



**EUCAIM**  
**CANCER IMAGE EUROPE**

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## **D2.4: Training evaluation: guidelines, best practices, lessons learned**

**Responsible Partner(s): DKFZ**

**Author(s):** Hanna Leisz (DKFZ), Heinz-Peter Schlemmer (DKFZ), Ana Blanco Sanchez (QUIBIM), Celia Martín Vicario (QUIBIM), Francesca Pia Caputo (UNIFI), Emanuele Neri (UNIFI), Javier Soto Perez-Olivares (SERMAS), Laure Saint-Aubert (MEDEX), Marco Aiello (SYNLAB), Marta Martínez Calle (QUIBIM), Olga Tsave (AUTH), Patricia Serrano Candelas (HULAFE), Santiago Andrés Frid (HCB-FCRB), Valentina Formica (UNIFI)

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**Contributors:** Ricard Martínez (UV)

**Reviewers:** Irene Marín (HULAFE), David Rodríguez (CSIC-IFCA)

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## List of Abbreviations and Acronyms

AI: Artificial Intelligence

AI4HI: AI for Health Imaging

ALTAI: Assessment List for Trustworthy Artificial Intelligence

API: Application Programming Interface

CDM: Common Data Model

DPO: Data Protection Officer

EDIC: European Digital Infrastructure Consortium

EHDS: European Health Data Space

ELSI: Ethical, Legal, and Social Issues

ERIC: European Research Infrastructure Consortium

FAIR: Findable, accessible, interoperable, re-usable

GDPR: General Data Protection Regulation

HPC: High Performance Computing

IAM: Identity and Access Management

IPR: Intellectual Property Rights

LMS: Learning Management System

LS AAI: Life Science Authentication and Authorization Infrastructure

PI: Principal Investigator

SME: Small and medium size enterprise

WCAG: Web Content Accessibility Guidelines

WMA: World Medical Association

WP: Work Package

# 1. Introduction

## 1.1. Aim and Scope of the Deliverable

The goal of European Federation for CAncer IMages (EUCAIM) is to build a pan-European digital federated infrastructure of cancer-related radiological and nuclear medicine images and other related digital information, which will be used to develop Artificial Intelligence (AI) tools for Precision Medicine. EUCAIM aims at preserving the data sovereignty of data holders and will address the fragmentation of existing cancer image repositories throughout Europe by building on repositories of the AI4HI initiative, European research infrastructures and national/regional repositories.

This document evaluates the D2.2 Training Plan (due M12) and introduces the Learning Management System (LMS) that will constitute the training platform for EUCAIM. The evaluation of the Training Plan and specification of the training according to user roles (defined in D4.2 Final EUCAIM Operational Platform) was based on the most recent advancements in the EUCAIM project and includes information from central documents and deliverables that were created up until M18. D2.4 therefore outlines:

D2.4 Section	Description
1. List of deliverables and work packages related to training	<ul style="list-style-type: none"><li>● reference documentation for training contents</li></ul>
2. Analysis of suitable Learning Management Systems (LMS)	<ul style="list-style-type: none"><li>● What is a LMS?</li><li>● LMS requirements in EUCAIM</li><li>● Overview of alternative LMS</li><li>● Outline of key features of the Moodle LMS</li><li>● Advantages and disadvantages of Moodle</li><li>● Learning pathways created for EUCAIM</li><li>● Groups in Moodle</li><li>● Training evaluation options in Moodle<ul style="list-style-type: none"><li>○ The Kirkpatrick Evaluation Model</li></ul></li></ul>
3. Evaluation of Training Plan (D2.2)	<ul style="list-style-type: none"><li>● The EUCAIM training modules as defined in the training plan are reviewed and specified according to the relevant deliverables and documentation provided by WP2, WP3, WP4, WP5 and WP6</li><li>● In contrast to the so far envisioned module structure for the</li></ul>

	<p>training, D2.4 introduces a shift towards a user profile based structure:</p> <ul style="list-style-type: none"> <li>○ the foreseen contents of the modules are transferred from a topic based structure to a user centric structure;</li> <li>○ based on the four basic user profiles (data holders, software providers, data users and management), the training contents are elaborated.</li> <li>● Therefore training contents are defined according to: <ul style="list-style-type: none"> <li>○ profile of the user</li> <li>○ scope of the training</li> <li>○ learning objectives</li> </ul> </li> </ul>
4. EUCAIM guidelines for training	<ul style="list-style-type: none"> <li>● formulation of EUCAIM specific guidelines for training</li> </ul>
5. Lessons learned	<ul style="list-style-type: none"> <li>● Recommendations for sustainability</li> </ul>

## 1.2. List of Deliverables and Work Packages Related to Training

### WP2:

- D2.2: Training Plan
- D2.3 Requirement analysis of Real World Data Holders
- Description of Technical requirements for Data Holders
- Stakeholders Management Plan

### WP3:

- D3.6: Data Management Plan

### WP4:

- D4.2: Final EUCAIM Operational Platform
- D4.4: Final Rules of Participation Report
- D4.13: End User Guide to the System

### WP5:

- D5.1: Early release of the Data Federation Framework

- D5.2: The EUCAIM CDM and hyper-ontology for data interoperability: initial version
- D5.4: Data Pre-processing Tools and Services
- D5.11: Interim set-up of local nodes for data federation

## 2. Analysis of Suitable Learning Management Systems

A Learning Management System (LMS) is a software application designed to facilitate the administration, documentation, tracking, reporting, and delivery of educational courses and training programs. Ideally, it serves as a centralized platform for managing various aspects of the learning process, whether in educational institutions or corporate training environments.

Learning Management Systems generally offer course management, allowing institutions to create, manage, and deliver course content. This includes uploading materials such as videos, documents, and interactive activities. They also manage learners' roles and permissions, enabling instructors to monitor learning progress and participation. All learning activities on an LMS platform typically can be tracked and reported, i.e. the LMS offers tools for assessments such as quizzes and assignments to track learners' progress as well system-based metrics to monitor interaction with the system.

In terms of terminology in the context of this section, we are defining the different user roles within an LMS as follows

- 1) on the training provider's side: administrators, instructors, educators
- 2) on the training recipient's side: learners

Both providers and recipients of training are considered users of the LMS - not to be confused with the users that are defined in the overall context of EUCAIM (see section 3.1), who in the context of the LMS belong to the "learners" group.

## 2.1. LMS Requirements in EUCAIM

There are several LMS requirements that were identified in the context of EUCAIM. In the following these requirements are explained and subsequently ranked according to their level of relevance for EUCAIM.

**User Access Requirements:** In terms of user access, we require a LMS that can integrate the same access and authentication method as the EUCAIM dashboard, i.e login via the Life Science Authentication and Authorization Infrastructure (LS AAI).

**LMS Administration:** An LMS that enables the simultaneous work of several educators working on the same courses is required in order to ensure efficient collaboration within the training team.

**Monitoring:** Tracking and analysing a learner's progress as well as completion of mandatory training segments is required. Additionally further metrics such as login rates, time spent on training etc. shall be verifiable.

**GDPR Compliance:** An LMS enabling GDPR compliance is required.

**Hosting:** We require a LMS that can be hosted on EUCAIM's server.

**Costs:** An open-source system that will not result in additional costs is required.

**Learning Pathways and Customizability:** We require an LMS that allows for individual learning pathways that can be created according to the specific EUCAIM user profiles introduced in this document (see section 3.1). For EUCAIM, there are two training pathways in order to be able to combine mandatory course elements such as the legal and ethical training required for any EUCAIM user with elective course elements that depend on the user's individual profile. Furthermore, the system needs to be customizable, especially in terms of integration of various media sources, user access to profile specific contents that can be adapted in case a user's profile changes (i.e. changing the learning pathway if needed), ensuring accessibility regardless of a user's abilities or disabilities.

<b>LMS Requirement</b>	<b>Ranking (low, medium, high)</b>
User Access Requirements (LS AAI integration)	high
LMS Administration	medium
Monitoring	medium
GDPR Compliance	high
Hosting	high
Costs	high
Learning Pathways and Customizability	high

*Table 1: LMS Requirements in EUCAIM*

## **2.2. Overview of Alternative Learning Management Systems**

In order to identify a suitable LMS for EUCAIM based on the aforementioned requirements, we analyzed five LMS that are commonly used in public education and corporate training: Moodle, Canvas, Blackboard, Google Classroom, and TalentLMS. Those five LMS were analyzed according to user category, cost, customization, user interface, support, scalability and fulfilment of GDPR requirements.

	LMS				
	Moodle	Canvas	Blackboard	Google Classroom	TalentLMS
<b>User category</b>	Large institutions, universities	Education, universities	Large institutions, corporate use	Small institutions, primary and secondary education	Large institutions, corporate use
<b>Cost</b>	Free (except cloud-based version)	Subscription-based	Licensing fee	Free	Subscription-based
<b>Customization</b>	Extensive	Limited	Moderate	Limited	Moderate
<b>User interface</b>	Highly customizable but complex	User-friendly	Complex	User-friendly	User-friendly
<b>(Community) Support</b>	Very high	Limited	Dedicated support team	Limited	Limited
<b>Scalability</b>	High	Moderate	High	Low	Moderate
<b>GDPR compliance</b>	Yes	Yes	Yes	Yes	Yes
<b>Compliance with EUCAIM requirements (as defined in 2.1)</b>	Yes	Partly	Partly	Partly	Partly

*Table 2: Analysis of Learning Management Systems*

Based on this initial analysis, we decided to take a closer look at the Moodle LMS. Customizability, GDPR compliance and privacy, as well as sustainability considerations in terms of recurring costs were considered to be the decisive factors. In the following section, Moodle’s key features, advantages and disadvantages are highlighted.

### 2.3. Moodle: Key Features, Advantages and Disadvantages

Moodle is a widely used open-source LMS designed to facilitate the creation, management, and delivery of online courses. It supports a diverse range of educational and training needs across various sectors, including education, corporate training, and non-profit organizations.

Its key features for training providers are:

- **Course creation and management:** Moodle allows educators to build courses from scratch, offering flexibility in course structure and delivery formats.
- **Course administration:** Administrators and trainers can manage access, set timelines, and create learning paths for learners.
- **Assessment tools:** The platform includes various assessment methods such as quizzes, assignments, and interactive activities. It also features a gradebook for tracking learning performance.
- **Customization options:** Training providers can tailor Moodle to their specific needs with a large set of plugins and custom themes, some of them are fee-based. It is therefore highly adaptable and suitable for different research and learning environments.
- **Community support:** Moodle benefits from a large global community that contributes to its development and offers extensive resources for educators. This collaborative model ensures continuous improvement of the platform.
- **Multimedia support:** The LMS supports various media formats, enabling instructors to use multimedia applications tailored to the specific learning pathways of their target learners.

In the context of providing training in EUCAIM, we have decided to use Moodle in particular because of the following advantages which correspond to our requirements:

- **Cost-effectiveness:** Being an open-source platform, Moodle is free to download and use, eliminating licensing fees associated with proprietary LMS solutions (with the exception of Moodle cloud which includes a fee, and some fee-based themes).
- **Scalability:** Moodle can accommodate a wide range of user contexts, from small learning groups to large institutions. Its modular design allows it to grow alongside organizational needs.
- **Flexibility:** The platform is customizable and can be adapted for various educational goals and branding requirements. Organizations can modify the interface and functionalities to better suit their specific needs.

- **Authentication:** Moodle allows for customized authentication and authorization methods. In the context of EUCAIM, the LS AAI Login for users can also be used to login on the Moodle platform.
- **Privacy focus:** Moodle provides users with control over their data, i.e allowing users to submit data requests to access or delete their personal information, which can be a significant advantage for privacy-conscious organizations. Data can be stored on self-hosted servers or with a third-party hosting provider. This flexibility allows organizations to ensure that the data remains within certain geographic boundaries, one of the GDPR requirements.
- **GDPR compliance:** Moodle is GDPR-compliant and offers built-in features to help institutions comply with the regulation. Moodle offers tools such as:
  - Privacy API: Allows users to access, export, and delete their personal data.
  - Data Retention: Institutions can define policies for how long data should be retained.
  - User Consent: The system requires explicit consent for data collection and processing from users.
- **Control over data:** Since organizations can host Moodle on their own servers, they have full control over data storage and processing, including compliance with local privacy laws.
- **Data processors:** If using third-party hosting (MoodleCloud), Moodle has data processing agreements in place to ensure GDPR compliance. This option has been discarded for EUCAIM since it would generate additional costs.
- **Accessibility:** Accessibility refers to an LMS's commitment to ensuring that all users, regardless of their abilities or disabilities, can effectively access the offered educational content. This includes compliance with established accessibility standards as well as the implementation of features that support diverse learning needs. Moodle is designed to meet the Web Content Accessibility Guidelines (WCAG) 2.1 AA accessibility standards<sup>1</sup>, ensuring that its functionalities are perceivable, operable, understandable, and robust for all users. This compliance is crucial for providing equal access to educational resources. WCAG 2.1 AA encompasses a broad set of recommendations aimed at enhancing the accessibility of web content. Adhering to these guidelines will improve access for a diverse range of individuals with disabilities, including those with visual impairments, hearing loss, limited mobility, speech disabilities, photosensitivity, and combinations thereof. These guidelines apply to web content accessed on various devices, including desktops,

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<sup>1</sup> <https://www.w3.org/TR/WCAG21/>

laptops, tablets, and smartphones. Moodle supports screen readers, which assist users with visual impairments by reading aloud text and describing interface elements. Features like skip-to-content links enhance navigation for screen reader users. To ensure that all users can access visual content, Moodle encourages the use of alternative (alt) text for images. The platform furthermore includes an accessible media player that supports closed captions and transcripts, making video content more accessible to users with hearing impairments. Users also have options to customize their viewing experience, such as adjusting font sizes or using dyslexia-friendly fonts through browser extensions, enhancing usability for individuals with specific learning disabilities.

The WP2 training team tested Moodle and conducted a first internal training workshop. While the above mentioned advantages became apparent, there are also a few disadvantages in handling Moodle courses to be considered:

- **Content management and interface:** While Moodle is designed to be intuitive, allowing both instructors and learners to navigate the system easily, it has some limitations in creating the learning content pages. Especially in terms of formatting and creating content, Moodle proves to be rather tedious. Formatting is limited to a few functions and there is no preview function to check how pages are displayed to the learner. Additionally, there is no option to track changes for multiple instructors/trainers working on the same course. The interface is rather complex with an overload of functions and requires administrators and trainers new to Moodle to take extensive training in how to administrate the platform and courses.
- **Course structure:** Unless streamlined and followed-up very closely, course structures can become confusing and complex due to the high flexibility Moodle offers. It is therefore important to continuously reiterate the navigation through a course in order to ensure that its structure is comprehensible and intuitive to learners.

Overall, we assessed that the advantages of Moodle outweigh the disadvantages. Based on the internal Moodle training session and taking into account how comparable Moodle training environments such as the Dutch training course DANS (a collaboration between EU Consortia projects and Research Data Netherlands)<sup>2</sup> were structured, we agreed on a workflow to ensure that the creation of course contents can be realised with manageable effort. This requires for example integrating content only after finalising necessary review iterations with EUCAIM colleagues as to limit re-formatting tasks to a minimum. Furthermore,

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<sup>2</sup> <https://danstraining.moodlecloud.com/>

we are in constant exchange about the structure of the Moodle courses to ensure that the learners will be able to follow it accordingly.

#### **2.4. Learning Pathways in Moodle**

Moodle offers a range of learning pathways which are structured sequences of courses designed to facilitate learners' progression through specific skills or subjects. They can be tailored to meet individual learning needs and preferences, enhancing engagement and effectiveness, thus enabling a learner to become proficient in a particular skill, subject, or competence. Moodle offers two types of training pathways:

- **Sequential learning paths** which follow a particular order. This kind of guided learning is intended for complex subjects or skills and the learner needs to understand specific concepts or gain knowledge before continuing with the task at hand.
- **Non-sequential learning paths** refer to courses or course sections that are related, yet the learner can decide in which order to take them.

For EUCAIM, we have decided to incorporate both training pathways in order to be able to combine mandatory course elements such as the legal and ethical training required for any user with elective course elements that depend on the user's individual profile.

To cater to the different user profiles, the EUCAIM Moodle platform offers four training courses, each designed to provide targeted information. The respective modules as defined in the D2.2 Training Plan are included in the courses, however, the general structure is now user profile based instead of thematic/module-based. The accessibility of the four courses also depends on the user's profile (see 3.1) and is organised as follows (see also section 3.2 for a detailed outline of the courses):

1. **Public training course** (general information, accessible with guest account)
  - General introduction and overview, information on how to register etc. (corresponds to module 5 of D2.2 Training Plan)
  - Targeted user profiles: MANAGEMENT (including ELSI, IPR Experts, Professional Societies, Patients' Associations, Infrastructures (EDIC/ERIC), Government Representatives, Data Protection Authorities)

2. **Consortium only** (training for internal purposes, accessibility through internal invitation)
  - Legal and ethical training tailored to consortium members working in the project
  - Additional training materials created by the consortium for the consortium
  - Targeted user profile: EUCAIM partner consortium
  
3. **Mandatory legal and ethical training for users**
  - Separated legal and ethical mandatory training course tailored to the user profile required to be granted access to the platform (corresponding to module 1 of the D2.2 Training Plan)
  - Targeted user profiles: DATA HOLDERS, SOFTWARE PROVIDERS, DATA USERS (all registered and authenticated through the LS AAI)
  
4. **Training for EUCAIM platform users** (covering the entire user journey through the EUCAIM platform, accessible with a LS AAI login)
  - In-depth training (corresponding to modules 2-4 of the Training Plan)
  - Targeted user profiles: DATA HOLDERS, SOFTWARE PROVIDERS, DATA USERS (all registered and authenticated through the LS AAI)

## 2.5. Moodle Groups

Moodle's groups feature allows instructors to organize learners into smaller cohorts for various activities and assessments, thus enabling the delivery of training contents to specific target groups.

### Types of Groups

- **Manual Groups:** Instructors create these groups and assign learners manually. This method is useful when specific group compositions are required.
- **Auto-Generated Groups:** Moodle can automatically create groups based on predefined criteria, such as the number of learners per group or the total number of groups needed.
- **Groupings:** A grouping is a collection of groups that allows instructors to apply settings or restrictions to multiple groups simultaneously. For example, an instructor might create different groupings for various assignments.

## Advantages of using groups

- **Differentiated Instruction:** Instructors can tailor assignments or resources for different groups based on their needs, such as creating separate materials for learners with different profiles.
- **Access Control:** Groups can be used to restrict access to certain activities or resources. For instance, a forum set to "Separate groups"-mode will only allow members of that group to see each other's posts.

For the EUCAIM training for users, we envision using manual groups according to the specific user profiles defined in the WP2 Stakeholders Management Plan. The different user profiles are explained in 3.1.

## 2.6. Evaluating Training Activities in Moodle

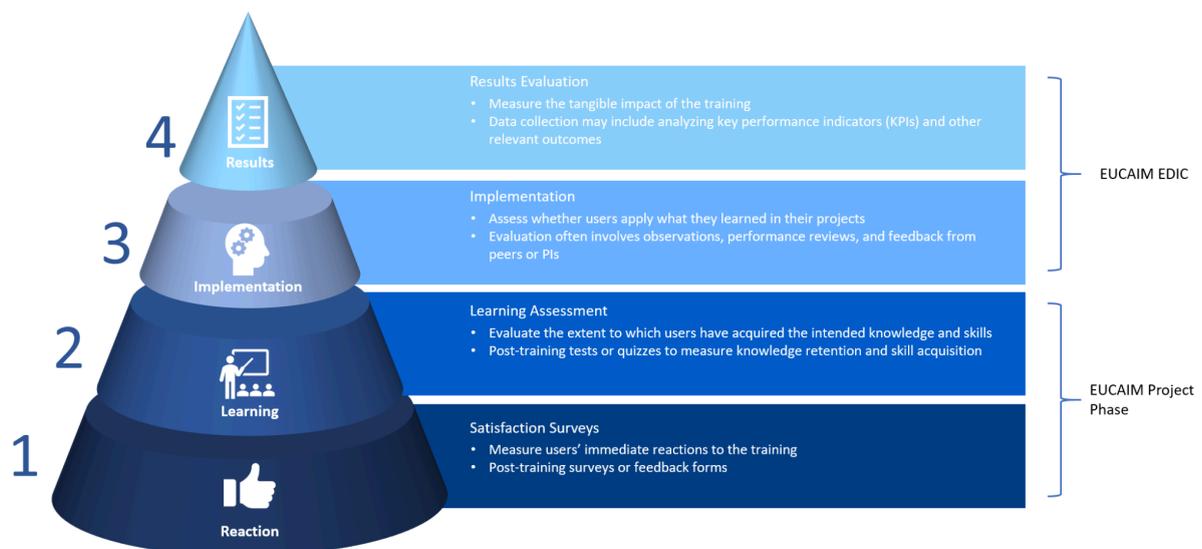
Moodle provides a range of evaluation metrics that help assess learning performance and engagement effectively. These metrics are essential for understanding how learners interact with the learning materials and their overall progress. The key evaluation metrics available in Moodle are:

- **Login Rate:** Measures how frequently learners log into the Moodle platform, providing insights into engagement levels.
- **Activity Completion:** Tracks whether learners complete assigned activities, such as quizzes, which can indicate their engagement and commitment to the course.
- **Quiz Performance:** Analyzes scores from quizzes and tests to evaluate understanding of course material. This metric can highlight areas where learners may face difficulties.
- **Engagement Analytics:** Utilizes metrics such as time spent on course materials, frequency of interactions, and participation in activities to gauge overall learner engagement.
- **Retention Rates:** Measures how many learners continue through the course compared to those who drop out, providing insights into course effectiveness and learner satisfaction.
- **Custom Reporting Plugins:** Tools which enhance reporting capabilities, allowing for deeper insights into various metrics such as course completion times and detailed learner engagement analytics.
- **Feedback activity:** To gather feedback from learners, Moodle offers a survey tool, which allows for creating customized surveys.

In order to evaluate the training and assess relevant KPIs for training, the Kirkpatrick Evaluation Model<sup>3</sup> will serve as the method to obtain this information. The Kirkpatrick Evaluation Model is a widely recognized framework for assessing the effectiveness of training programs. Developed by Donald Kirkpatrick in the 1950s, this model breaks down the evaluation process into four distinct levels, each focusing on different aspects of training outcomes.

By assessing each level systematically, organizations can identify strengths and weaknesses in their training initiatives and make informed decisions about future learning strategies. Additionally, while Levels 1 and 2 are relatively straightforward to measure, Levels 3 and 4 require more complex and long-term data collection and analysis, making them more challenging but also more informative regarding long-term training effectiveness. Therefore, we propose to implement level 1 and 2 evaluation activities for the duration of EUCAIM as a project but lay the groundwork for a long-term full level evaluation in the future. The results of the level 1 and 2 assessments will be documented in T2.5/D2.7.

### Learning and Impact Evaluation for EUCAIM Training



*Learning and impact evaluation according to the Kirkpatrick Model*

<sup>3</sup> Kirkpatrick, D. L. (1959). Techniques for Evaluation Training Programs. Journal of the American Society of Training Directors, 13, 21-26.

### **Level 1: Reaction**

- Objective: Measure the learners' immediate reactions to the training.
- Focus: This level assesses how learners felt about the training experience, including their satisfaction, engagement, and perceived relevance of the content to their roles.
- Methods: Typically evaluated through post-training surveys or feedback forms. Questions may cover aspects such as training objectives, course materials, and facilitator effectiveness.

How learners react and perceive the training will be monitored by conducting a satisfaction survey. A measure of the degree of usage, completion rate and time spent on training will be included. This will be implemented with the Moodle built-in Feedback function, or with the Questionnaire add-on.

### **Level 2: Learning**

- Objective: Evaluate the extent to which learners have acquired the intended knowledge and skills.
- Focus: This level determines whether the training objectives were met and if learners can demonstrate understanding of the material.
- Methods: Assessment can include post-training tests or quizzes to measure knowledge retention and skill acquisition.

To measure the extent to which learners acquired the intended knowledge, specific tests will be administered in relevant sections of the Moodle courses. The content of each test will be defined on the basis of learning objectives of the topic. This will be implemented with the Moodle Quiz function.

### **Level 3: Behavior**

- Objective: Assess whether learners apply what they learned in their projects.
- Focus: This level examines changes in behavior resulting from the training. It looks at whether learners are able to implement new skills or knowledge effectively in their projects.
- Methods: Evaluation often involves observations, performance reviews, and feedback from peers or PIs several months after training to allow time for behavior changes to manifest.

The related evaluation can be performed with the administration of specific questionnaires. Since the implementation of knowledge acquired through the training requires a period of

maturation and a contextualized assessment, these questionnaires should be provided to learners after completion of their projects.

#### **Level 4: Results**

- Objective: Measure the tangible impact of the training.
- Focus: This level evaluates the overall effectiveness of the training in achieving set goals.
- Methods: Data collection may include analyzing key performance indicators related to the successfulness and completion of a learner's project and other relevant outcomes.

This is a long term achievement, therefore, during the project phase of EUCAIM, it will only be possible to evaluate KPIs retrieved from the Level 1 and 2 evaluations. Specific surveys administered to the learners that try to assess training effects that exceed the EUCAIM project phase will be subject to the training implementation of the future EDIC.

### **3. Evaluation of Training Plan**

#### **3.1. User Profiles for Training in EUCAIM**

From the *Stakeholder Management Plan*, the classification of stakeholders into four groups is based on their expertise and expectations from the EUCAIM platform. Briefly, the categories are explained below.

**Data Holders (Providers of Images and Clinical Data):** Data holders, including hospitals, repositories, European projects, research infrastructures, cancer screening programs and patient associations acting as data altruism organizations, among others, are essential for EUCAIM's projects since they provide high quality, standardized images and related clinical data. Moreover, they contribute with feedback and participate in workshops, and promote the platform within their institutions to encourage broader engagement.

EUCAIM supports stakeholders by aiding data integration, ensuring standardization and interoperability, and guiding compliance with GDPR and EHDS standards for safe and ethical data sharing. The support will be given also through tailored training courses provided by the T2.2 working groups. It fosters research collaborations, enhancing the value of shared data.

**Software Providers (Software, Tools, AI Models):** Software providers, from SMEs to large companies, from imaging Repositories to European Projects, contribute with innovative software and AI models to enhance the EUCAIM platform. In return, EUCAIM offers visibility, networking opportunities. Providers are expected to deliver seamless, high-quality software, engage in feedback sessions to improve the platform, and comply with EUCAIM's standards to ensure interoperability and usability.

**Data Users (Researchers, Innovators, SME and Large Companies):** Data users, including SMEs, Large Companies, hospitals, universities, research centers, innovators, AI modelers, and policymakers, gain access to high-quality cancer imaging data under request, training resources, and networking opportunities through EUCAIM. These resources support AI development, research, innovation, and collaboration in cancer imaging. In return, data users are expected to leverage the platform for advancements in cancer diagnostics, provide feedback to improve data quality and usability, and promote EUCAIM to expand its community.

**Management (Dissemination, Legal, Ethical, and Patient Associations):** The management group, including ELSI and IPR experts, professional societies, patient associations, government representatives, and data protection authorities, offers expertise in legal, ethical, and social aspects, shaping EUCAIM's framework and sustainability strategy. In return, EUCAIM engages them in consultations, initiatives, and public outreach, providing visibility and partnership opportunities.

**Data Holders – LS AAI registration required**

Hospitals, repositories, European projects, data altruism organisations

- (1) **Mandatory legal and ethical training for data holders**
- (2) **Training for EUCAIM platform users**
  - Specifically tailored to data provision

**Software Providers – LS AAI registration required**

SME, industry

- (1) **Mandatory legal and Ethical Training**
- (2) **Training for EUCAIM platform users**
  - Specifically tailored to software provision

**Data Users – LS AAI registration required**

SME, hospitals, universities, industry, biomedical research institutions

- (1) **Mandatory legal and Ethical Training**
- (2) **Training for EUCAIM platform users**
  - Specifically tailored to data access, data usage and FAIR data

**Management – public training course**

ELSI, IPR experts, professional societies, patients' organisations, European infrastructures (EDICs, ERICs), government representatives, data protection agencies

- (1) **Introduction to the EUCAIM platform**
  - Introduction to EUCAIM
  - User registration
  - Legal and ethical aspects
  - Understanding the data federation
  - Media library

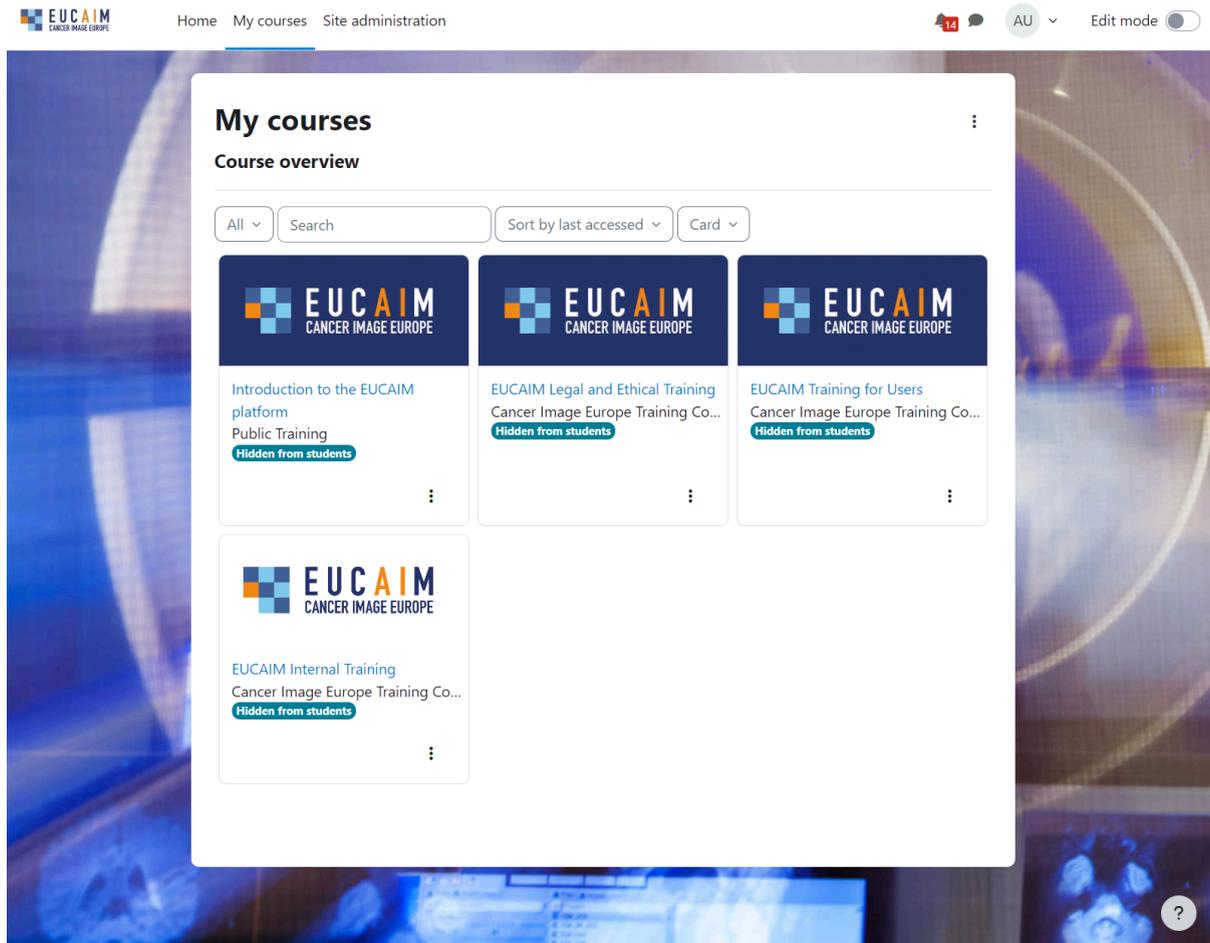
*User Profiles for Training (users who combine several profiles, e.g. provide data and use data, can have access to the full training spectrum)*

### 3.2. EUCAIM Moodle Courses According to User Profiles

The EUCAIM training courses<sup>4</sup> are explained below: in contrast to the initial module based outline in the training plan (D2.2), the team decided to include a separate mandatory legal and ethical training course that will be specifically shaped to user profiles categories and

<sup>4</sup> <https://training.eucaim.cancerimage.eu/>

sub-categories (see 2.4 and 3.1). The courses tailored to the different user profiles are described in detail in tables 3-5, followed by an explanation of the respective concepts for each training topic. Note that the training course for internal purposes (consortium only) is not listed in this overview as it is only used to collect internal documents, records of sessions, meetings and webinars and share this information among consortium members. Therefore, the internal training course is made available to the consortium through the training team but is not subject to the development of training materials by the training team.



*Courses in the Moodle Platform: Introduction to the EUCAIM platform (public), EUCAIM Legal and Ethical Training (registered users), EUCAIM Training for Users (registered users), EUCAIM Internal Training (consortium only)*

## Introduction to EUCAIM - Public Training Course

User Profile	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
<b>MANAGEMENT</b>	ELSI, IPR Experts, Professional Societies, Patients' Associations, Infrastructures (EDIC/ERIC), Government Representatives, Data Protection Authorities, the general public and potential new users	Introduction to the EUCAIM platform (public, guest account)	<b>Introduction to EUCAIM</b> <ul style="list-style-type: none"> <li>History and mission of EUCAIM</li> <li>Project Summary</li> </ul>	<b>Introduction to EUCAIM</b> <ul style="list-style-type: none"> <li>Understand the project's genesis and mission</li> <li>Gain insights into EUCAIM's development</li> </ul>
			<b>User registration</b> <ul style="list-style-type: none"> <li>How to obtain an LS AAI registration</li> </ul>	<b>User registration</b> <ul style="list-style-type: none"> <li>Be able to create a LS AAI account and access the full functionalities of the dashboard</li> </ul>
			<b>Legal and ethical aspects</b>  <i>For Ethical Representatives (Data Protection Authorities, ELSI, IPR Experts, Government Representatives, EDIC/ERIC):</i> <ul style="list-style-type: none"> <li>Provide information on the functionalities of the platform, educating DPOs and ethical committees</li> </ul>  <i>For Patients Associations:</i> <ul style="list-style-type: none"> <li>Inform about the secondary use of health data for research (GDPR Compliance), review of data use information and analyses of generated results</li> </ul>	<b>Legal and Ethical Aspects</b>  <i>For Ethical Representatives (Data Protection Authorities, ELSI, IPR Experts, Government Representatives, EDIC/ERIC):</i> <ul style="list-style-type: none"> <li>Understand the platform's commitments to ethics, privacy and ensuring patients' rights</li> <li>Understand the specific requirements for operating in the EHDS</li> <li>Be able to discriminate projects that are submitted without meeting mandatory compliance requirements</li> <li>Understand the new ethical dimensions of AI</li> <li>Distinguish the nature of AI-based projects in order to establish purely ethical or experimental requirements under the Medical Device Regulation</li> </ul>  <i>For Patients Associations:</i> <ul style="list-style-type: none"> <li>Enable them to understand the platform's commitments to ethics, privacy and ensuring patients' rights</li> <li>Receive comprehensive information about the platform and its potential uses and benefits</li> <li>Transparency of the EUCAIM possibilities</li> </ul>
			<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Emphasize the application of FAIR principles in data sharing for innovation, including the development of AI-based tools, diagnostics, and personalized medicine solutions.</li> <li>Cover regulatory requirements and collaboration opportunities in multi-stakeholder environments.</li> </ul>	<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Understand how FAIR data principles enhance innovation and collaboration in the development of tools and solutions for cancer research.</li> <li>Gain insights into navigating regulatory requirements and leveraging data for commercial applications.</li> </ul>

Table 3: EUCAIM Public Training Course

## Mandatory Legal and Ethical Training for Users

Note that in contrast to the public training course and the training for EUCAIM platform users, the user profiles for the legal and ethical training are containing a more granular structure, with the aim of delivering a highly specific training. Therefore, a course dedicated specifically to the legal and ethical training for users will be offered.

User Profile	Sub-Category	Scope of the training	Learning Objectives
DATA HOLDERS	IT teams of Hospitals, clinical centers and screening programs (RWDH)	<ul style="list-style-type: none"> <li>For federated nodes, requirements to federate their data to EUCAIM, guidelines for data collection, curation and management (metadata and CDM), recommendations on data mapping (data standards and formats) and execution of distributed processing.</li> <li>For data converging directly into the EUCAIM platform, compliance with GDPR and anonymization procedures to respect patients privacy regulations.</li> </ul>	<ul style="list-style-type: none"> <li>Understand and apply concepts related to legal and ethical compliance-oriented design</li> <li>Data protection by design and by default</li> <li>Design requirements of AI systems from their risk level</li> <li>Understand the specific requirements for operating in the European Health Data Space (EHDS)</li> <li>Understand and being compliant with the requirements of federation</li> </ul>
	Repositories and European Projects	<ul style="list-style-type: none"> <li>Recommendations on data mapping (data standards and formats), guidelines to follow to be integrated into EUCAIM while being compliant with the GDPR and national regulations.</li> </ul>	
	Patients Associations- Data altruism organisations	<ul style="list-style-type: none"> <li>Information about the secondary use of their health data for research and innovation (GDPR Compliance) including anonymisation processes, review of data use information and analyses of generated results</li> </ul>	<ul style="list-style-type: none"> <li>Understand the platform's commitments to ethics, privacy and ensuring patients' rights</li> <li>Receive comprehensive information about the platform and its potential uses and benefits.</li> </ul>
SOFTWARE PROVIDERS	SME, Large Companies	<ul style="list-style-type: none"> <li>Information about the Platform and its potential use for R&amp;I</li> </ul>	<ul style="list-style-type: none"> <li>Understand the requirements demanded by the platform and information to be provided for product development on the platform</li> <li>Acquire the competences established for data users in the European framework</li> <li>If the software provider is external, with whom we are going to contract for their tools, their training should be limited to the legal and ethical requirements of the platform</li> <li>If the software providers have only testing purposes, their training should be coupled with the data user training.</li> </ul>

User Profile	Sub-Category	Scope of the training	Learning Objectives
	Repositories and European Projects	<ul style="list-style-type: none"> <li>Recommendations and guidelines to follow to integrate their analytical AI software developed for clinical research and innovation</li> </ul>	<ul style="list-style-type: none"> <li>Understand the requirements demanded by the platform to integrate and use the provided software</li> <li>Acquire the competences established for data users</li> <li>If the software provider is external, with whom we are going to contract for their software, their training should be limited to the legal and ethical requirements of the platform</li> <li>If the software providers have only testing purposes, their training should be coupled with the data user training.</li> </ul>
	Research Institutions and Hospitals <i>(Universities, Biomedical Research Institutions and clinical staff)</i>	<ul style="list-style-type: none"> <li>Training to use the EUCAIM Platform and related AI and HPC tools for clinical research including common data formats (CDM and metamodel), exploitation of the platform data for selection of patient cohorts</li> </ul>	<ul style="list-style-type: none"> <li>Understand and apply the requirements deriving from the applicable legislation; translate regulatory obligations into research design</li> <li>Operate in the EHDS</li> <li>Ensure transparency with patients and authoritative non-interference in consent-based processes</li> <li>Know and understand specific duties such as safety and non-identification commitments</li> <li>Understand the specific requirements arising as a result of the use of AI</li> <li>Identify strategic collaboration frameworks with essential enablers in their organisations: data protection officer, security officer, data analysts and others</li> </ul>
<b>DATA USERS</b>	SME, Industry, AI developers	<ul style="list-style-type: none"> <li>Information about the Platform and its potential use for R&amp;I</li> </ul>	<ul style="list-style-type: none"> <li>Understand and apply the requirements deriving from the applicable legislation; to translate regulatory obligations into research design</li> <li>Understand the specific requirements arising as a result of the use of AI tools</li> </ul>

*Table 4: Mandatory Legal and Ethical Training*

In light of the importance of implementing safety measures for security, cataloguing, metadata, interoperability, data holders and software providers will receive training that will cover all the necessary aspects through a synergic collaboration of WP2, WP3, WP5, WP7.

## Training for EUCAIM Platform Users - Course for Registered Users

User Profiles	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
DATA HOLDERS	Real World Data Holders, Repositories, European Projects, Research Infrastructures, Biomedical Research Institutions, Data Altruism Organisations	EUCAIM Training for Users (LS AAI registration required)	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Explains user profiles and general learning objectives</li> </ul>	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Be able to understand the user profiles and learning objectives for each user profile</li> <li>Understand groups functionality and be able to switch to another user profile moodle group in order to receive the training relevant for the respective group.</li> </ul>
			<b>Technical Training</b>  <i>For Local Data Managers (IT teams):</i> <ul style="list-style-type: none"> <li>Setting up, configuring, and maintaining the node infrastructure and connectivity for data provision within EUCAIM</li> <li>Configuring the transfer of data to the reference nodes</li> </ul>  <i>For non-technical profiles (clinicians, data scientists, researchers, ethical committees):</i> <ul style="list-style-type: none"> <li>Gaining a high-level understanding of the federation infrastructure and the technical safeguards in place for data</li> </ul>	<b>Technical Training</b>  <i>For Local Data Managers (IT teams):</i> <ul style="list-style-type: none"> <li>Understand the technical requirements by tier level</li> <li>Hardware Installation: Perform the physical setup of hardware components, ensuring compliance with power, stability, and ventilation requirements.</li> <li>Installing Required Software: Install and configure essential software components needed both for federated querying and processing, and data preparation and data transfer to the reference nodes.</li> <li>Network Configurations: Configure network settings, including firewall adjustments and static IP assignment, to establish stable connectivity with EUCAIM.</li> <li>Federated Node Integration: Set up and integrate node components to enable secure communication with EUCAIM central services.</li> <li>Registering to Services: Register the node and its services in the EUCAIM Identity and Access Management System (IAM) to complete integration and enable data federation capabilities.</li> <li>Maintenance and Monitoring: Monitor node performance, conduct regular maintenance tasks, and use local monitoring tools to maintain node health and functionality.</li> <li>Best Practices for Security: Apply best practices for node security, including physical security measures, access control, and data encryption.</li> <li>Backup and Recovery: Implement backup and recovery strategies to ensure data continuity and recoverability in case of system failure or data loss.</li> </ul>  <i>For non-technical profiles (clinicians, data scientists, researchers, ethical committees):</i> <ul style="list-style-type: none"> <li>Federation Basics: Gain a basic understanding of how EUCAIM's federated structure works and how it secures</li> </ul>

User Profiles	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
			security	<ul style="list-style-type: none"> <li>clinical data to facilitate research and innovation collaboration.</li> <li>Data Security Basics: Understand the basic technical safeguards that ensure patient data privacy and security within the EUCAIM federation.</li> </ul>
			<b>Data Provision</b> <ul style="list-style-type: none"> <li>Training on tier-level data preparation requirements and practical use of tools for de-identification, quality control, curation, harmonization, and annotation</li> </ul>	<b>Data Provision</b> <ul style="list-style-type: none"> <li>Understand data preparation requirements by tier-level</li> <li>Learn how to use the available tools for data de-identification, data quality and cleaning, data harmonisation and data annotation.</li> </ul>
			<b>EUCAIM Hyperontology/CDM</b> <ul style="list-style-type: none"> <li>Provide knowledge about EUCAIM hyperontology and CDM for data consistency and usability.</li> </ul>	<b>EUCAIM Hyperontology/CDM</b> <ul style="list-style-type: none"> <li>Gain an in-depth understanding of the EUCAIM hyperontology.</li> <li>Gain an in-depth understanding of the EUCAIM CDM.</li> <li>Learn how to structure and prepare data in alignment with EUCAIM hyperontology standards.</li> <li>Understand how to integrate data seamlessly into the EUCAIM infrastructure while maintaining compatibility and quality.</li> <li>Learn how to integrate data according to their tier level.</li> </ul>
			<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Focus on understanding the technical requirements for secure, efficient, and compliant access to clinical and imaging data</li> <li>Includes data infrastructure, interoperability standards, and FAIR data principles.</li> </ul>	<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Learn how to implement, maintain, and optimize systems for data sharing that adhere to FAIR principles, while ensuring compliance with ethical and legal standards.</li> <li>Understand interoperability frameworks and secure data transfer protocols.</li> </ul>
			<b>Library</b> <ul style="list-style-type: none"> <li>Contains relevant documentation</li> </ul>	<b>Library</b> <ul style="list-style-type: none"> <li>Be able to find relevant documentation</li> </ul>
			<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Explains how to use the helpdesk</li> </ul>	<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Be able to register for the helpdesk in order to create a ticket for any issue that may arise and that will need attention from EUCAIM staff.</li> </ul>

User Profiles	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
SOFTWARE PROVIDERS	SMEs, Large Companies, AI developers	EUCAIM Training for Users (LS AAI registration required)	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Explains user profiles and general learning objectives</li> </ul>	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Be able to understand the user profiles and learning objectives for each user profile</li> <li>Understand groups functionality and be able to switch to another user profile moodle group in order to receive the training relevant for the respective group.</li> </ul>
			<b>Technical Training</b> <ul style="list-style-type: none"> <li>Gaining a high-level understanding of the federation infrastructure and the technical safeguards in place for data security</li> </ul>	<b>Technical Training</b> <ul style="list-style-type: none"> <li>Federation Basics: Gain a basic understanding of how EUCAIM's federated structure works and how it secures data to facilitate research collaboration.</li> <li>Data Security Basics: Understand the basic technical safeguards that ensure patient data privacy and security within the EUCAIM federation</li> </ul>
			<b>Software Provision</b> <ul style="list-style-type: none"> <li>Explains SW provision, including technical requirements, security practices, documentation standards, and tool submission and validation</li> </ul>	<b>Software Provision</b> <ul style="list-style-type: none"> <li>Learn the technical requirements and process for dockerization and registration across different environments (federated and reference nodes)</li> <li>Develop skills to validate tools, ensuring they meet quality standards and function reliably across environments</li> <li>Develop skills in creating comprehensive documentation, including user manuals, installation guides, and usage guidelines.</li> <li>Learn about the implementation of security practices</li> </ul>
			<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Focus on understanding the technical requirements for secure, efficient, and compliant access to clinical and imaging data.</li> <li>Includes data infrastructure, interoperability standards, and FAIR data principles.</li> <li>Focus on advanced data access methods, computational tools, and frameworks for analyzing clinical and imaging data in oncology research. Includes real FAIR data application.</li> </ul>	<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Learn how to implement, maintain, and optimize systems for data sharing that adhere to FAIR principles, while ensuring compliance with ethical and legal standards.</li> <li>Understand interoperability frameworks and secure data transfer protocols.</li> <li>Learn to effectively access, integrate, and analyze clinical and imaging FAIR data.</li> </ul>
			<b>Library</b> <ul style="list-style-type: none"> <li>Contains relevant documentation</li> </ul>	<b>Library</b> <ul style="list-style-type: none"> <li>Be able to find relevant documentation</li> </ul>
			<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Explains how to use the helpdesk</li> </ul>	<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Be able to register for the helpdesk in order to create a ticket for any issue that may arise and that will need attention from EUCAIM staff.</li> </ul>

User Profiles	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
DATA USERS	SMEs, Hospitals, Universities, Large Companies, Research Centers, Innovators	EUCAIM Training for Users (LS AAI registration required)	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Explains user profiles and general learning objectives</li> </ul>	<b>Introduction to EUCAIM Training</b> <ul style="list-style-type: none"> <li>Be able to understand the user profiles and learning objectives for each user profile</li> <li>Understand groups functionality and be able to switch to another user profile moodle group in order to receive the training relevant for the respective group.</li> </ul>
			<b>Technical Training</b> <ul style="list-style-type: none"> <li>Gaining a high-level understanding of the federation infrastructure and the technical safeguards in place for data security</li> </ul>	<b>Technical Training</b> <ul style="list-style-type: none"> <li>Federation Basics: Gain a basic understanding of how EUCAIM's federated structure works and how it secures clinical data to facilitate research and innovation collaboration.</li> <li>Data Security Basics: Understand the basic technical safeguards that ensure patient data privacy and security within the EUCAIM federation.</li> </ul>
			<b>Data Access</b> <ul style="list-style-type: none"> <li>Guiding users to follow data access procedures</li> <li>How to correctly fill a data access request</li> <li>Describe the process for evaluating a data access request</li> </ul>	<b>Data Access</b> <ul style="list-style-type: none"> <li>Make users autonomous and aware in forwarding a request for access to data that is formally correct and well-framed in a research and/or innovation project.</li> <li>Understand the differences between the data harvest model (for new observational studies with RWD) and the data push model (with already existing repositories coming from the secondary use) within EUCAIM</li> </ul>
			<b>EUCAIM Hyperontology/CDM</b> <ul style="list-style-type: none"> <li>Provide knowledge about EUCAIM hyperontology and CDM.</li> </ul>	<b>EUCAIM Hyperontology/CDM</b> <ul style="list-style-type: none"> <li>Acquire a basic understanding of EUCAIM hyperontology principles and CDM data structure.</li> </ul>
			<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Provide foundational knowledge on accessing and utilizing clinical and imaging data for research while ensuring compliance with ethical and FAIR principles.</li> <li>Covers data integration, data preprocessing, and use-case-specific considerations in oncology research.</li> </ul>	<b>FAIR Data</b> <ul style="list-style-type: none"> <li>Understand how to access and use clinical and imaging data in compliance with FAIR principles.</li> <li>Gain practical knowledge on integrating and preparing data for analysis, ensuring ethical considerations and privacy preservation.</li> <li>Learn to effectively access, integrate, and analyze clinical and imaging FAIR data.</li> </ul>
			<b>Data Provision</b> <ul style="list-style-type: none"> <li>Explains how to annotate and harmonise data</li> </ul>	<b>Data Provision</b> <ul style="list-style-type: none"> <li>Learn how to use the available tools for data annotation and harmonisation.</li> </ul>
			<b>Library</b>	<b>Library</b>

User Profiles	Stakeholders	Moodle Course	Scope of Training	Learning Objectives
			<ul style="list-style-type: none"> <li>Contains relevant documentation</li> </ul>	<ul style="list-style-type: none"> <li>Be able to find relevant documentation</li> </ul>
			<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Explains how to use the helpdesk</li> </ul>	<b>EUCAIM Helpdesk</b> <ul style="list-style-type: none"> <li>Be able to register for the helpdesk in order to create a ticket for any issue that may arise and that will need attention from EUCAIM staff.</li> </ul>

*Table 5: Training for EUCAIM platform users*

### 3.2.1. Concept for Legal and Ethical Training

The legal and ethical training is coordinated by the University of Pisa (UNIFI), which involves the legal team, the experts of WP3, to ensure the fulfillment of the legal requirements and knowledge to gather the access to the EUCAIM platform.

The idea of this training is to create an educational environment that can offer the necessary knowledge and tools to correctly use and explore the EUCAIM platform.

It is important to highlight that the legal and ethical training is the only mandatory training course for all platform users and, independently of their role, it will educate users to correctly use it while being compliant with the ongoing regulations. It will also adhere to the actions and tasks that the users aim to perform on the platform.

The two main ways to deliver the training are:

- A general, high-level training program would streamline initial development efforts due to its broad scope, but would likely result in a high volume of legal support requests from users seeking individualized guidance as they progress. Anticipating the future needs of the EUCAIM project, this approach may place considerable demand on the legal team, increasing the risk of an ongoing, resource-intensive support cycle
- A more detailed, structured program would require greater effort to develop upfront, but could reduce users' need for specific legal guidance, thus lowering long-term support demands on the legal team

The team decided to create tailored material according to the different users profiles and to optimize the material in relation to their purpose, trying to limit the users' needs to ask for help and support.

A general list of contents for this training course will be provided and will be adapted specifically to the EUCAIM project and platform overview. The education will provide:

- basic concepts in the European Health Data Space,
- admitted secondary uses of electronic health data,
- requirements for data sharing; legal and ethical requirements for data provision,
- requirements for applying for and obtaining permission to access data,
- legal and ethical requirements for data usage

The training materials on the General Data Protection Regulation (GDPR) will cover the following key areas:

### **Fundamental Concepts:**

- understanding personal data, including processing requirements and safeguards for special categories of data,
- clarification of the distinction between anonymised and pseudonymised data, addressing common misconceptions related to data de-identification,
- consent and data donation frameworks for organizations facilitating altruistic data sharing: compliance requirements,
- ensuring transparency and safeguarding patient rights,
- ensure appropriate policy or relevant actions have been taken into account for managing unexpected outcomes of the data use.

### **Data Protection by Design and by Default:**

- specific GDPR requirements for developing information systems and other technological processes involving data processing,
- guidelines for designing research and innovation methodologies (minimum mandatory information, number of subjects, cases etc.),
- design and governance standards for managing data in high-risk artificial intelligence (AI) applications.

### **GDPR-Compliant Data Sharing and Access:**

- requirements for data sharing and access within the GDPR framework, with emphasis on regulatory compliance.

### **Ethical Considerations and Legal Compliance:**

The course will also address ethical obligations, incorporating education on the Helsinki Declaration of the World Medical Association (WMA) as well as relevant national laws. Specific areas include:

- European Health Data Space regulations,
- Artificial Intelligence governance, particularly:
  - Conducting Fundamental Rights Impact Assessments
  - Utilizing the Assessment List for Trustworthy Artificial Intelligence (ALTAI) and the EU Artificial Intelligence Act

- Intellectual Property Rights (IPR) and trade secret protections
- Accountability practices, including documentary evidence of ethical and legal compliance for data re-use

The guidelines that will be created and delivered will be particularly focused on self-learning and the team will require a control over the actual time that users spend on the specific document to ensure the overall lecture of it. In texts, a scrolling control will be required while if presentations or videos will be produced, time constraints will be set, according also to the Moodle platform and tools. This ensures that the team can verify whether users have thoroughly reviewed all the provided materials.

Guidelines will be framed to be exploitable from users from different countries and with disabilities at different levels which will be leveraged with the use of automatic translation in the most spoken European languages, subtitles and alternative communication methods.

Since the legal and ethical training course is the only mandatory course, a final user assessment of the provided educational materials will be conducted.

Outside the Moodle platform, the team and the legal experts suggested holding webinars to promote the dissemination of the legal training and to face aspects related to the ethical and privacy issues. The importance for the platform users to be compliant to the GDPR and the main patients' privacy's rights will be highlighted through a series of distributed and open webinars.

### **3.2.2. Concept for Technical Training**

The technical training is structured into two main levels, designed to align with the different technical capabilities and responsibilities of the users.

#### Basic Technical Training

This level is aimed at non-technical users, including clinicians, researchers, innovators, ethical committees, and patient organizations, among others, who will benefit from a general understanding of the federated infrastructure. The basic technical training covers the fundamentals of the EUCAIM federated infrastructure and explains how it ensures data security and privacy.

This material is particularly useful for addressing general queries about the technical aspects of the infrastructure. It also facilitates informed decision-making by ethical committees when evaluating projects that utilize the EUCAIM federated infrastructure.

### Advanced Technical Training

The advanced training is targeted at Local Data Managers responsible for managing local nodes within the federated network. These profiles require specific, detailed technical knowledge to set up, configure, and maintain a federated node, as well as transfer data to the reference nodes, in compliance with EUCAIM's standards.

The advanced technical training material includes:

- hardware and software installation,
- network and connection configuration,
- integration into the federated network,
- node monitoring, maintenance, and troubleshooting,
- backup and recovery procedures.

An effective technical training program for IT personnel ensures that all nodes are installed and operated consistently to maintain the security and stability of the federated infrastructure. Additionally, it reduces dependency on the technical support team by enabling Local Data Managers to resolve issues autonomously.

This structured approach to technical training ensures that all EUCAIM users have access to the level of technical detail they require. Non-technical users will gain a clear understanding of the federated infrastructure and its security features, while IT teams will acquire the expertise to independently set up and maintain local nodes, ensuring compliance with EUCAIM standards and minimizing support needs.

### **3.2.3. Concept for Training of Data Provision**

Data provision training will focus on equipping users with both theoretical knowledge and practical skills in the essential aspects of data provision, ensuring they are capable of handling data in compliance with EUCAIM standards and policies.

The training material for data provision covers the following key areas:

- Understanding data preparation requirements by tier-level. The training begins with an overview of the different tiers implemented in EUCAIM and their corresponding data preparation requirements.
- Users will be guided through the data preparation process (data de-identification, data cataloguing, data quality and curation, data harmonization and annotation).

Participants will learn how to prepare data, ensuring it meets the required standards of quality, compliance and consistency.

- Practical training on the available tools in EUCAIM for data preparation will also be provided.

This training has been designed to target two types of users:

- Data holders: They will be trained covering the entire content of this module and it is mandatory for these users.
- Data users: who may have access to the specific sections explaining image annotation and how to use the available tools in EUCAIM for this purpose. This is intended to improve data users' experience within EUCAIM.

#### **3.2.4. Concept for Training of EUCAIM Hyperontology/CDM**

The EUCAIM Hyperontology/CDM (Common Data Model) training program is designed to provide both data holders and data users with the necessary knowledge and skills to effectively interact with and leverage the EUCAIM infrastructure. The training focuses on understanding the EUCAIM hyperontology framework, the CDM, its application in ensuring data consistency and usability, and its role in supporting the integration and utilization of data across the platform.

The training program is divided into two tracks: one for data holders and another for data users, tailored to their unique roles and responsibilities within the EUCAIM infrastructure.

##### Training for data holders

The aim is to equip data holders with the knowledge and tools required to prepare and integrate their data into the EUCAIM infrastructure in compliance with EUCAIM hyperontology standards and CDM. The training designed for the data holders will cover the following key areas:

- introduction to EUCAIM hyperontology,
- data structuring following the CDM and preparation,
- data integration into EUCAIM according to tier-level.

##### Training for data users

The goal is to provide data users with an essential understanding of EUCAIM hyperontology and CDM to facilitate effective data exploration and utilization for research and innovation.

### **3.2.5. Concept for Training of Software Provision**

This section aims to provide software providers with a comprehensive understanding of the technical, security, and documentation requirements necessary for the successful deployment and operation of their software.

The software provision training material is focused in the following areas:

- technical requirements for software provisioning process,
- software dockerization and registration across different environments (federated and reference nodes),
- software validation to ensure quality standards,
- generation of comprehensive documentation for software users,
- security practices.

### **3.2.6. Concept of Training for Data Access and FAIR Data**

This section aims to equip users with the skills to effectively access, process, and share clinical and imaging data across EUCAIM. Emphasis will be placed on aligning with the FAIR principles to enhance data discoverability, usability, and collaboration, ultimately supporting high-impact cancer research and fostering a culture of responsible and efficient data sharing. This module will cover key aspects regarding FAIR data and data access for different profiles (data holders, data users, software providers, and managers), such as:

- guiding users to follow data access procedures,
- how to correctly fill a data access request,
- describe the process for evaluating a data access request,
- understand EUCAIM Tiers model
- FAIR data principles, interoperability standards, and secure data transfer protocols,
- the potential of FAIR data in multi-centric biomedical research,
- technical requirements for data FAIRification implementation and maintaining,
- how to access, integrate and analyze FAIR data.

This section is designed for different types of users: management (focusing on innovation, regulatory requirements and collaboration), data holders (aimed at providing the technical requirements and infrastructure), software providers (including technical details and advantages of data FAIRification), and data users (explaining the basics of data access and FAIR data and use-case-specific considerations).

## 4. EUCAIM Guidelines for Training

For the duration of the EUCAIM project phase, we have defined training guidelines according to which the training will be delivered. The training is based on the following principles:

- follow an asynchronous training procedure: no scheduling required, learning is completely self-paced and can therefore be integrated into the individual's personal schedule;
- implement a backward design: educational content development is based on considering the user profiles first and consequently the desired learning outcomes according to these profiles;
- integrate EUCAIM resources in the training structure: make use of the strong collaborative efforts in EUCAIM and re-use and adapt materials and contents that already have been created by the different EUCAIM experts;
- security by design: include all relevant target groups (i.e. internal, public and platform users) and choice of LMS supporting security by design;
- create training pathways according to user profiles: enabling the delivery of user specific training;
- scalability: the EUCAIM training platform built during the project phase is scalable and can be adjusted in accordance with the needs of a future EDIC.

## 5. Lessons Learned and Future Recommendations

The decision to use a LMS to deliver user specific training was based on the vast advantages of an LMS described in this document. The main learning is that using an LMS on the one hand requires more effort than simply creating training materials that can be disseminated through a web page, but on the other hand allows for very specific delivery of training that can be targeted to specialized groups, it allows for enhanced evaluation and monitoring. In addition, for the future establishment of EUCAIM as an EDIC, the choice to use a LMS solution also opens up the possibility to further develop the training, to adapt to the needs that arise on the side of the users once the platform is running in full operational mode and to enhance the users' learning experience.

The Moodle based training platform developed during the project phase of EUCAIM lays the groundwork that will enable the EDIC to further develop this training offer. In summary this basic training platform contains:

- Four structured training courses with user specific groups that allow for delivering tailored training,
- integration of a set of plug-ins and features that are chosen based on the analysis in this document (see section 2),
- user management through the integration of the LS AAI and groups functions in Moodle.

The Moodle platform furthermore allows for a high degree of scalability especially in terms of communication and interaction options for users (e.g. such as forums, lectures etc.), however, upscaling the platform will require sufficient personnel to maintain, update and support the training. In terms of the sustainability of EUCAIM as an EDIC, we therefore propose to take into account the following options for training:

- a) free and open self-training,
- b) partnerships with training organizations for the commercialization of courses,
- c) contracted in-house training.