, thus, a more realistic vision of the achievable results and their expected features while being early enough in the project to mobilise their institutional, legal teams for the protection of the relevant IPR.

The responses to the ARTEMIS Results Identification Form will be analysed and gathered as part of *D9.3 - Preliminary KER exploitation and data sustainability strategy*, due in December 2025 (Month 24).

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RESULTS IDENTIFICATION FORM

Participant entity:
Contact person:

1. Key Exploitable Result (KER) table

KER description	Owner(s)	WPs
KER1: Processing pipelines for omics and digital imaging data, for the extraction of quantitative metrics as inputs to the multiscale models (joint result or set of individual results)	HULAFE, IMPERIAL, VHIR, DKFZ, ULEI	WP3
KER2: Multi-modal clustering of patients and pattern identification	BU	WP4
KER3: Multiorgan Multiscale Multilevel model of liver-heart axis for MAFLD -Virtual Twin models (joint result or set of individual results)	INRIA, DKFZ, ALU-FR, ULEI, MUV	WP5-6
KER4: MAFLD patient multimodal data visualisation module of ARTEMIs CDSS	MEDEX	WP7
KER5: ARTEMIs CDSS	MEDEX, BU, INRIA, DKFZ, ALU-FR, ULEI, MUV	WP7-8
KER6: Federated data exploitation infrastructure with variables processed to the common data model	MEDEX, APHP, JUH, VHIR, UKHD, CUSL, HULAFE, CHA, ULS, MUV, SHEBA, BU	WP2
KER7: Set of methodologies for assessment of trustworthiness (accuracy, robustness, reproducibility, explainability) in the models´ performance.	INRIA, ALU-FR, ULEI, MUV, BU	WP8

The above table is a preliminary version. It is upon continuous revision with partners´ inputs to this Form.

2. Description of the expected results

Please provide a short description of expected Results for which you are main developer.

Short description of your expected Results (may or not be listed in the preliminary table above)

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Result 1: *Result n:*

3. Application fields

Please provide a brief description of other application fields which are of potential relevance to your above-mentioned Results:

Result 1: • *Application field 1:* • *Application field n:* *Result n:* • *Application field 1:* • *Application field n:*

4. Differentiation against State of the Art (SOA)

Please list the main advantageous features of the above-mentioned Results, compared to existing SoA or solutions/tools that are already on the market (if any).

Main features of the above-described results: *Result 1:* • *Feature 1:* • *Feature n:* *Result n:* • *Feature 1:* • *Feature n:*

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5. Closest existing solutions to ARTEMIs results

Please, list the solutions closest to your expected Results in ARTEMIs results. If any is so similar that might potentially compromise the novelty of the Result, please provide some details (solution name, company name, links…)

Description:
Solution/ tool 1:
Solution/ tool n:

6. Ownership:

Please indicate if you are working on your own or under co-development with other partners, in the same task leading to the above-mentioned Results:

☐ *On my own*

☐ *Collaboratively with Partners indicate*

7. IPR protection mechanims:

Please indicate the mean(s) of protection that you are considering, in principle:

☐ *Secret know-how*

☐ *Patent*

☐ *Utility Model*

☐ *Open-source software license*

☐ *Other type of software license*

Please indicate if you may have any institutional support in the process of protecting the generated IPR:

☐ *Yes*

☐ *No*

Please indicate if you foresee a need for support from the WP9 team:

Comment:

3

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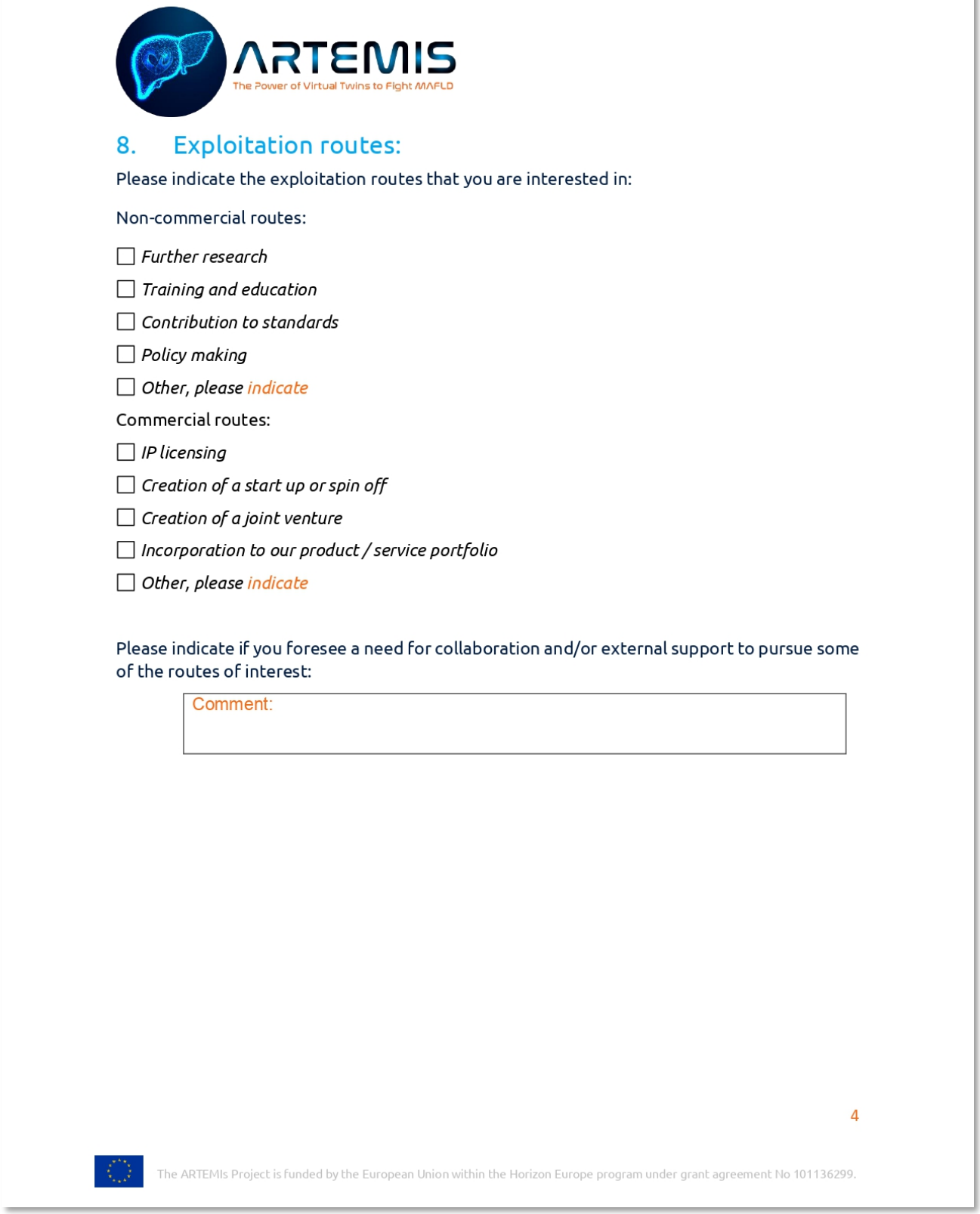

ARTEMIS
The Power of Virtual Twins to Fight MAFLD

8. Exploitation routes:

Please indicate the exploitation routes that you are interested in:

Non-commercial routes:

- ☐ *Further research*
- ☐ *Training and education*
- ☐ *Contribution to standards*
- ☐ *Policy making*
- ☐ *Other, please indicate*

Commercial routes:

- ☐ *IP licensing*
- ☐ *Creation of a start up or spin off*
- ☐ *Creation of a joint venture*
- ☐ *Incorporation to our product / service portfolio*
- ☐ *Other, please indicate*

Please indicate if you foresee a need for collaboration and/or external support to pursue some of the routes of interest:

Comment:

4

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Figure 6 - ARTEMIs results identification form

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3. ARTEMIs CDSS

The main joint result expected from the ARTEMIs project is the CDSS. Implementing the project according to the work plan will deliver a CDSS prototype evaluated in the clinical context by a multi-country and multidisciplinary team of clinical experts.

On this assumption, the exploitation strategy is focused on this main result, which is integrative of other results for this specific application context, as shown in Figure 7. Any deviations in the execution of the work plan will be informed to the WPLs. If deviations implied a need to adjust the plan for developing the Exploitation Strategy, a revision of the D9.1 report would be undertaken.

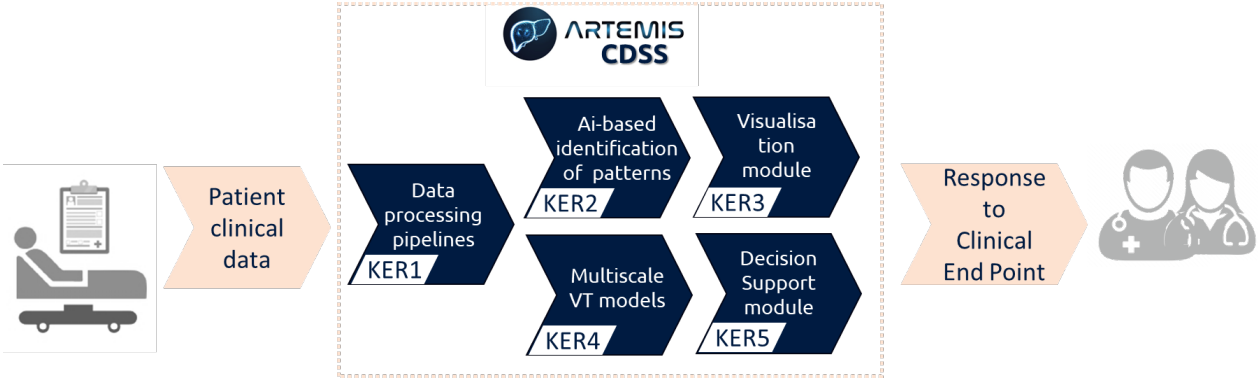

Figure 7 - ARTEMIs CDSS as the main joint result of the project

3.1 Expected features

ARTEMIS CDSS will be designed to provide an instant overview of the patient's multimodal data and exploit integrated virtual twin models to assist in predicting the evolution of the disease and cardiovascular outcomes, the response to a specific treatment, intervention or simply better life habits. This will be achieved through the integration and orchestration of multiscale (from molecular to full organ), multilevel (signal transduction, metabolism, tissue mechanics, blood flow and transport) and multiorgan (liver and cardiovascular system) virtual twin models. All in all, the system will contribute to the personalised management of these patients.

The modular CDSS prototype, illustrated in Figure 8, will consist of a **visualisation module** to display relevant information and a decision support module, where the user can call use-case-specific 'virtual twin' models, depending on the stage of the disease and the questions to be addressed.

The CDSS will be designed for multidisciplinary clinical panels, including hepatologists, radiologists, pathologists, cardiologists, oncologists, and surgeons. The system will deliver clinically meaningful outcomes in routine practice, providing robust results, with mechanisms explained and with confidences, biases and hypotheses transparently disclosed.

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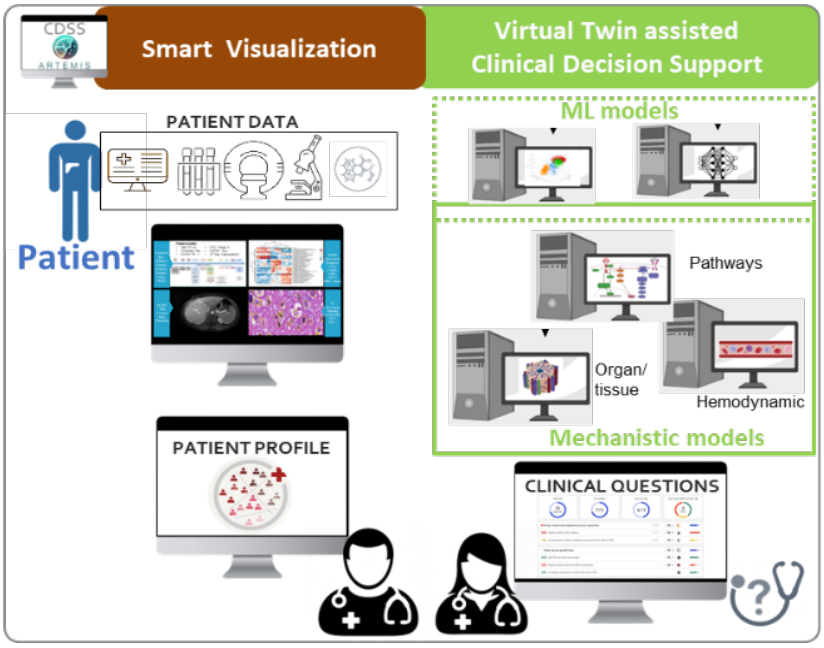

Figure 8 - ARTEMIs modular CDSS

The CDSS is aimed at assisting the clinical management of liver patients in the context of different use cases:

- Clinical use case 1: Liver disease staging in MASLD patients - Prediction model of disease fibrosis changes (progression and regression), with the ability to distinguish between fast and non-fast fibrosis progression among MASLD patients.
- Clinical use case 2: MASLD and progression of cardiovascular diseases.
- Clinical use case 3: Prediction of clinical outcomes in patients with cirrhosis and portal hypertension who receive TIPS placement or liver transplantation.
- Clinical use case 4: Management of Hepatocarcinoma (HCC) patients.

3.2 Critical aspect of its exploitation

The uses of the CDSS that have been preliminarily identified include:

- help identify populations at higher risk (e.g. fast fibrosis progression, cardiovascular complications, HF development after TIPS intervention, to name some of the ones targeted in the ARTEMIs use cases).
- assist decisions on targeted interventions, considering the patient´s signatures extracted from multi-dimensional molecular and imaging data, to enable the implementation of a fully personalised medicine.
- contribute to the training of the clinicians,
- facilitate communication with patients and enhance patients' uptake on their condition.

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The exploitation elaboration strategy will deepen the analysis of the CDSS's unique value proposition for clinical practitioners and other stakeholders.

The exploitation strategy will also address key aspects of the system adoption in the healthcare market, including:

- **Regulatory aspects:** Address regulatory requirements at the national and European levels to ensure compliance and approval of the CDSS for use in clinical settings.
- **Cybersecurity and patient privacy protection aspects**: Evidence the implementation of measures to safeguard patients' confidential medical information through compliance with quality certifications.
- **Trust and accountability aspects**: Establish mechanisms to promote users' trust in the CDSS's accuracy and reliability.
- **Usability and interoperability with existing computer systems**: aspects related to the integration in clinical environments to facilitate its adoption and continuous use. The CDSS will be connected with the hospital information system (HIS) to integrate the patient data seamlessly, and also integrate processing pipelines to extract relevant information from raw data (e.g. radiomics).

It is foreseen that solutions such as ARTMIs CDSS will be available in routine clinical practice by the end of this decade, considering massive digitalisation financing to be mobilised by the Next Generation Europe and Digital Europe Programme in the context of the Digital Decade 2030.

4. DATA SUSTAINABILITY

The main objective of the ARTEMIs project is to develop and evaluate Virtual Twins to support the management of liver diseases. In this project, the infrastructure for sharing patient data is essential for enabling VT developments and not an end in itself. The data platform will facilitate data sharing among the clinical data holder and the researchers working in the data processing pipelines and model developments in full legal and ethical compliance.

This project is committed to the principle of Open Science and promoting the re-use of data for research wherever possible. For this reason, WP9 includes *T9.3—Sustainability of the data exploitation infrastructure*. This task will define the sustainability mechanisms to ensure that the data platform continues to be available for research use after the end of the ARTEMIs project, with an operational model aligned with the European Health Data Space Regulation (EHDS-R).

4.1 The European Health Data Space regulation

As part of the European Data Strategy introduced in February 2020, the EC announced its plan to establish a single European data market, aiming to overcome current legal and technical barriers that hinder the exchange and exploitation of data. One of the four fundamental pillars of this strategy is the development of shared European data spaces to establish a unified market for data within Europe and ensure data sovereignty and global competitiveness. A total of 9 European

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Data Spaces in different key economic sectors is planned. These data spaces are aimed to promote wider accessibility, enhanced quality, and increased reusability of data held by both public and private entities.

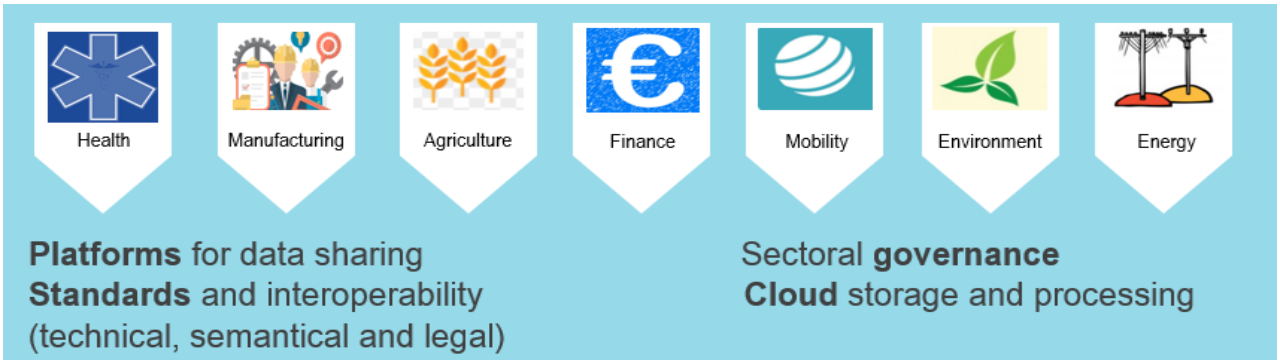

Figure 9 - The foreseen European Data Spaces. Source DG-Sante webinar

The European Health Data Space is the first of the Data Spaces to be constituted.

On April 24, 2024, the European Parliament adopted the provisional agreement on the EHDS-R. The next step is to publish the Regulation in the Official Journal of the EU. Twenty days after this publication, the regulation will enter into the implementation timeline. Each Member State (MS) of the EU must gradually implement the law, starting with creating the Health Data Access Bodies (HDABs) and Digital Health Authorities by mid-2026.

This regulation addresses the secondary use of electronic health data and outlines permitted uses, including research, innovation, policy-making, patient safety, and regulatory activities. The regulation proposal attempts to strike a balance between promoting the general interest in data accessibility and safeguarding patients' individual rights and freedoms. The “secondary use” phase of the EHDS-R implementation is by 2030.

Four key actors play central roles in the data access process: data holders, data users, providers of data intermediation services and health data access bodies.

- Data holders encompass natural or legal persons, including public, non-profit, and private organisations operating in healthcare, research, or Union institutions. Under relevant regulations, they possess the right or obligation to make certain electronic health data available for secondary use.
- Data users, whether natural or legal persons, submit data access applications and lawfully obtain access to personal or non-personal electronic health data for secondary use, adhering to the permissible purposes stipulated by the EHDS Regulation.
- Providers of data intermediation services or data intermediaries, as well as legal persons such as marketplaces, operate under a model based on neutrality and transparency and aim to facilitate the exchange of substantial data.
- Health Data Access Bodies (HDABs) are public sector entities responsible for making decisions regarding data access requests, issuing data permits, and ensuring trusted governance throughout the process. HDABs act as intermediaries between data holders

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and users, facilitating a transparent and standardised environment. The EHDS regulation mandates the creation of HDABs in each MS.

For the data access process, trusted governance is ensured through HDABs, which provide access to health data, establish secure processing environments, and issue data permits adhering to data minimisation and purpose limitation principles. HDABs hold the authority to evaluate data access requests, grant data permits, and guarantee independent and conflict-free operations. Data users can directly request data access from HDABs, with varying processes depending on datasets involving multiple data holders or single data holders within an MS. For datasets with multiple data holders or single data holders processing data in multiple MS, data permits must be sought from the relevant HDAB.

HDABs and data users function as joint controllers, as defined by the General Data Protection Regulation (GDPR). The EC will provide a template for joint-controller arrangements, outlining the responsibilities and obligations of both parties.

The current proposal for EHDS regulation establishes legal obligations for data holders to disclose data to HDABs. HDABs and data holders are allowed to charge fees for accessing and processing health data. These fees must adhere to principles of transparency, proportionality, objectivity, and competition promotion. They must relate to the cost of making the data accessible for reuse.

Some of the EHDS regulation areas already appear in regulations adopted in the EU, such as the GDPR [9] and the Data Governance Act (DGA)[10]. The EHDS repeats several rights of individuals established in the GDPR and develops some of them. Furthermore, the EHDS regulation also includes references to Regulation 2017/745 on Medical Devices and the Artificial Intelligence Act. The European Parliament endorsed the AI Act in March 2023[11].

4.2 The ARTEMIs cohort

ARTEMIS cohort will include both retrospective RWD and data from existing cohorts, aiming to giving developers access to data as early as possible. The clinical partners in the consortium have identified existing cohorts that can be reused in ARTEMIs for the new research purpose of VT development. Thus, a significant part of the ARTEMIs cohort will correspond to patient data previously collected by the clinical partners in other projects or research activities. Finally, some prospective data collection is also planned at later stages and for small patient groups.

The ARTEMIs datasets will correspond to GDPR-compliant, FAIR, multimodal, longitudinal health data (e.g., clinical history, medical imaging, laboratory data, and others). During the project, the Consortium will decide on conditions for data access by external researchers. It is foreseen that selected datasets will be publicly accessible for reuse in research from the selected Open Science Repositories once the results from this Project have been published. Furthermore, some of the ARTEMIs partners are participants in the Digital Programme pilot infrastructure initiatives started in January 2023 to share cancer imaging data (Cancer Image Europe, EUCAIM) under a hybrid (central /federated) model.

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679
[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020PC0767
[11] https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/698792/EPRS_BRI(2021)698792_EN.pdf

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The sustainability of the datasets is a transversal topic relevant to many publicly funded projects in the area of health. ARTEMIs will participate in the **Project Portfolio activities** for the *HORIZON-HLTH-2023-TOOL-05-03 call - Integrated, multi-scale computational models of patient pathophysiology ('virtual twins') for personalised disease management.* ARTEMIs will collaborate with the other seven projects funded under this call to identify common approaches to ensuring the sustainability of access to (some) data collections for reuse in research after the end of the project´s execution period. Furthermore, the planned collaboration with the **EDITH initiative** is very relevant concerning sustainability.

The sustainability of access to data can be achieved in different ways:

- Maintaining ARTEMIs (planned as a hybrid central/federated infrastructure) as an independent repository with its own governance and financing mechanisms. The governance and financing model would need to be defined before the end of the ARTEMIs project.
- Migration of the ARTEMIs datasets subject to long-term access for research purposes to an existing repository with controlled access. The repository governance might have sovereignty over the access requests. The required Data Transfer Agreements would have to be signed before the end of the project.
- Migration of some of the ARTEMIs datasets to an existing open-access Repository.
- Other options identified during the implementation of the ARTEMIs project.

Matical Innovation will lead the work of defining the sustainability strategy and will represent ARTEMIs in any sustainability working groups that may be organised by the Call Project Portfolio, the EDITH initiative, or others. The General Assembly will make all important decisions. At critical decision points, thematic sessions on sustainability will be organized during a Consortium meeting or convened as an extraordinary meeting.

The decisions on the actions to ensure sustainability will be documented as part of the deliverables D9.3 and D9.4, due in Months 36 and 48, respectively.

5. CONCLUSION

This document provides an overview of how the definition of a robust exploitation strategy will be approached. The strategy will be carefully designed to address the specific needs and opportunities of the ARTEMIs results. A detailed plan has been defined to ensure that the actions required to develop the strategy are taken promptly, that the necessary internal resources are mobilised, and that representatives of the most relevant stakeholder groups are consulted. The plan aims to ensure the future societal impact of ARTEMIs.

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6. FUTURE WORK

The future work corresponds to following the roadmap defined in this report, gathering the required information and knowledge to elaborate a sound exploitation strategy for the ARTEMIs CDSS. This strategy will include an analysis of the competitive landscape, geographical and sectorial target markets, potential revenue models and key alliances, and a preliminary analysis of cost and financing resources for the period to market readiness.

The most immediate works include:

- To elaborate the Value Proposition Questionnaire for the different stakeholder groups targeted by this project.
- To identify two representatives of each target group (internal or external to the Project) and confirm their availability to complete the questionnaire or have a telephone interview.
- Analyse the results from the questionnaires and interviews and document them in D9.2 - ARTEMIs value proposition for the different target groups, learnt from interviews and questionnaires, due in Month 12.

The calendar of the main planned actions for the complete duration of the project is presented in Figure 10.

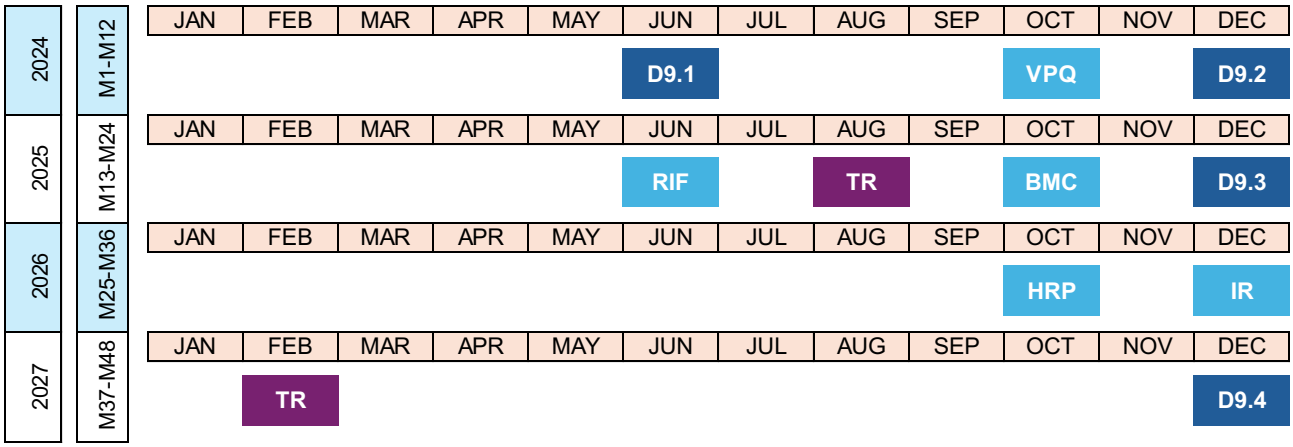

Figure 10 – Calendar of planned works

Table 6 - Planned works

Year 1 - 2024	
D9.1	M6, Deliverable "Exploitation Plan"
VPQ	M10, Value Proposition Questionnaire
D9.2	M12, Deliverable "ARTEMIs value proposition for the different target groups, learnt from interviews and questionnaires"

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Year 2 - 2025	
RIF	M18, Results Identification Form requested to partners
TR	M20, Update on the Exploitation Plan as part of the Technical Report for the Reporting Period 1 (RP1)
BMC	approx M22, collaborative session for Business Model Canvas development, at CM.
D9.3	M24, Deliverable "Preliminary KER exploitation and data sustainability strategy"
Year 3 - 2026	
HRP	M34, ARTEMIs CDSS result published in the Horizon Results Platform
IR	M36, Start process aimd to have the ARTEMIs CDSS featured in the Innovation Radar
Year 4 - 2027	
TR	M40, Update of the Exploitation Plan as part of the Technical Report for the RP2
D9.4	M48, Deliverable "Final strategy for KER exploitation, including a preliminary business plan, and for data sustainability "

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