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## D10.2 Action Plan for Repository Sustainability

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## Abbreviations

AI	Artificial Intelligence
AI4HI	Artificial Intelligence for Health Imaging
API	Application Programming Interface
BBMRI-ERIC	Biobanking and Biomolecular Resources Research Infrastructure–European Research Infrastructure Consortium
DDPP	Digital Decade Policy Programme
DSA	Digital Services Act
DSA	Data Sharing Agreement
DGA	Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance)
EDIC	European Digital Infrastructure Consortium
EHDEN	European Health Data & Evidence Network
EHDS	Proposal for a of the European Parliament and of the Council on the European Health Data Space
ELSI	Ethical, Legal and Societal issues
ESR	European Society of Radiology
FAIR	Findable, accessible, interoperable, and reusable
FTE	Full time equivalent
GDPR	General Data Protection Regulation
HIS	Hospital information system
ICT	Information and communications technology
IPR	Intellectual property rights
MCP	Multi-Country Projects
NGO	Non-Governmental organization
OMOP	Observational Medical Outcomes Partnership
PACS	Picture archiving and communication system

RIS	Radiology information systems
T&C	Terms and Conditions
TCO	Total Cost of Ownership

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## 1. Introduction

The Deliverable D10.2 is part of WP10 “CHAIMELEON Repository Sustainability after project end”, framed under T10.1 “Actions to ensure CHAIMELEON repository Sustainability”.

The deliverable has the aim to design the CHAIMELEON repository sustainability plan during and beyond the duration of the project while providing a governance structure to pursue this goal. The sustainability plan can be thought of as made of two different sets of actions that together can guarantee the CHAIMELEON sustainability: the short-term actions and long-term actions.

The short-term actions and promotional actions (paragraph 3) consists of including CHAIMELEON metadata in the EIBIR Imaging Biobank Catalogue (paragraph 3.1) and in the creation of specific “Open Challenges “ and/or “Open Competitions” to promote and incentivise the use and popularity of the repository (paragraph 3.2). In the paragraph 3.3, the importance of the legal framework and the design of the European Union’s digital transformations policies are stressed out for the CHAIMELEON sustainability.

The long-term sustainability plan can provide a long-term existence of the repository: this goal can be achieved in the context of the EHDS (paragraph 4.1) and thanks to the EUCAIM project (paragraph 4.2). The importance of the inclusion of the CHAIMELEON repository in the EUCAIM framework is presented together with the needed steps to take for the integration process (paragraph 4.3). Legal and ethical issues of the integration are reported in paragraph 4.4.

The Governance structure is defined in paragraph 5.1, while the access model (to define the access roles and the responsibilities related to the access itself) and the definitive version of the DSA are presented in paragraph 5.2 and 5.3, respectively.

A summary of the cost and revenues is made in the next paragraph, 6.

Briefly, the conclusions for the deliverable D 10.2 are drawn in paragraph 7.

## 2. Objectives

The objectives of the deliverable D10.2 are set as following:

- To describe short-term sustainability and promotional actions to ensure and promote the visibility, usability and exploitation of the CHAIMELEON repository services and resources to potential users.
- To define and frame the CHAIMELEON long-term sustainability with a specific focus on the EUCAIM project as a European flagship initiative. Legal and ethical aspects of the transitions need to be set and discussed by the Consortium as far as the possible governance structure modification.
- To designate the final governance structure of the repository in order to identify the key roles and Committees that will take care of the maintenance and management of its functionalities beyond the end of the project.
- To settle the access model to be coherent and in compliance with the final version of the CHAIMELEON Data Sharing Agreement (DSA) & Terms and Conditions (T&C)

## 3. Short-Term sustainability and Promotional actions

Short-term actions and promotional actions are fundamental to the CHAIMELEON repository visibility, usability and exploitation of the repository services and resources to potential users.

The inclusion of the CHAIMELEON repository's metadata in the EIBIR Imaging Biobank Catalogue is a powerful tool to incentivize and advertise the repository across the research and clinical communities.

Setting "Open Challenges" and/or "Open Competitions" can be Use-Case specific and they can be launched addressing different scientific topics based on the validation of AI tools and the promotion of the CHAIMELEON platform to meet clinical or scientific demands. The key aspects of the challenges will be effectiveness and efficiency, encouraging a creative sense and synergies, while supplying high quality and FAIR data and a structured use-case specific dataset.

The EIBIR Catalogue and the arrangement of "Open Challenges" will provide a strong visibility for the platform playing an important role for the CHAIMELEON business strategy.

Overall, the sustainability of the CHAIMELEON repository is dependent on the legal framework and the design of the European Union's digital transformation policies and the distinction should be made between the "operational governance" and the final legal structure.

### 3.1 EIBIR Imaging Biobank Catalogue

Among the short-term actions to ensure sustainability of and promote the CHAIMELEON repository, the project partners are prepared to include metadata about the CHAIMELEON repository in the EIBIR Imaging Biobank Catalogue<sup>1</sup>. This catalogue has been set up by project partner EIBIR in collaboration with the European Society of Radiology (ESR) in response to the growing need of a collection of metadata on existing imaging biobanks and imaging

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<sup>1</sup> <https://molgenis.eibir-edc.org/#/>

collections since the amount of available imaging data from clinical practice and scientific research is growing rapidly and quantitative imaging biomarkers, radiomics and artificial intelligence rely on large imaging datasets for training and validation. The EIBIR Imaging Biobank Catalogue, currently softly launched, features descriptions of imaging biobanks and image collections. EIBIR Imaging Biobank Catalogue will include the metadata about the CHAIMELEON repository to advertise it towards the research community.

### 3.2 Open Challenges

Short-term sustainability for CHAIMELEON is a strategy to design multiple tools to promote, give value and exploit the repository services and resources to potential users such as researchers, healthcare providers, and industry partners: "**Open Challenges**" and/or "**Open Competitions**" are a powerful channel that can be used to achieve these goals.

These challenges can be Use-Case specific and they can be launched addressing different topics such as the training and refinement of AI tools, the co-creation as a by-product of the synergy between the CHAIMELEON platform and the participants, and the testing of AI tools to meet clinical or scientific demands.

The idea behind these competitions is that they will not only be related to the biomedical imaging field, but also to the scientific request of Use-Case specific clinical data: the ultimate goal is to give **visibility** to the CHAIMELEON platform and to get the possibility for the platform itself to be known around the world in the scientific field as a well organised and structured database.

Besides ensuring the sustainability of the platform, the **co-creation process** can be considered as a part of CHAIMELEON **business strategy**: this process requires an optimised balance between the competition aspect (the nature of the "Open Challenge" ) and the cooperation activities.

A key point for a valuable co-creation strategy is to develop and set tailored resources and policies to safeguard the innovative ideas and contributions that arise during the challenges.

Through Collaboration with all the participants, the CHAIMELEON Innovation Committee can learn to better meet the proper scientific requirements and needs while providing accessibility, usability and performance. Privacy and new scientific ideas will be safeguarded by the CHAIMELEON Consortium.

What CHAIMELEON is offering is **high-quality data**, a well organised use-case specific database with imaging and not only imaging data. Thanks to the challenges the Consortium is stimulating creative capabilities, scientific knowledge and collaborations, the participants' scientific work will be evaluated in terms of their AI **model performance** against predefined quantitative metrics.

Moreover, it should be taken into account the meaning of value which can be generated by co-creating with stakeholders. Stakeholders need to consider which value can be expected from joining such projects and challenges so they can be motivated to engage in-depth into new product and service development.

Knowing the received benefits generated by joint innovation projects will support the CHAIMELEON biobank in motivating their participants to embrace and take part in these competitions.

The participation in the challenge will provide access to the platform and its tools and financial rewards are set for the winner of each use case. The most important value of these competitions is to foster a **creative sense** of shared knowledge and expertise, and to

encourage stakeholders to be participants. The winners will not only receive a financial reward, they will also engage in a scientific collaboration with the Consortium, as their AI models will be evaluated by clinical partners in relevant use context. . In agreement with the EU's **Open Science policy**, we will encourage a sharing knowledge environment and a stimulating collaboration network.

Furthermore, a questionnaire checklist can be developed for the stakeholders that consists of open-ended exploratory questions. The objective will be to gather insights about the platform and the perception of the involved stakeholders regarding the value that might arise during co-creation innovation projects.

In the perspective of the EUCAIM integration, "Operational Challenges" rules of participation, rewards and recognition could be modified or integrated.

### 3.3 Legal governance: Data Sharing Agreement & Terms and Conditions

The sustainability of the CHAIMELEON Project is highly dependent on the legal framework and the design of the European Union's digital transformation policies. Therefore, a distinction must be made between the "operational governance" and the final legal structure. The first concept refers to the compliance model that allows the project to operate during its development phase, the second to the final structural design. The design of the short-term legal sustainability pursues very specific objectives:

- **To ensure the feasibility of data sharing by partners who have the capacity to generate the datasets.**

This first objective has been achieved through two steps. The first involves the design of a legal and material strategy to guarantee the generation of data at source that ensures adequate compliance with GDPR and national laws. In this phase, very specific recommendations were made to partners to ensure:

- Compliance with national ethical requirements.

- The implementation of a two-layer anonymisation strategy. The first one by removing the direct identifiers. The second by using the software available in the MEDEXPRIM suite. This second layer is legally supported by data processor contracts in accordance with article 28 of the GDPR.

Additionally, the UPV, UV and MEDEXPRIM teams will implement a further re-identification risk analysis at the level of the final repository. Moreover, as described in the D2.2 First Complete verification of GDPR compliance of repository prototype, the design of the repository for data processing is based on the principles and methodologies of data protection by design.

The second phase is supported by a Data Sharing Agreement (DSA) described below.

- **To ensure that data access users carry out the processing of data and/or develop AI tools with due guarantees.**

This goal is achieved through the implementation of a controlled processing environment. From a technological point of view, this means that access to and use of the repository requires the authorization of user permissions, and implies the application of security measures, including those aimed at guaranteeing the traceability of uses. From a legal point of view, this



also implies that the natural person, or the legal entity in which he or she provides his or her services, must accept the terms and conditions (T&C) of the platform.

- **To define a governance framework** (see section 5 below).

### 3.3.1 Data Sharing Agreement

The DSA is defined as a contractual agreement that aims to specify the rights and obligations of the Parties concerning the provision and use of Data for the creation of the repository. This document should be agreed between those parties providing data. It should be noted that in drafting both the DSA and the T&Cs, consideration has been given to adapting conventional language to the definitions of the DGA<sup>2</sup> and the EHDS<sup>3</sup>. This is why the term data holder is used to refer to data providers.

The document is structured in a central body and various Appendixes. The set of guarantees necessary for the data processing and AI development are defined by the contractual clauses of the first one. Thus:

1. It ensures that the partners playing the role of "data holder" will provide the data while ensuring the legitimate origin of the data as well as the non-infringement of the law in its production and subsequent usage (clause four) and the duty to notify the Consortium of any legal requirement associated with the dataset they may have shared (clause 3.7).
2. Defines the rules for access to data by data users (clause three) and the conditions that ensure the rights of users with access to data through the fifth clause on "licence terms".
3. A procedure is defined to facilitate the future accession of third parties as "data holders" through a flexible procedure whose management as well as the representation of the partners is delegated to the Project Coordinator.
4. The third clause includes a set of provisions aimed at defining the platform's governance model, ensuring data flow, information security and user access conditions. This clause makes it possible to define the institutional structure necessary for the operational and ethical governance of the platform.
5. The ninth clause ensures the possibility of integrating the platform in EU-funded projects that pursue the objective of creating imaging platforms with a wider scope of content and disease typologies, and thus enable CHAI MELEON Project to fulfil its objective of long-term sustainability. Thanks to this clause, the integration will be done automatically without prejudice to the right of each partner to give prior notice of its refusal to this integration. In such a case, the datasets of the latter data holder would be excluded from the integration.

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<sup>2</sup> Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance). Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868>

<sup>3</sup> Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A197%3AFIN&qid=1651653740334>

The annexes to the DSA complete all the elements necessary to provide due process safeguards for the processing of data and/or the deployment of AI technologies, in addition to or further developing the core body clauses.

1. Appendix I. Definition of roles, functions, and data flows.

This section defines the specific role that the parties deploy on the platform and to identify the contact persons in the partners' staff needed to ensure the security of the information and regulatory compliance.

2. Appendix II. Security and confidentiality measures at the platform.

This section defines the basic framework for ensuring information security. Continuous updating is foreseen as security is a dynamic process and highly dependent on the state of the art, evolving threats and vulnerabilities.

3. Appendix III. Declaration of Accession.

This section, in connection with the provisions of the third clause, facilitates the sharing of datasets by an "Adhering Party".

4. Appendix IV: description of the "Data".

This section includes a description of the repository content.

5. Appendix V: Technical requirements for feeding the CHAIMELEON repository

This section defines all the processes that ensure the proper integration of the datasets into the repository.

6. Appendix VI. Terms and conditions for data users.

This section, described below, is included for information purposes in order to ensure that parties are aware of the obligations imposed to the data users. On the other hand, it allows the direct attribution of access permissions to the repository to those data holders who at the same time access the data as data users.

### 3.3.2 Terms & Conditions

The T&C are an essential instrument for the design of a controlled ecosystem for the access and use of datasets. This document includes the set of rights, obligations and responsibilities that should apply to users who are granted permission to access data. This document is aligned with the objectives of the EHDS in several areas:

1. In the definition of the intended purposes for the use of the data.
2. By setting out requirements for the design of processing operations and the provision of ethical and legal safeguards.

3. By defining a set of very precise obligations aimed at ensuring that data will not be used for unlawful or harmful purposes, defining security and traceability obligations and the respect of patients' rights, particularly those related to privacy.

4. By defining appropriate penalties in case of non-compliance.

Moreover, a precise description of the material conditions of use is provided by means of a service level agreement. Finally, registered users and those requesting information are informed of the platform's privacy policies.

## 4. Long-term sustainability: EUCAIM Project

Long-term sustainability is an active process of establishing *Inside to Outside* initiatives, developing networks and procedures that become a lasting part of the CHAIMELEON project. Taking short-term actions and addressing long-term challenges is essential for the success of the platform. However, a well-defined governance and a high-impact short-term sustainability actions are not, in themselves, a guarantee of long-term success.

Planning for long-term sustainability is a way to set actions that will lead to the fulfilment of a long-term goal and there is no single formula to achieve it, as it is a multi-determined task. Long-term sustainability becomes more complex when considering how the resources of one project can affect the resources in another. Indeed, long-term sustainability of the CHAIMELEON project goes side by side with other Horizon 2020 projects including the Artificial Intelligence for Health Imaging (AI4HI) Network, such as the PRIMAGE, EuCanImage, INCISIVE and ProCancer-I project. Moreover, the sustainability of CHAIMELEON will be strongly ensured with the recent EUCAIM project. Lastly, all actions and initiatives at EU level to create a strong European Health Union, including some central components such as an European Health Data Space (EHDS) and the European Cancer Imaging Initiative, will promote and support the long-term sustainability for CHAIMELEON project.

### 4.1 European Health Data Space (EHDS)

Since the access to high-quality data will become increasingly relevant in the near future, the European Health Data Space (EHDS) is one of the central building blocks of a strong European Health Union. In this context, the CHAIMELEON repository represents an invaluable resource that allows access to huge amounts of FAIR (Findable, Accessible, Interoperable and Reusable) data.

The EHDS aims to promote better exchange and access to different types of health data (e.g. the electronic health record (EHR) and genomics data), not only to support healthcare delivery (primary use of health data) but also for health research and health policy making purposes (**secondary use of health data**). The main goal of EHDS is to help the EU to achieve a quantum leap forward in the way healthcare is provided to people across Europe and how the researchers can access the health-data. It offers a consistent, trustworthy and efficient framework to use health data for research, innovation, policy-making and regulatory activities, while ensuring full compliance with the EU's high data protection standards.

The EHDS is envisioned to be built on 3 main pillars: (1) a strong system of data governance and rules for data exchange; (2) data quality; (3) strong infrastructure and interoperability. The

CHAIMELEON data organisation and properties have an excellent alignment with this framework.

The EHDS is based on one of the most important concepts in European data governance: **data altruism**, where data is made available without reward for purely non-commercial usage that benefits communities and researchers. Even if there are different levels among Member States in maturity of digitalisation and interoperability in healthcare, CHAIMELEON is trying to be on the same page as the EHDS needs.

The EHDS is ambitious in the sense that it wants to advance digital health for all Member States and to make the healthcare systems of the EU ready for the digital future.

Furthermore, the EHDS will help to boost the work under **Europe's Beating Cancer Plan**. Pooling and sharing knowledge, experience and data will help to develop practical solutions for cancer patients. The EHDS will also enable the development of innovative approaches to cancer registration, allowing for more timely and efficient collection of information on various types of cancers.

In our vision, CHAIMELEON represents a pivotal project in the definition of this scenario and it can provide very useful insights as a pilot project in the field of cross-border cancer imaging sharing for secondary use. Satisfying the EHDS requirements and protocols, can ensure the CHAIMELEON platform **usability** and is considered a powerful tool for **long-term sustainability**.

#### 4.2 EUCAIM: a European flagship initiative

In order to guarantee the long-term sustainability of the CHAIMELEON platform, it is important to maximise **stakeholder engagement** by providing an interoperable and accessible platform. To achieve this task, the EUCAIM project offers a precious opportunity to increase visibility and the usability of the platform itself. The cornerstone of the EUCAIM project will be the creation of a digital federated European infrastructure for cancer images data, addressing the EU imaging biobanks fragmentation. Indeed, the lack of a unified infrastructure at EU level affects the secondary use of health data for research, innovation, policy making and regulatory purposes. The EUCAIM project is developed with the goal to link up resources and databases of cancer imaging data across the EU, while ensuring adherence to high ethics standards, trust, security and protection of personal data.

EUCAIM is promoted by the European Cancer Imaging Initiative, one of the flagships of the **Europe's Beating Cancer Plan (EBCP)**, which is a key pillar of the European Health Union. The aim of the European Cancer Imaging Initiative is to foster innovation and deployment of digital technologies in cancer treatment and care, to achieve more precise and faster clinical decision-making, diagnostics, treatment and predictive medicine for cancer patients.

Being part of a pan-European Cancer Images infrastructure is a powerful tool to ensure CHAIMELEON long-term sustainability: the EUCAIM project will provide a central hub that will link EU-level and national initiatives, hospital networks as well as research repositories with cancer images data. Clinicians, researchers and innovators will have cross-border access to an interoperable, privacy-preserving and secure infrastructure for federated, distributed analysis of cancer imaging data.

EUCAIM will be built upon the results of the work of the 5 H2020 projects who formed the already mentioned **"AI for Health Imaging"** (AI4HI) Network, which consists of 86 affiliated institutions from 20 countries. These projects are developing Artificial Intelligence algorithms to detect the cancer from imaging and are establishing federated repositories for cancer

images: in particular, CHAIMELEON can offer **different Use-Case specific datasets**, and CHAIMELEON itself can be integrated with EUCAIM providing high-quality and **FAIR** data. The CHAIMELEON integration process in EUCAIM could be done in two different modalities: to be fully embodied in the EUCAIM central hub or to become a federated node of the network. The integration actions will take place in the next months and possible modifications in terms of governance and access model will be evaluated by the consortium according to the EUCAIM progress.

#### 4.3 CHAIMELEON as a federation node: the integration steps

The architecture of the CHAIMELEON repository has been defined considering open protocols and standard components to facilitate extensibility and integration. The integration of the CHAIMELEON repository in the EUCAIM federation at the technical level should focus on the following areas:

- Integration at the level of the AAI (Authentication and Authorisation Infrastructure): The components of the CHAIMELEON repository use a centralised AAI model that supports external Identity Providers with a single sign on. The services use OpenID and define a set of roles with different permissions and access rights. Therefore, the integration with other services supporting OpenID will be feasible and will require defining the roles and rights for users from the federation.
- Integration at the level of the search API: the CHAIMELEON dataset service manages the information of the datasets in the repository. The service is callable from a well-defined API<sup>4</sup>. In order to make queries interoperable, a mediator service should be developed to transform the queries from a standard format to the specific syntax of the CHAIMELEON dataset API.
- Integration at the access level: currently, CHAIMELEON provides as a result of a query an accessible URLs for a dataset. This URL can be used from an aggregator platform to forward a user to the result of a federated search.
- Processing services: CHAIMELEON repository prevents users from downloading data, and the processing of the data should take place inside the platform. Federated platforms will require implementing distributed processing services. As CHAIMELEON already implements a processing batch service based on Kubernetes, it could be evolved to form part of a distributed processing system.

Therefore, the design of CHAIMELEON is appropriate for its integration as part of a federation of repositories.

#### 4.4 Legal and Ethical aspects of the transition

As noted above in paragraph 3, the DSA elaborated for CHAIMELEON anticipates a possible integration into EUCAIM. Therefore, the Project is internally prepared for integration into EUCAIM during its initial life cycle. However, the transition process will be highly dependent on two factors.

##### 1. The evolution of the regulatory framework.

In this area it should be noted that the legal aspects are pending either the national implementation conditions of the DGA or the approval of various regulations in the pipeline.

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<sup>4</sup> <https://app.swaggerhub.com/apis/UPV-CHAIMELEON/Dataset-service/1.0.0>

### A.-Data Governance Act<sup>5</sup>.

It should be underlined that this law has already been published and its full implementation is scheduled for 24 September 2023[1]. This regulation provides relevant definitions to the Project:

- (8) 'data holder' means a legal person, including public sector bodies and international organisations, or a natural person who is not a data subject with respect to the specific data in question, which, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal data or non-personal data;
- (9) 'data user' means a natural or legal person who has lawful access to certain personal or non-personal data and has the right, including under Regulation (EU) 2016/679 in the case of personal data, to use that data for commercial or non-commercial purposes;
- (10) 'data sharing' means the provision of data by a data subject or a data holder to a data user for the purpose of the joint or individual use of such data, based on voluntary agreements or Union or national law, directly or through an intermediary, for example under open or commercial licences subject to a fee or free of charge;
- (11) 'data intermediation service' means a service which aims to establish commercial relationships for the purposes of data sharing between an undetermined number of data subjects and data holders on the one hand and data users on the other, through technical, legal or other means, including for the purpose of exercising the rights of data subjects in relation to personal data, excluding at least the following:
  - (a) services that obtain data from data holders and aggregate, enrich or transform the data for the purpose of adding substantial value to it and license the use of the resulting data to data users, without establishing a commercial relationship between data holders and data users;
  - (b) services that focus on the intermediation of copyright-protected content;
  - (c) services that are exclusively used by one data holder in order to enable the use of the data held by that data holder, or that are used by multiple legal persons in a closed group, including supplier or customer relationships or collaborations established by contract, in particular those that have as a main objective to ensure the functionalities of objects and devices connected to the Internet of Things;
  - (d) data sharing services offered by public sector bodies that do not aim to establish commercial relationships;

Based on these definitions, CHAIMELEON can be described as the grouping of a set of data holders that seek to make datasets available to data users through a data sharing agreement between them. It could be stated that the Consortium, together with the DSA, offers the profile of a data intermediation service. However, from the point of view of the necessary legal certainty, it should be noted that the Consortium itself has not acquired a separate legal personality. This obliges it to govern its relationships through the DSA and the processing of personal data of registered users by means of a joint-controllership agreement. From the point of view of legal liability and risk coverage, this model presents significant difficulties and is neither adequate nor sustainable in the long term. This is particularly relevant to fulfil the requirements of article 12(h) of DGA that states that:

the data intermediation services provider shall, in the event of its insolvency, ensure a reasonable continuity of the provision of its data intermediation services and, where such data intermediation services ensure the storage of data, shall have mechanisms in place to allow data holders and data users to obtain access to, to transfer or to retrieve their data and, where such data intermediation services are provided between data subjects and data users, to allow data subjects to exercise their rights;

Moreover, from the point of view of the data holders, the composition of the Consortium is heterogeneous. The DGA offers different types of data intermediation services:

- Those provided by public sector bodies created under national law.

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<sup>5</sup> See Official Journal of the European Union, N. L 152/1 (3.6.2022)

- Intermediation services between data holders and potential data users.
- Intermediation services between data subjects that seek to make their personal data available or natural persons that seek to make non-personal data available, and potential data users.
- Data cooperatives.

According to these options, and without prejudice to the relationship with the public sector bodies of the partners within the framework of their respective Public Health Services, it seems that the reality of CHAIMELEON would correspond to that of an "Intermediation service between data holders and potential data users". It should be noted that the entry into operation of CHAIMELEON under DGA obliges to notify this activity to the competent authority, with the following content (article 11(4) of the DGA)

- (a) the name of the data intermediation services provider;
- (b) the data intermediation services provider's legal status, form, ownership structure, relevant subsidiaries and, where the data intermediation services provider is registered in a trade or other similar public national register, registration number;**
- (c) the address of the data intermediation services provider's main establishment in the Union, if any, and, where applicable, of any secondary branch in another Member State or that of the legal representative;
- (d) a public website where complete and up-to-date information on the data intermediation services provider and the activities can be found, including as a minimum the information referred to in points (a), (b), (c) and (f);
- (e) the data intermediation services provider's contact persons and contact details;
- (f) a description of the data intermediation service the data intermediation services provider intends to provide, and an indication of the categories listed in Article 10 under which such data intermediation service falls;**
- (g) the estimated date for starting the activity, if different from the date of the notification.

On the other hand, prior to the final release phase of the platform, a process of verification of compliance with the provisions of article 12 of the DGA, regarding the conditions for providing data intermediation services, must be developed.

#### B.- Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space

It should be noted that this rule is still under discussion. The "First Presidency compromise proposal (Chapters I and IV)" was recently published<sup>6</sup>. Therefore, all decisions taken in this area must be functional to the final version of the rule.

Nevertheless, the information published allows us to identify aspects of strategic interest, which are listed below:

- The definition of the platform's purposes. It should be noted that the T&C are aligned with several of the secondary uses defined by the EHDS.
- Decisions on the integration of datasets from other areas.
- The guarantee of adequate interoperability and security conditions.

<sup>6</sup> Available at <https://data.consilium.europa.eu/doc/document/ST-13318-2022-INIT/en/pdf>

- The assurance of intellectual property rights and trade secrets.
- The platform's framework of action as a "grouping of data holders" or as "single data holders" and its insertion in relations with data access bodies.
- The guarantee of the rights of natural persons, considering that "anonymized data" will be processed.
- The delimitation of the applicable standard (DGA v EHDS) in relation to the setting of fees.

C.- Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts<sup>7</sup>.

This Proposal sets out a regulation of AI systems based on three pillars: the guarantee of fundamental rights, a human-centred approach and control of technology, and a risk-based approach. Health-related AI systems are addressed in different areas of the Proposal. Thus:

- It must be ensured that the risks to people's health have been foreseen as part of the management of "serious incidents".
- They can be included by the Commission or states in the classifications as high-risk systems..
- They require special transparency towards users, and in our view, towards society as a whole.
- Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system.
- Very specific measures are imposed to ensure the correct use of data and data governance<sup>8</sup>.

From the design point of view, the proposal includes the obligation to technically document the decisions taken with a content perfectly defined by its Annex IV. The set of measures adopted will in the future be very relevant for obtaining declarations of conformity.

**2. The decisions of the Consortium for the release of the platform and at the end of the project.**

Taking into account the above observations, there will be a transition process during which the Consortium should plan the following strategic decisions and/or activities:

- a) The legal form to be adopted. Alternatively, it will have to decide whether its integration in EUCAIM makes the direct integration in such project and the formula to achieve such goal advisable.
- b) The design and implementation of a methodology for validation, deployment and maintenance of the conditions required by Chapter III of DGA for data intermediation services.

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<sup>7</sup> Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623335154975&uri=CELEX%3A52021PC0206>

<sup>8</sup> Available at [https://lexpency.org/eu/52021PC0206/ART\\_10/](https://lexpency.org/eu/52021PC0206/ART_10/)



c) The constant monitoring of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space procedures.

d) The constant monitoring of the Proposal for an Artificial Intelligence Act. Until full approval of the Artificial Intelligence Act, the development of AI technology on the CHAIMELEON platform, by any of the Consortium partners or by third parties (in the Challenges) should apply the Assessment List for Trustworthy AI (ALTAI). ALTAI was developed by the High-Level Expert Group on Artificial Intelligence set up by the European Commission to help assess whether the AI system that is being developed, deployed, procured or used, complies with the seven requirements of Trustworthy AI, as specified in our Ethics Guidelines for Trustworthy AI.

1. Human Agency and Oversight.
2. Technical Robustness and Safety.
3. Privacy and Data Governance.
4. Transparency.
5. Diversity, Non-discrimination and Fairness.
6. Societal and Environmental Well-being.
7. Accountability.

## 5. Governance for Sustainability

As mentioned previously, a governance structure is required for the long-term sustainability of the CHAIMELEON platform. Governance is made of many bodies which are linked to the repository Directorate and it is really important to give a specific role to each part of it. The final governance structure is proposed in this paragraph, keeping in mind that in the integration process with EUCAIM, the governance structure itself can be subject to modifications.

The Data Access Committee will evaluate, analyse and provide the access to the repository for external users, with respects to the legal, ethical and privacy aspects: the access model is here presented in its updated version in compliance with the final version of the CHAIMELEON DSA.

### 5.1 Governance structure

According to the deliverable D10.1 “Perspective assessment of the Repository Sustainability”, the CHAIMELEON governance structure is reported below.

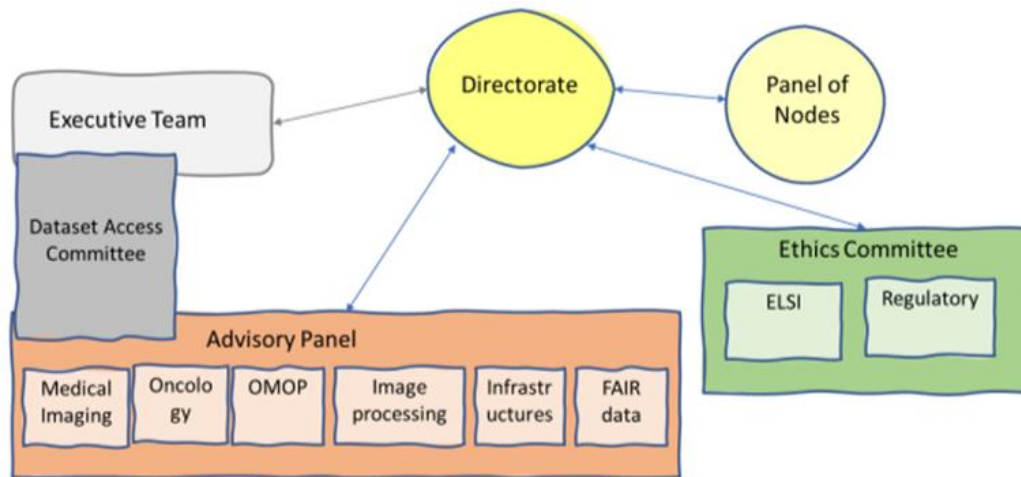


Figure 1. Proposed governance structure for a fully functional CHAIMELEON repository, from D10.1.

The CHAIMELEON governance is responsible for all maintenance activities dealing with regularly checking, updating and deploying of patches in order to avoid vulnerabilities.

A reorganised CHAIMELEON governance structure is proposed here: each body embedded in the scheme below plays the role as mentioned in the deliverable D10.1. In addition to the previous CHAIMELEON governance model, we are enlightening the importance of the Cloud Services as a part of the Data Access Committee. Moreover, the link between each body has been revised and modified.

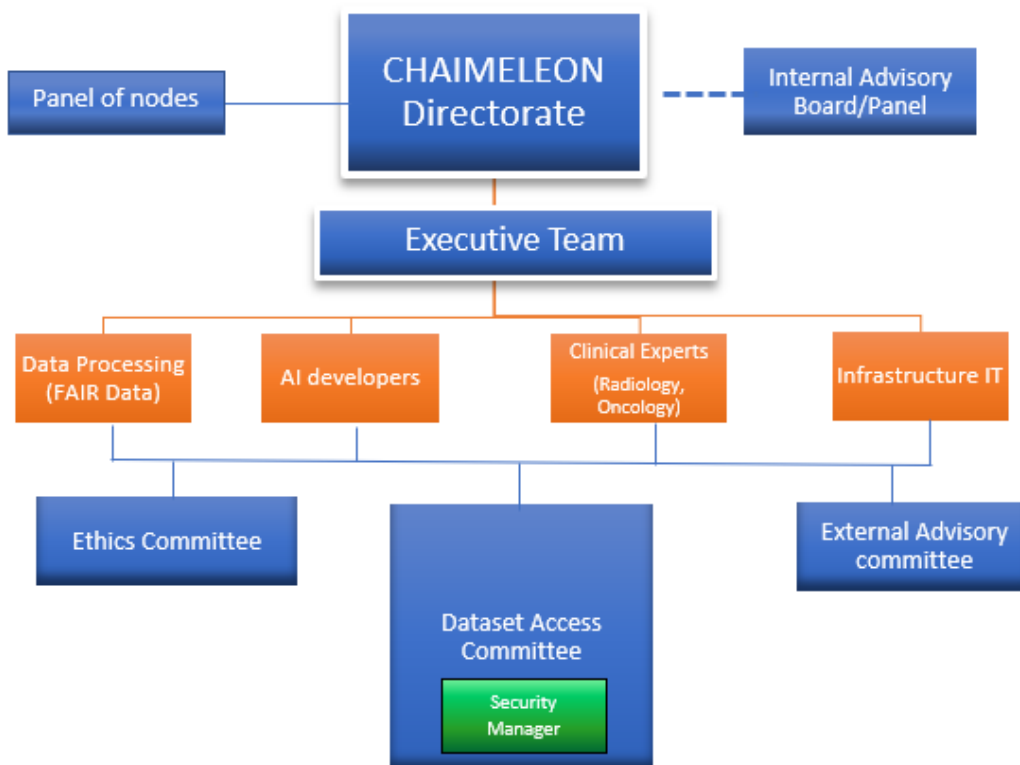


Figure 2. Re-organized structure of CHAIMELEON Governance

Briefly, we mention the role for each body of the Figure 2 scheme.

### **Directorate**

This supervisory body is responsible to make substantial decisions such as defining the policies of the repository and controlling its functioning in the main areas.

It is made of a Technical, a Scientific and a Legal /Ethics Director: they will appoint a Dataset Access Committee, in charge of the evaluation of the access requests for primary or secondary use of the datasets, with members from the Executive Team and the Internal Advisory Panel.

### **Executive team**

This technical team is responsible for all functions necessary in accordance with the legislation in force or with the repository's own needs for its ordinary functioning.

### **Panel of nodes**

The representative body of the data provider nodes of the repository.

### **Ethics Committee**

An Ethics Committee should be set up both for a strictly ethical point of view and for the point of view of the future EU Regulation on AI, different ethical variables can be identified depending on the nature of the data processing.

### **External Advisory Committee and Internal Advisory Board**

The establishment of an Advisory Body is fundamental to guide the tasks of the repository, to promote interaction with all public and private sectors, to propose programmes, actions or new developments. Specific areas to promote standardisation, interoperability and formation and education will be designed.

In the External Advisory Committee, a plural body is proposed, open to society, as mentioned in the D10.1

### **Dataset Access Committee**

In compliance with the final version of the Data Sharing Agreement and Terms and Conditions, the Data Access Committee should be composed of at least the following members:

- 1- A representative of HULAFE with the role of chairing this specific body of the CHAIMELEON governance
- 2- A representative of one of the projects partners having the status of data holder
- 3- A representative of a project partner with data user status

In the Data Access Committee, there will also be included two experts playing the role of advisors on ethics, privacy and security. These will be:

- The Data Protection Officer of the project
- A security expert to be appointed by the UPV

The **Cloud Services and Security Manager** (Security Officer), as mentioned in the final version of the Data Sharing Agreement and Terms and Conditions, has the highest level of permissions to manage and monitor the platform. For the CHAIMELEON repository, this role is carried out by UPV (reachable by email: [security.chaimeleon-eu@i3m.upv.es](mailto:security.chaimeleon-eu@i3m.upv.es)) and its presence is designed for the following motivations:

- 1- Infrastructure Management

- 2- Application and Service container building: ensuring that the applications are working under a restricted environment, even under the container. This role provides the function of controlling the registration and un-registration of the applications in the official catalogue of the repository.
- 3- Assign Roles to Accepted Users: analysis and approval of the user access requests; the Cloud Services and Security Manager User is also in charge of the Assignment of User Roles based on the actions to perform on the repository.
- 4- Security Management: for this task, security assessment, risk evaluation applying software patches, subscribing to security vulnerability bulletins, validating backups, contact point for security incidents tools and controls will be provided.

The complexity of the governance structure (and thus, its associated costs) will be according to the needs of the consolidation and expansion phases that the repository will undergo. The number of members of each proposed committee and their time investment, will be sized to ensure an effective governance, without imposing a large burden on the financial sustainability of the repository.

In the **perspective of the EUCAIM integration** as a part of the long-term sustainability, the CHAIMELEON governance structure may be subject to changes and modification to adhere to the EUCAIM governance structure.

In particular, there will be a difference if CHAIMELEON will be part of EUCAIM in terms of a part of its Central Hub or like a Federated Node of EUCAIM.

During the execution of CHAIMELEON, the repository will need to fulfil the conditions to be federated: after the CHAIMELEON project end, the Consortium and EUCAIM will ensure that CHAIMELEON itself will reach conditions for the sustainability as a Federated Node, otherwise it will become part of the EUCAIM central hub.

This final decision will impact a possible change in the CHAIMELEON governance structure or will delete/add other bodies to meet EUCAIM governance organisation.



Figure 3. CHAIMELEON as a part of EUCAIM after the integration process.

## 5.2 Access model

The access model designed for the repository is consistent with the previously provided in the deliverable D10.1 “Perspective assessment of the repository Sustainability”. However, progress has been made in the drafting of the “Terms and conditions for Data User” agreement (which is part of WP2 “Ethical and legal aspects”) and a practically definitive version is already available, although it has not been yet formalised by the different interested parties (all partners who will process the data in the repository). The main changes and developments in the design of the repository’s access and usage model are described below.

HULAFE has been appointed by the consortium as the partner in charge of granting access to the platform and the right to use the data to the data users who contribute to the objectives of the project, after they have accepted and signed the “Terms and Conditions for Data User”. Furthermore, the consortium has mandated HULAFE, through the Data Sharing Agreement, to take the initiative, if it deems necessary, to create a Data Access Committee, to designate its members and to define its organisation with the membership described above.

The CHAIMELEON repository will use controlled access, thus only registered users will be able to submit a data request. The repository will implement the registration and authentication system, under the leadership of UPV, that will be in full respect of the “Terms and conditions for Data User” agreement. To register, each user will need to accept the conditions of use of the repository.

The data permit will allow the data user to use the data only in the terms and for the purposes expressly authorised and in compliance with the security measures of the platform.

The request of access by a registered data user shall provide a detailed explanation of the intended use of the data and the dataset chosen from the CHAIMELEON catalogue. This request must be accompanied by documentation that supports the purpose and the compliance with legal and ethical standards.

The use of the repository will be free of charge during the execution period of the CHAIMELEON project.

Before the end of the project, the members of the Consortium will decide on a data access strategy and data promotion. It is envisaged that after the end of the project, the use of the CHAIMELEON repository will be:

- Controlled (for registered users only) open (free of charge) access: a selection of datasets will be accessible under this model, in order to comply with the open access mandate of this project.
- Controlled (for registered users only) restricted (fee payment) access: access to other datasets could be conditioned to the payment of a fee in accordance with the provisions of the European Union legislation or the applicable national legislation. Any fees shall include and be derived from the costs related to conducting the procedure for requests and will be proportionate and objectively justified.

In order for the datasets generated during the CHAIMELEON project to remain accessible after the end of the project, running costs will be incurred for the maintenance of the repository's IT infrastructure and governance structure. An open access mandate for these datasets implies that the running costs will need to be funded through other mechanisms, such as public funding. The integration of CHAIMELEON into EUCAIM will ensure access to public co-financing from the Digital Europe programme.

The timeline in Figure 4 shows different envisaged phases for the CHAIMELEON repository, during and after the end of the H2020 project.

During the H2020 project, only participants in the project and a group of participants in the Open Challenge, will have access to the repository. The participants in the Open Challenge will sign a Terms and Conditions document adjusted to this specific use case, as they have additional commitments to fulfil.

The EUCAIM timeline plans for a first version of the platform during 2024, comprising the federation of nodes of the AI4HI projects, including CHAIMELEON. This will imply that CHAIMELEON would be accessible to users from the EUCAIM consortium. In 2025, a final release of the pilot platform is planned, and its implementation in a set of representative use cases with participation of external entities to the EUCAIM consortium.

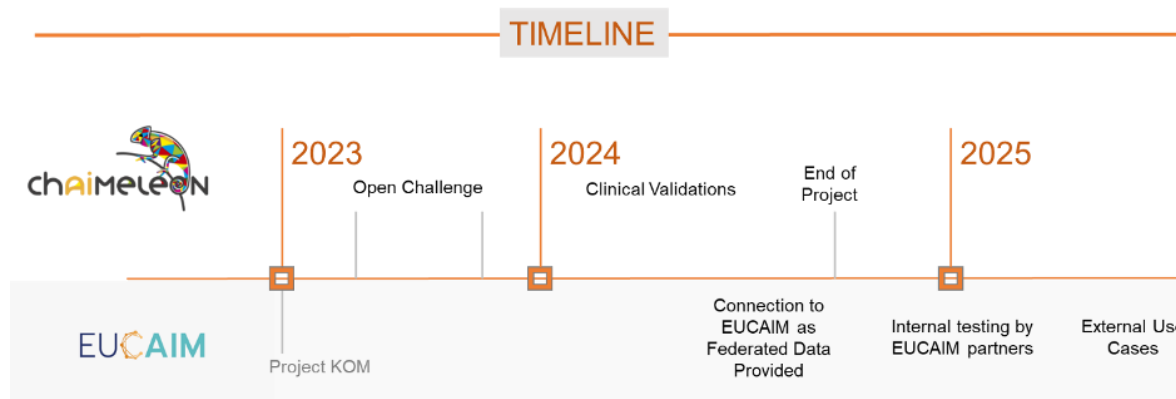


Figure 4. Timeline for CHAIMELEON next stages and federation in EUCAIM

### 5.3 Stakeholder outreach

Outreach to stakeholders and dissemination activities are critical in ensuring the longevity and sustainability of the CHAIMELEON repository. By communicating and engaging with various stakeholder groups within the activities of WP11, the project aims to raise awareness and create widespread acceptance and uptake of its repository and results. These groups include information technology experts, medical scientists, health industry, decision makers, the general public, and multipliers/professional organisations. The First Dissemination & Communication Plan (D11.2) outlines the objectives, strategies, and means of communication for each of these groups, which has been followed up by the Interim Dissemination and Communication Plan (D11.4).

To promote the CHAIMELEON result and the repository in particular, the project follows various dissemination routes including the publication of scientific papers and presentations at conferences as well as the distribution of promotional materials. For example, in addition to a general project video, to date, three demo videos introducing the CHAIMELEON repository have been produced and widely disseminated through the project's dissemination channels. The project website serves as a hub to sustain all project activities during the project and beyond its runtime.

Additionally, CHAIMELEON is capitalising on existing partnerships, especially with major European professional societies, to identify early adopters and opinion leaders to maximise the impact of the project. The project also actively seeks collaboration with other initiatives and projects to ensure the continuation of the CHAIMELEON efforts and the sustainability of the repository. For example, CHAIMELEON is working with the AI4H initiative and the H2020 SINFONIA project, among others. This collaboration involves information exchange through joint meetings, newsletters, and online dissemination activities, all of which contribute to the project's sustainability.

## 6. Cost and Revenues

In this paragraph, the Business model is here illustrated with a focus on the possible modifications with respect to the CHAIMELEON integration process with EUCAIM. Specific sections are dedicated to European Digital Infrastructure Consortium (EDIC), Legal Entity and Data processing AI tools providers. A summary of the cost analysis and public fundings are here reported to provide useful information about CHAIMELEON financing.

### 6.1 Business model

The possibility to undertake a commercial exploitation of the repository, in the sense of offering data access services for research purposes at a fee per use, is contemplated. Key aspects related to the definition of a business model for the repository have been analysed in the *D11.5 Year 2 Exploitation plan for project results*, including the repository's Unique Value Proposition, IPR position, target market and users, competitive landscape.

Since December 2022, with the signature of the Grant Agreement for EUCAIM Project, the opportunity of achieving a long-term sustainability for the CHAIMELEON repository, as part of across-country European infrastructure has been confirmed.

Still, this is not precluding that CHAIMELEON repository (as part of EUCAIM) may be engaged in commercial exploitation. In fact, the design of a business model for EUCAIM is one of the tasks of the pilot deployment project, under the leadership of MAT, a partner in CHAIMELEON and a contributor to this report.

European Digital Infrastructure Consortium (EDIC):

The long-term sustainability of EUCAIM may be linked to the recently proposed figure of a European Digital Infrastructure Consortium (EDIC) as a specific mechanism to implement Multi-Country Projects (MCP) for the establishment of the Digital Decade 2030. The “European common data infrastructure and services” is listed as a possible area of activity for the MCP, and thus EUCAIM is in principle, a MCP which might be eligible to be instrumented as an EDIC.

An EDIC is a legal entity set up by a decision of the European Commission, through an administrative-formal procedure, after a formal commitment of a Member State to host the entity, and two more Member States to become a member of the entity ERIC. It has legal personality and full legal capacity recognised in all EU Member States.

The internal structure of an EDIC is flexible and defined in the Statutes by its members, while respecting the requirements set out in the Digital Decade Policy Programme (DDPP) decision.

The DDPP Decision does not restrict an EDIC from engaging in economic activities (activities that consist of offering goods and/or services on a given market). Both non-economic and economic activities should be admissible, as long as they are linked to the implementation of the MCP. The EDIC Statutes should state whether or not economic activities may be carried out.

#### Legal entity

EUCAIM is planned as a hybrid infrastructure, corresponding to a platform of federated nodes, with a Central Hub for the delivery of central services for data users and holders, as well as for centralised storage of some data collections. Through federation, costs can be reduced by taking advantage of economies of scale. The federation through a larger infrastructure will also allow for cost reductions in governance policies and legal strategies.

The Repositories of the AI4HI network, including CHAIMELEON, are committed to be part of the first federated platform pilot, for internal tests of tools and services. This first pilot is expected to be deployed before the end of CHAIMELEON project, in August 2024. Therefore, the project GA and the CA will still set the legal framework for the consortium collaboration and legitimate HULAFE as the representative of CHAIMELEON.

Once the H2020 project terminates, we need to take into considerations several aspects:

- Repository governance, including data access governance,
- Exploitation rights on the data collections. Currently, according to the Data Sharing Agreement and Consortium Agreement, enriched/harmonized datasets are joint results of the Consortium.

Several options are possible, among which:

- CHAIMELEON repository continues as a federated node of the EUCAIM platform with independent governance.
- CHAIMELEON repository continues as a federated node of the EUCAIM platform with its own infrastructure supported by HULAFE – UPV, and its governance is delegated to the EUCAIM central hub. A CHAIMELEON Legal entity is not constituted.
- CHAIMELEON transfer its data collections to the EUCAIM central hub, formalising the pertinent data transfer agreements.



Other options may be identified in the next project's period. A prioritisation decision will be made, and the required legal and operational actions will be needed to activate the option of choice, before the end of the project.

#### Data processing AI tools providers

CHAIMELEON repository will integrate a set of data processing tools. In particular, data processing AI tools based on image harmonisation have been developed within the frame of the CHAIMELEON project by Quibim. These harmonisation tools will be integrated in the Quibim platforms, QP-Discovery and QP-Care, design and developed by the company, and marketed as a SaaS model.

QP-Discovery is an advanced web-based cloud platform, to centrally manage, store and quantitatively analyse multi-omics data in clinical trials and RWE projects. It is built in an anonymization module complying with HIPAA/GDPR with two-factor authentication. QP-Discovery includes an embedded zero footprint DICOM viewer for radiological readings, semi-automatic treatment response evaluation, AI driven organ/lesion segmentation and automatic quantification of imaging biomarkers. This all-in-one platform offers the ability to centralise all raw anonymised data and extracted biomarkers, allowing the generation of predictive models based on RWE with a high generalisation and accuracy. The platform's infrastructure is based on Microsoft Azure, ensuring state-of-the-art security, scalability and global deployability.

Quibim's goal is to enter long-term partnerships with BioPharma companies to jointly develop different projects, based on the scientific challenges where both parties believe we can collaborate based on the access to data and expertise.

In EUCAIM, Quibim will provide the Atlas portal, based on QP-Discovery, to the central hub as main core services, being involved on the finetuning, adaptation and integration of the Atlas portal. QP-Discovery will be adapted and tested to meet with the requirements related to the set-up of processing environments for data analysis, annotation, harmonisation (based on the CHAIMELEON outcomes) and exploitation, including it in the EUCAIM business model.

QP-Care is the platform that serves as an entry point to the different analysis suites. Thus, QP-Care allows the user to import new studies into the Quibim environment, either automatically or manually through a guided interface. In case of an automatic import, the user must download the QP-Link tool. This is a proprietary application that allows the connection between a DICOM node (e.g., modality or PACS) and Quibim's cloud services through standard DIMSE and DICOMWeb operations. Once the image studies have reached the Quibim environment, they will be automatically analysed using the corresponding analysis suite.

In this respect, Quibim is creating dedicated suites for a more complete evaluation of pathologies that may affect a specific anatomy. Our first suites to be released are QP-Prostate and QP-Brain, and QP-Liver and QP-Lung are already in the works. Upon successful completion of an analysis suite run, the results can be returned to PACS in an automated fashion.

Regarding the commercial strategy, for mass adoption, we partner with distributors either regional or global. The regional partners are companies specialising in healthcare products related to Radiology. They carry multiple products from multiple vendors. They only address a specific region, mostly one country.

The global partners are larger healthcare organisations with a large market share in their specific product area. Think of companies who produce and sell Radiology equipment such as Philips and Canon, or PACS providers like Sectra and Change Healthcare.

## 6.2 Summary of the cost structure

An analysis of the cost structure for the first year of the repository operational (post-project end) phase has been described in the *D10.1 Prospective assessment of the Repository sustainability* and *D11.5 Year 2 Exploitation plan for project results*. The estimations were done considering plausible assumptions and aimed at an operational efficiency of the CHAIMELEON repository. The validity of some technical and operational assumptions will be assessed as part of the platform validation works to be undertaken during the project year 3. In the meantime, the assumptions made in those previous deliverables, and the preliminary cost estimation are still valid. Thus, the annual costs for the repository operation are estimated at 390k€, split in 320k€ fixed costs and 70k€ variable costs, considering a cost minimisation scenario where costs related to aspects such as new developments for upgrading its functionality, are not contemplated. A summary breakdown of costs is included in Table 5.

Table 5: Preliminary annual cost analysis for the operational phase of CHAIMELEON repository

<b>Fixed costs</b>	
Technical costs	€ 196.754,00
Central IT resources	€ 54.254,00
Technical staff for maintenance and user support	€ 42.500,00
Technical staff for support of sites already deployed	€ 100.000,00
Governance (administrative, financial and management) costs	€ 75.000,00
Promotional costs	€ 20.000,00
ELSI costs	€ 29.000,00
<b>Total fixed costs</b>	<b>€ 320.754,00</b>
<b>Variable costs</b>	
Technical costs for new data holder	€ 40.000,00
Fee for data provision	€ 30.000,00
<b>Total variable costs</b>	<b>€ 70.000,00</b>
<b>TOTAL COSTS</b>	<b>€ 390.754,00</b>

### 6.3 Public funding

During CHAIMELEON project year 2, the Consortium has secured additional financing of the Digital Europe Programme to support the long-term sustainability of the repository, corresponding to the EUCAIM pilot infrastructure deployment project, as previously described in 4. *Long-term sustainability: EUCAIM Project*. CHAIMELEON Coordinator is the Scientific Coordinator of EUCAIM, and all CHAIMELEON partners are also partners in EUCAIM.

As it was proposed in the deliverable D.10.1 “Prospective assessment of the Repository sustainability”, additional public funding for sustainability of the CHAIMELEON repository will be along the following main lines, which are the same explored before except for a new mechanism for data infrastructures and services in the Union, the European Digital Infrastructure Consortium:

a) R&D funding for new developments aimed to incorporate new functionalities in the Repository (research prototype):

The Horizon Europe programme is a potential funding scheme for this type of action. Calls under the Health Challenge will be periodically scrutinised for the identification of relevant funding opportunities, in particular calls under the Mission Cancer initiative.

b) Implementation support funding for advancing the repository to TRL9:

b.1) National co-funding, expected by the Digital Europe programme: EU MS are invited to use European Regional Development Fund (ERDF) funds for co-funding initiatives supported by the Digital Europe Programme. The national or regional ERDF Managing Authorities are responsible for making these decisions.

b.2) Next Generation Europe (NGEU) funds: The NGEU funds are a package of programmes intended to support the recovery from the COVID-19, through a combination of grants and loans. Each EU Member State has established national targets for the related investments. Promotion of digitalisation and the adoption of AI solutions in transversal sectors including healthcare, is an important issue in the European Agenda. Therefore, co-funding to support connectivity of national institutional repositories and imaging biobanks to EUCAIM/CHAIMELEON may be an eligible action under this funding scheme.

c) Consolidation and expansion phase:

c.1) Becoming a European Digital Infrastructure: the figure of European Digital Infrastructure Consortium (EDIC) is created and regulated by Decision 2022/2481 of the European Parliament and of the Council for the establishment of the Digital Decade 2030 Strategy, published in the OJEU on 14/12/2022. They are constituted as mechanisms for the implementation of large-scale multi-country projects to achieve the objectives of the Digital Decade 2030 Strategic Programme. Not only Member States but other public or private entities may join an EDIC as affiliated parties with financial or non-financial contribution.

Being part of an EDIC could be a way to support CHAIMELEON’s sustainability in the area of “European common data infrastructure and services” of the list of areas of activities for multi-country projects, provided in the Decision 2022/2481. An EDIC can be used for establishing new infrastructures and operating them or for operating already existing infrastructures that consider it useful to change their legal structure to become an EDIC. The infrastructures may

be single-sited or distributed. EUCAIM has been proposed to be in the list of possible multi-country projects selected by Member States and the Commission.

For multi-country projects, it is foreseen to combine funds from Union programmes with national resources as well as from third countries and private entities, provided that they support digital transformation. In addition, under certain conditions, they may benefit from contributions from both the Recovery and Resilience Mechanism and the European Regional Development Fund or the Cohesion Fund.<sup>[CB1] [AS2] c.2)</sup>

The Connecting Europe Facility (CEF): CEF is a funding scheme for the promotion of growth, jobs and competitiveness through targeted infrastructure investment at European level. This scheme is only eligible for the pan European expansion of mature technologies and solutions. It may be of relevance for EUCAIM/CHAIMELEON repository extensive deployment across Europe in the longer term.

## 7. Conclusions

In conclusion, we believe that the CHAIMELEON action plan for the sustainability of the repository is a complex and multi-determined aspect. In this document we addressed the main challenges to overcome in the next months according to different possible scenarios.

We rethought the repository sustainability challenge, dealing with it as made of two distinct action plans: one for the short-term sustainability and one for the long-term sustainability taking into account the inclusion in the EUCAIM project.

We presented an updated model of the governance structure, also considering the next steps towards the integration in the EUCAIM project.

Lastly, we presented the CHAIMELEON business and access model, in compliance with the final version of the DSA & TC.