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A European Cancer Image Platform Linked to Biological and Health Data for Next-Generation Artificial Intelligence and Precision Medicine in Oncology

Deliverable D8.3:
Quality Assurance Guidelines

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Lead Beneficiary	Universitat de Barcelona (UB)
Author(s)	Isabell Tributsch, Katharina Heil, Karim Lekadir
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Acronyms

Name	Abbreviation
European Commission	EC
Project Coordinator	PC
Project Manager	PM
Work Package	WP

Table of Contents

1 Executive Summary

The Quality Assurance Guidelines establish standard procedures, best practices and overall rules to be used by all partners in the EuCanImage consortium. The Guidelines come into play in distinct situations during the project. These are, amongst others:

- Outline of the guidelines that will be followed by the consortium members to ensure high quality research, development and reporting.
- Outline of the measures to ensure high quality research and software development.
- Description of the procedures to identify scientific, technical or dissemination risks, or deviations from the Work Plan and contingency strategies to address these risks.
- Presentation of a list of research and performance indicators for each activity that will be evaluated during quality monitoring.

This document will assist the overall organisation, led by the Project Manager (PM) as well as Project Coordinator (PC) to guarantee the best possible project outcome.

The PC supervises the project execution from a scientific point of view and acts as the intermediary between the consortium and the European Commission, being in direct contact with EuCanImage's EC Project Officer.

2 Ensuring high quality research and development

In order to get the best possible results, considering content as well as its presentation, the following sections define guidelines for internal quality control and best practice.

This approach will also help all EuCanImage partners to stick to deadlines and submit material, including deliverables as well as reports on time and in accordance with the work plan.

2.1 Ensuring high quality research

To ensure high quality research, the EuCanImage Consortium will take the following approach:

- Deliver high quality deliverables, including reports and demos.
- Carry out constant progress monitoring, including regular calls amongst WP and working group members.
- Integrate a self-assessment strategy, especially regarding software development measures, set in place at institution level.
- Define of performance indicators, being are shared in this document. This will help everyone to keep on track and cross-compare with others.
- Paying great attention to data quality. The FAIR principle is used as a reference throughout the project, which will guarantee highest quality datasets and best practices.
- Publish work performed during the project in highly valued journals (aiming for high impact factors) and conferences.

Regarding journals and conferences, EuCanImage members will aim towards top conferences in their field of expertise. A concrete list can also be found in the project proposal (Section 2.2 a) *Dissemination and exploitation of results*. Publications also include conference proceedings, among others.

2.2 Ensuring high quality software development

Based on the interdisciplinary and highly computational focus of the EuCanImage project, best practices in software development are crucial to enable collaboration and guarantee quality. It is each institution's responsibility to put in place the most practical and secure measures covering their tasks.

It is highly recommended to use modern development methodologies, such as peer programming. Code should be open source and good commenting standards, making code understandable and reproducible, need to be followed. These practices will also ensure that information is kept and remains maintainable during the time past the project period. The consortium relies on best practices being followed by all individual partners.

3 Best practices regarding deliverables and reporting

Reporting guidelines, including deliverables and reports are explained in detail in D8.2 EuCanImage Project Handbook, Section 9 *Reporting Guidelines*.

3.1 Document Style Guide

Table 1: EuCanImage document (and report) style guide.

Type	Guideline & Example
Font & Text Size	Verdana, 10 A deliverable template can be found here in the shared google drive folder.
Titling	Sentence case will be used for titling; most major and minor words are lowercase, example: "New frontiers in research: Understanding project design"
References	Each peer-reviewed journal has its own format that must be respected if there are submissions planned. The following guidelines for citations are only for project reports, documents, and presentations to maintain consistency throughout. The Vancouver style **format** is to be used as the basis.
Article citation	1. Schroeder S, Baumbach A, Mahrholdt H. The impact of untreated coronary dissections on the acute and long-term outcome after intravascular ultrasound guided PTCA. Eur Heart J 2000;21:137-145.
Book citation	2. Nichols WW, Rourke MF. Aging, High Blood Pressure and Disease in Human. 3rd ed. London/Melbourne: Lea and Febiger; 1990.
Chapter citation	3. Nichols WW, O'Rourke MF. Aging, high blood pressure and disease in humans. In: Arnold E, ed. McDonald's Blood Flow in Arteries: Theoretical, Experimental and Clinical Principles. 3rd ed. London/Melbourne/Auckland: Lea and Febiger; 1990. p398-420.

Webpage citation	4. Panteghini M. Recommendations on use of biochemical markers in acute coronary syndrome: IFCC proposals. eJIFCC 14. http://www.ifcc.org/ejifcc/vol14no2/1402062003014n.htm (28 May 2004).
Sentence and paragraph spacing	One space after full stop. Single spacing should be used throughout the documents.
Language	British English should be consistently used throughout the document.
Contractions	Avoid contractions in formal reports, e.g. use "I am" instead of "I'm".
Dates	DD/MM/YYYY or 28 March 2019
Numbers	Between zero and ten to be written in words, e.g. one, two, three […] ten. From 11 onwards to be written using Arabic numerals, e.g. 12, 13, etc. An exception would be at the start of a sentence when numbers should be written out, e.g. "Nineteen partners attended the event." Percentages should always use Arabic numerals followed by the "%" symbol, e.g. 5%, 9%, 33%, 100%. Numbers in the thousands should use a comma for separation, e.g. 1,400; 63,000; 8,900,145; etc. The full stop should be used to denote decimals, e.g. 1.12; 2.56; 75.98; etc.
Currency	Euro symbol should be placed before the amount with no space, e.g. €12.12
Lists	No comma before last item; e.g. apples, oranges and pears
Special Symbols	"And" is preferred over "&", except for example when used in titling to shorten text length.

3.2 Internal deliverable review process

Since the ultimate responsibility to submit deliverables (and reports) lies with the Project Coordinator (and the responsible partner) a EuCanImage internal review process will be set in place. Therefore, several deadlines are set to guarantee a smooth workflow (see **Error! R eference source not found.** for an overview).

1) A **reminder** regarding deliverable and report deadlines will be sent, latest **eight weeks prior to the deadline**, by the Project Manager to the main institution responsible for the deliverable/report.
2) The contacted person, if not otherwise communicated, is responsible to be compliant with the following deadlines.

3) The institution/individual **responsible** (see Point 2) needs to elaborate the deliverable or redirect the work to others. He needs to ensure that the deliverable is shared with other involved consortium members, allowing enough time for feedback.
4) A **first draft** of the deliverable needs to be **shared with the Project Coordinator** as well as the **Project Manager four weeks** prior to the deadline.
5) Feedback will be given within maximum two weeks.
6) Depending on the feedback and state of the deliverable there may be some feedback and several updates/iterations.
7) A **final draft** of the deliverable needs to be shared with the **Project Coordinator** and **Project Manager one week before the deliverable deadline**. If the deadline coincides with a weekend, it needs to be shared two working days before the deadline.

If the responsible institution/individual expects any alterations to the proposed plan, these need to be communicated to the Project Coordinator and Project Manager as soon as possible. Especially so, if the deliverable deadline might not be respected.

Table 2: Overview of the EuCanImge deliverable/report submission process (including deadlines)

Two months prior	One month prior	Two weeks prior	One week prior	Deliverable/ Report Deadline
PM sends reminder to responsible.	Responsible sends 1st draft to PC & PM	PC feedback to responsible	Responsible institution/individual sends final draft to PC & PM	PC & PM submit deliverable/report to EC portal
Advise PM about changes in responsibility	Responsible involves all partners in the elaboration process	Iterative process	Final review (last minute changes/format check)	

4 Procedures for risk assessment and contingency activities

This section establishes measures and best practices regarding risk and risk management in EuCanImage. The main aim is to identify risk early, point out potential problems to involved partners as well as the PC and PM and quickly identify mitigation strategies.

4.1 Risk assessment

Risks are events that if not identified and/or dealt with may cause problems. Their sources might be internal or external and should be handled through standardised risk management actions. For example, risks can be specific to a task, WP or partner, but they can also be more widespread affecting several tasks and/or partners.

Each partner, task and WP leader should establish internal self-assessment measures to identify alterations of e.g. foreseen timelines that may potentially leading to a delay in results. This is specifically crucial when expected output needs to be reported upon in deliverables and/or reports.

If risk emerges based on everyday tasks it is most likely spotted by the involved individual working on a specific task. In such cases risk should be reported in a "bottom-up" approach from the individual to the task and/or WP leader. Considering task and WP level risks, these can also be identified based on a "top-down" view and should be identified by the task and

WP leader. He/she is supposed to address the observed situation with other team members before informing the PC and PM.

The PC, as the ultimate contact point with the EC, needs to be informed about any significant risks/alterations to the work plan as soon as possible.

4.2 Risk categories and (response) action plans

Risks can be manifold and the more their impact on the project is understood, the better they can be dealt with.

Therefore, four distinct risk levels have been identified. These are defined by the scope of the risk and its potential impact on the project, also considering the level of its effect.

Level 1: A risk specific to one or several tasks in a WP. Emerging problems affect the individual tasks and should be solvable by the WP leader. It is most likely that the risk causes a delay in the task completion but should not show a major effect on the objectives set for the WP itself. These risks should be dealt with across WP partners. The PC and PM need to be informed. A contingency plan will be elaborated and should not cause more than two to three months delay.

Level 2: A risk affecting a whole WP, possibly setting its successful completion at risk. Such a risk needs to be dealt with by the WP leader with assistance of other WP leaders as well as the PC (and PM). It is crucial to define risk causing tasks and obtain an in-depth understanding of key problems. If the risk can be mitigated by specific internal measures, these should be formulated and agreed upon. Effects of such risks should not alternate the WPs outcome, but rather, require updates in the used approaches. An overall delay/alteration should not be more than eight months.

Level 3: This type of risk affects a number of WPs, e.g. due to the fact that results obtained by one WP are required by another and a delay impedes others to carry out their defined tasks. Such internal risks, need to be addressed with everyone involved, including task and WP leaders of the respective tasks/WPs. The PC (and PM) have to be kept in the loop and a contingency plan needs to be elaborated. Delays should not be longer than eight months and regular updates between the involved parties are crucial to minimise delay and the risk itself.

Level 4: The highest risk level describes risks that put several WPs at risk and potentially impact the whole project. In such cases all WP leaders, as well as PC and PM, need to be informed. An in-depth risk analysis needs to be carried out as soon as possible after having identified the risk. Having understood its impact lead to the elaboration of a contingency plan. The external advisory board can be consulted to assist during the design and definition of taken measures. It is highly important to set clear deadlines regarding established contingency measures. The PM is in charge of supervising progress. In very crucial cases the Project Officer might be informed. If possible formal adjustments might be required and should be dealt with, with adequate time frames (the more time is available for conversation and negotiation, the better).

4.3 Risk monitoring and control

As previously highlighted all risks need to be flagged as soon as possible, involving key players as well as the PC and PM.

In cases where contingency plans are established, the PC and PM control progress based on established measures and deadlines.

Communication with the EC and EuCanImage's Project Officer is carried out by PC and PM (UB).

5 Research and performance indicators

This section outlines specific performance indicators for individual WPs and tasks, overall referred to as activities, defined in the project proposal.

Research specific indicators describe references to measure research progress, whereas performance indicators also capture details, such as the number of publications in first-tier conferences and journals in the respective fields.

The following tables represent WP specific indicators.

5.1 Indicators WP1

WP 1 focuses on the legal and ethical framework of the EuCanImage project.

Table 3: Overview of activities, research, and performance indicators in WP1.

Activity	Research Indicator	Performance Indicator
Assessment of legal and ethical constraints for data sharing	1. Assessment of the legislation in force in Europe and selected member states. 2. Define roles with legal liabilities and responsibilities. 3. Define forms of different user privileges and data access rights. 4. Analyse issues of data sharing with additional countries.	1. Responses from all data centres in the project (7 total) to the ELSI assessment questionnaire. 2. All active legal actors defined and classified in the policy framework and corresponding documents (D1.2). 3. At least 3 key juridical discrepancies (across countries or across use cases) identified and addressed in the policy frameworks. 1. At least 3 key issues identified and fully analysed, with proposed mitigations or resolutions, on EU-US data exchanges.
Set up of policy and contractual framework for governing transactions of cancer imaging data	1. Set up of a policy and contractual framework and ensure that obligations are met. 2. Identification of areas of particular concern or importance. 3. Reduce data transaction costs by implementing	1. 2 fully developed templates for Data Transfer and Data Processing agreements validated by WP1 and at least by 3 local legal teams at project's data centres, made available to the whole consortium.

	computable clauses in smart contracts	2. 3 published proposals for policy making in the area of: Imaging data management, EU-US biomedical data exchanges, ethical use of AI in cancer imaging. 1. 2 Smart contracts, specific to the EuCanImage blockchain implementation, implemented and deployed in test environment, covering data assets and users permissions.
Privacy-by-design review and requirements analysis	1. Analyse privacy-preserving technologies using privacy-by-design and by-default approaches.	1. 1 platform requirements document reviewed and annotated with legal and ethical requirements before implementation. 1. 1 requirements document validated by WP1 teams for implementation.
Analysis of ethical and social implications of AI-based cancer imaging solutions	1. Perform literature review on the topics of ethics in AI, automated clinical decision making and general medical ethics. 2. Organise workshop with experts on ethichs in AI to address and review the FUTURE Guiding Principles for AI in cancer imaging. 3. Address societal concerns to assess social and moral contexts. 4. Formalise a conceptual framework for AI in oncology.	1. Review of at least 4 publications on ethics of AI. 2. 1 Workshop will be held with experts on ethics of AI to review the FUTURE Guiding Principles for AI in cancer imaging. 3. Organisation of at least 3 semi-structured interviews and ECOUTER exercises with stakeholders. 4. Publication of 1 research and development guideline paper to design AI systems in oncology imaging.
Deployment of new approaches and incentives for open science	1. Analyse ethical, legal and economic analysis for data sharing incentives to data owners. 2. Select most suitable, scalable and flexible DOI system based on the TCIA experience. 3. Evaluation of legal and ethical frameworks for licensing data in exchange for value.	1. At least 5 of the EuCanImage publications during the project utilizing DOIs. 2. At least 2 documented and active functionalities in the data catalogue and back-end supporting users in the specification and sharing of DOIs as they utilized the platform. 1. At least 2 external data controllers among businesses and research

		sharing at least 1 data set on the platform.

5.2 Indicators WP2

WP 2 focuses on the clinical use cases, the requirements and feedback for the EuCanImage project.

Table 4: Overview of activities, research, and performance indicators in WP2.

Activity	Research Indicator	Performance Indicator
Definition of clinical requirements, specifications and consensus	1. Create definitions of all use cases (liver, colorectal and breast). 2. Define imaging and non-imaging parameters that will support creation of the AI algorithms. 3. Create consensus on clinical requirements for AI development and assessment. 4. Create consensus on platform functionalities, clinical and research uses by implementing Delphi method. 5. Regular update of consensus and communication to respective WPs. 6. Provide the quality control measures for the annotation process.	1. Approval of at least six out of eight use cases definitions by all clinical centers participating in the particular use case. 2. Consensus reached by all the clinical centers on the set of imaging parameters in at least six out of eight use cases. 3. At least 3 non-imaging parameters defined and implemented in at least six out of eight use cases' AI algorithms. 4. Considerations regarding all aspects (financial, healthcare, and legal) of AI development and assessment included in the consensus document. 5. 1 consensus document on platform functionalities published. 6. Updates of all consensuses performed after 2 and 3 years since starting the project by the Clinical Consensus Group. 7. Definition of quality control measures in the annotation process for all the use cases published.
Data deposition and annotation campaigns	1. Deposition of already annotated datasets from Consortium partners M1-M12. 2. Curation and deposition of the datasets from the clinical partners from M12.	1. Deposition of 5000 already annotated datasets in the EuCanImage platform by M18. 2. Curation and deposition of 80% of declared datasets in the central repository or making them available for

	3. Annotation campaigns in the participating clinical centers. 4. Exploitation of the intelligent distributed and collaborative annotation.	federated annotation and algorithm training by M36. 3. Annotation of 80% of datasests by M36 and 95% by M48. 4. At least one use case successfully completed with use of the intelligent distributed and collaborative annotation.
Development and evaluation of different AI solutions for EuCanImage's liver use cases	1. Develop different AI solutions for the liver use cases. 2. Refine and test FUTURE Guiding Principles 3. Implement and evaluate standardization methods for different scanners and imaging protocols. 4. Apply and assess data augmentation methods 5. Define a set of clinical indicators for performance and clinical effectiveness assessment of the AI solutions in liver use cases.	1. Finalize the development of at least two AI solutions for liver use cases. 2. 1 open access publication on 'FUTURE AI guiding principles' up to 12 months after the closure of project. 3. 1 open access publication on implementation of image standardization methods for different scanners and varying imaging protocols up to 12 months after the closure of project. 4. 1 open access publication on the application of data augmentation methods up to 12 months after the closure of project. 5. At least 1 internal document or an open access publication on the performance metrics and clinical effectiveness criteria for the assessment of the performance of the AI liver solutions.
Development and evaluation of new AI solutions for colorectal use cases	1. Creation of the automatic detection and classification AI algorithms for colorectal metastases. 2. Development of the automatic liver lesion segmentation algorithms. 3. Create a specific AI classifier for automatic detection and classification of infiltrated pelvic lymph nodes in rectal cancer. 4. Create a specific classifier for the response assessment to neoadjuvant	1. At least 1 AI algorithm for automatic detection of liver metastases based on the deep CNNs published in a scientific journal. 2. At least 1 AI algorithm for automatic detection and classification of infiltrated pelvic lymph nodes in rectal cancer based on the deep CNNs published in a scientific journal. 3. Classifier for the response assessment to neoadjuvant radio(chemo)therapy in

	radio(chemo)therapy in rectal cancer. 5. Define a set of clinical indicators for performance and clinical effectiveness assessment.	rectal cancer published in a scientific journal. 4. At least 1 internal document or an open access publication on the performance metrics and clinical effectiveness criteria for the assessment of the performance of the AI solutions for colorectal use cases.
Development and evaluation of new AI solutions for breast use cases	1. Building complex AI models including phenom-genome information. 2. Development of a solution for detection and classification of breast lesions in mammography. 3. Develop a specific prediction tool of pathological complete response to neoadjuvant treatments in breast cancer. 4. Develop a solution for classification of molecular subtypes of invasive ductal breast carcinoma. 5. Build solutions for adjustment of varying parameters of heterogenouos imaging studies. 6. Ensure and test interoperability between EuCanImage and TCIA. 7. Define a set of clinical indicators for performance and clinical effectiveness assessment of the AI solutions in breast cancer use cases.	1. Integration of complex information such as phenom-genome non-imaging data in at least one breast cancer AI model. 2. Complex AI model integrating imaging and non-imaging data with assessment of the sensitivity and specificity benefit over the current solutions developed. 3. At least 1 AI model based on MR scans that would be able to predict pathological response in breast cancer developed. 4. At least 1 AI classifier for molecular subtypes of breast cancer developed. 5. At least 1 internal document or an open access publication on the solutions for adjustment of varying parameters of heterogenous imaging studies coming from different vendors. 6. Integration of at least 2000 breast cancer TCIA datasets in the EuCanImage platform with successful use of the datasets for one of the breast use cases 7. At least 1 internal document or an open access publication on the performance metrics and clinical effectiveness criteria for the assessment of the performance of the AI solutions for published.

5.3 Indicators WP3

WP 3 develops the data platform and catalogue for cancer imaging and non-imaging data in the EuCanImage project.

Table 5: Overview of activities, research, and performance indicators in WP3.

Activity	Research Indicator	Performance Indicator
Establishment of the Data Management Plan	1. Data Management Plan (DMP) accepted by all partners.	1. A clear DMP which is update not more than once a year.
Adaptation of the image data repository	1. Secure access to image data repository of EuroBioImaging (EMC) for EuCanImage is provided. 2. Annotated images as well as image-derived data could be stored. 3. Federated storage (central and local) is possible.	1. At least 2 cohorts with data. 2. At least 1000 raw images, annotated images and image-derived data. 3. At least 1 partner with local XNAT storage.
Linkage of imaging with omics and phenotypic data types	1. SOP and infrastructure for linking the cancer images in the EuCanImage archive to repositories where corresponding non-image information will be hosted, curated and managed.	1. At least 2 requests in which linked data are provided to users.
Implementation of EuCanImage's catalogue	1. Data model for imaging metadata 2. Catalogue of imaging metadata.	1. At least 1 paper on metadata. 2. At least 5 cohorts in the catalogue.
Data access management	1. Process of acquiring access credentials according to the access rules of the respective imaging collections is in place. 2. Access is requested and provided.	1. At least 4 requests for access. 2. At least 2 successful data transfers.
Integrated web-portal	1. List of implemented functionalities.	1. At least 10 visiting/registered users.

5.4 Indicators WP4

WP 4 creates a suite for cancer imaging data curation, annotation and enhancement.

Table 6: Overview of activities, research, and performance indicators in WP4.

Activity	Research Indicator	Performance Indicator

Generate a suite for GDPR-compliant data anonymisation and transfer	1. Work with WP 1 to define a GDPR compliant framework 2. Develop synthetic image data for use in evaluation of anonymization and transfer tools. 3. Compare the performance of Posda anonymization and transfer tools and procedure with other candidate tools in use a clinical sites. 4. Work with WP 1 and the Clinical Working Group to define requirements for anonymization of non-image data.	1. One publication of the results of tool and procedure evaluation against synthetic data. 2. Integration of all Posda central site curation tools and procedures into the EuCanImage data platform. 3. Train personnel in the use of anonymization tools and procedures at least at one data submitting site. 4. A white paper that establishes an appropriate legal framework with each clinical site (WP 1) published. 5. Fully anonymised EuCanImage data from at least three clinical sites.
Develop tools for consistent and collaborative data annotation	1. Work with the Clinical Working Group to define requirements for annotation tools. 2. Define collaborative annotation workflow.	1. Integration of CMRAD annotation tools and procedures for 2 mammography use cases into the EuCanImage data platform. 2. Train personnel at five clinical sites in the use of annotation tools and procedures. 3. Establish appropriate legal framework with each clinical site (WP 1). 4. Annotate EuCanImage data from five clinical sites.
Quality control of image and non-imaging data	1. Work with the Clinical and AI Working Groups to define image quality standards and quality standards for non-imaging data. 2. Expand Curation and Annotation tools if needed and establish quality control procedures.	1. Integration of at least one initial quality control tool and procedure into the EuCanImage data platform. 2. Train personnel in the use of quality control tools and procedures at one central repository site. 3. Perform quality control on one set of EuCanImage data from at least five clinical sites.
Data enhancement through synthetic data generation	1. Define GANs for creation of synthetic data for each image type to be used by EuCanImage for evaluation of anonymization and transfer tools. 2. Work with AI Working Group to define required synthetic data for training and other uses.	1. Publish a set of synthetic data with open-access for evaluation of anonymization and transfer tools for all identified use cases. 2. Establish procedures and workflow for synthetic data generation and storage for at least one EuCanImage use case.

	3. Extend GANs or retrain to generate required synthetic data. 4. Apply established quality control procedures to the resulting data.	3. Create and store synthetic data for one AI application related to one EuCanImage use case. 4. Finalize and release a user-friendly toolbox for generating large samples of synthetic cancer images that reproduce the characteristics of a given sample.
Standardisation of cancer imaging data and features	1. Work with the Clinical and AI Working Groups to define required image preprocessing and postprocessing tools and procedures. 2. Work with the AI Working Group and WP 5 to define standard format for radiomics features. 3. Define mapping of radiomic features to IBSI ontology and create appropriate tools for implementing this mapping.	1. Produce a guideline document that will be integrated to the platform. 2. Finalize and release a toolbox for image standardization.
Learning-based automatisation of data curation and annotation steps	1. Gather experience from personnel who implement data curation and annotation. 2. Analyze the procedures and feedback to determine rate limiting steps. 3. Develop new tools to automate, if possible, the time consuming or error prone steps in the annotation and curation processes.	1. Publish one paper on the analysis of EuCanImage experience and analysis of curation and annotation procedures. 2. Deploy one automated procedure into the EuCanImage data platform. 3. Evaluate the effectiveness of the deployed automated procedures and write 1 publication.
Activity	Research Indicator	Performance Indicator
Generate a suite for GDPR-compliant data anonymisation and transfer	5. Work with WP 1 to define a GDPR compliant framework 6. Develop synthetic image data for use in evaluation of anonymization and transfer tools. 7. Compare the performance of Posda anonymization and transfer tools and procedure with other candidate tools in use a clinical sites.	6. Publication of the results of tool and procedure evaluation against synthetic data 7. Integration of Posda tools and procedures into the EuCanImage data platform. 8. Train personnel in the use of anonymization tools and procedures. 9. Establish appropriate legal framework with each clinical site (WP 1). 10. Anonymise EuCanImage data from each clinical site.

	8. Work with WP 1 and the Clinical Working Group to define requirements for anonymization of non-image data.	11. 20,000 fully anonymised and GDPR compliant datasets available on the platform.
Develop tools for consistent and collaborative data annotation	3. Work with the Clinical Working Group to define requirements for annotation tools. 4. Define collaborative annotation workflow.	5. Integration of CMRAD annotation tools and procedures into the EuCanImage data platform. 6. Train personnel in the use of annotation tools and procedures. 7. Establish appropriate legal framework with each clinical site (WP 1). 8. Annotate EuCanImage data from each clinical site.
Quality control of image and non-imaging data	3. Work with the Clinical and AI Working Groups to define image quality standards and quality standards for non-imaging data. 4. Expand Curation and Annotation tools if needed and establish quality control procedures.	4. Integration of quality control tools and procedures into the EuCanImage data platform. 5. Train personnel in the use of quality control tools and procedures. 6. Perform quality control on EuCanImage data from each clinical site.
Data enhancement through synthetic data generation	5. Define GANs for creation of synthetic data for each image type to be used by EuCanImage for evaluation of anonymization and transfer tools. 6. Work with AI Working Group to define required synthetic data for training and other uses. 7. Extend GANs or retrain to generate required synthetic data. 8. Apply established quality control procedures to the resulting data.	5. Create synthetic data for evaluation of anonymization and transfer tools. 6. Establish procedures and workflow for synthetic data generation and storage. 7. Create and store synthetic data for AI applications. 8. Finalize and release a user-friendly toolbox for generating large samples of synthetic cancer images that reproduce the characteristics of a given sample
Standardisation of cancer imaging data and features	3. Work with the Clinical and AI Working Groups to define required image preprocessing and postprocessing tools and procedures. 4. Work with the AI Working Group and WP 5 to define	3. Produce a guideline document that will be integrated to the platform 4. Finalize and release a toolbox for image standardisation

	standard format for radiomics features. 4. Define mapping of radiomic features to IBSI ontology and create appropriate tools for implementing this mapping.	
Learning-based automatisation of data curation and annotation steps	4. Gather experience from personnel who implement data curation and annotation. 5. Analyze the procedures and feedback to determine rate limiting steps. 6. Develop new tools to automate, if possible, the time consuming or error prone steps in the annotation and curation processes.	2. Publish the analysis of EuCanImage experience and analysis of curation and annotation procedures. 3. Deploy automated procedures into the EuCanImage data platform. 4. Evaluate effectiveness of the automated procedures.

5.5 Indicators WP5

WP 5 focuses on the artificial intelligence development platform and interfaces.

Table 7: Overview of activities, research, and performance indicators in WP5.

Activity	Research Indicator	Performance Indicator
Provide computational environment for building AI workflows	1. Implementation of the virtual research environment (AI-VRE).	1. Integration of radiomics, machine learning and interpretability tools into a virtual research environment (At least 10 tools in total).
Creation of a scalable library for advanced feature extraction and selection	1. Implementation of a pipeline for cancer image feature extraction. 2. Implementation of cancer radiomics functionalities to produce cancer image quantification workflows.	1. Integration of radiomics technologies from euCanSHare, Euradiomics, and FASTR (3 in total). 2. Integration of textural radiomics, fractal analysis, radial gradient methods, deep learning-based radiomics, and qualitative radiomics (At least 100 features in total).
Development of a machine learning toolbox for integrated predictive modelling	1. Implementation of image-based AI models for cancer decision support. 2. Implementation of predictive models.	1. Integration of different types of variables (imaging, molecular data, lifestyle, clinical measurements). (In all 8 use cases, with genetic markers integrated at least in use case 8). 2. Integration of random forests, support vector machines,

		artificial neural networks, convolutional neural networks, multiple kernel learning, non-imaging data such as genomic and clinical data, in addition to imaging data. (At least 4-5 different approaches implemented and tested).
Development of an AI passport for dynamic and distributed learning	1. Implementation of an AI passport for enabling traceability of AI in cancer imaging. 2. Implementation of a Blockchain-based privacy-preserving federated learning framework.	1. Authenticity of the AI passport based on at least one open-source technology from CEF Digital - Connecting Europe. 2. Establishing secure inter-connection among different components, connecting clients, servers, and aggregators. 3. Approx. 10 information types about the AI models implemented (e.g. identifier, training datasets, authorship, licencing, etc).
Development of a toolbox for interpretable AI in cancer imaging	1. Definitions of interpretable and explainable AI model in the toolbox.	1. At least one interpretability tool submitted on interpretable and explainable AI into the EuCanImage platform.
Definition of FUTURE Guiding Principles for AI in cancer imaging	1. Final definition of the FUTURE Guiding Principles for AI in cancer imaging. 2. Website for the proposed FUTURE Guiding Principles for AI in cancer imaging.	1. Guiding Principles are refined based on the AI models and validations of the project. 2. Involvement of other experts from outside of the consortium from about 10 other institutions in Europe and beyond.

5.6 Indicators WP6

WP 6 focuses on the open-access platform for assessing and benchmarking AI solutions in cancer imaging.

Table 8: Overview of activities, research, and performance indicators in WP6.

Activity	Research Indicator	Performance Indicator
Definition of metrics, criteria and procedures for testing performance and robustness	1. List of metrics to asses performance of AI for imaging.	1. At least one paper submitted with radiomics Quality Score 2.0.
Development and integration of "In Silico Trial" platform to validate	1. Platform tested for at least two research questions with two different datasets.	1. At least one review paper on In Silico trial submitted. 2. At least two submitted papers In Silico trials for imaging.

prospective AI models on real data		
Assessment of clinical effectiveness	1. Document describing method for CE of AI for imaging.	1. Document approved by the consortium. 2. One paper submitted with a CE analysis for a given research question.

5.7 Indicators WP7

WP 7 covers EuCanImage's dissemination, communication and exploitation.

Table 9: Overview of activities, research, and performance indicators in WP7.

Activity	Research Indicator	Performance Indicator
Development of dissemination strategy, branding and communication materials	1. Develop dissemination and communication strategy. 2. Implement project website. 3. Develop project video for lay audience. 4. Develop project video for end users. 5. Establishment of project Twitter account. 6. Prepare annual Newsletters.	1. Dissemination and communication strategy available by M14 and update by M24. 2. Website running and updated every second month. 3. Video shared on project website and social media channels by M6. 4. Video shared with end users/stakeholders. 5. At least 30 Tweets per year. 6. At least 3 newsletters by the end of the project.
Stakeholder analysis and awareness strategy	1. Prepare survey to assess stakeholders/end users. 2. Prepare means to raise awareness for project among identified stakeholder groups.	1. Portfolio and database of EuCanImage stakeholders with at least 100 quality contacts. 2. Strategy to engage with stakeholders/end users by M24.
Stakeholder outreach and awareness campaigns	1. Prepare information package for stakeholders. 2. Provide information package and regular updates to stakeholders. 3. Encourage stakeholders to contribute data to the platform.	1. 50-100 initial scientists registered to the EuCanImage data platform by the end of the project. 2. 10 potential data contributors expressing interest in EuCanImage.
Participation in and organization of dissemination events, workshops and hands-on sessions	1. Organization workshops during the annual meetings of ESOI and EACR.	1. Three workshops organized by the end of the project.

E-learning material and online events	1. Gather available materials and disseminate training activities to consortium members and stakeholders.	1. Training activity repository established and released to stakeholders.
Exploitation and sustainability planning	1. Conduct exploitation online seminars. 2. Assess exploitable project results and route for exploitation.	1. At least two online exploitation seminars by the end of the project. 2. EuCanImage`s exploitation plan.

5.8 Indicators WP8

WP 8 comprises the scientific coordination and project management of the EuCanImage project.

Table 10: Overview of activities, research, and performance indicators in WP8.

Activity	Research Indicator	Performance Indicator
Scientific coordination and reporting	1. Support the knowledge exchange and communication between different groups. 2. Spotting potential risk before it arises. 3. Preparing high-quality periodic reports.	1. Organization of 6 working group meetings and 1 inter-working-group meeting. 2. Set up of Risk Matrix. 3. Submission of at least 80% of all deliverables on time.
Administrative, financial and operational management	1. Prepare and maintain all relevant documentation. 2. Coordination of all financial aspects.	1. Project Handbook ready by M3. 2. Submission of all three financial reports to the EC.
Ethics requirements management	1. Ensure strict alignment to all ethical requirements.	1. Obtaining the ethical authorizations from all 5 clinical partners. 2. Description of the security measures implemented to prevent access to personal and sensitive data internally published.
Joint coordination and synergies with other initiatives	1. Establish interactions with relevant partners in the cancer research domain.	1. AI4HI Network is set up including all 4 projects from the same EC call. 2. At least one joint D&C activity done.
Innovation and IPR management	1. Analysis of the main project innovations. 2. Identifying potential partners and stakeholder by analyzing the relevant markets. 3. Active exploitation and business modelling to	1. Performing at least one Innovation Radar Method survey. 2. Organization of at least two Innovation Management Seminar. 3. A leads list of at least 30 interested parties from industry and medical centres.

	ensure adequate outreach strategy.	

6 Ethical clearance

Being compliant with all ethics related aspects is of highest interest and importance to all EuCanImage partners.

Since an additional ethics WP (number 9) was added to the project during Grant Preparation, ethical clearance is now covered in WP9 (deliverables D9.1 – D9.6, all following POPD and NEC requirements). More precisely the six deliverables cover aspects such as:

- Checking if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s). Reviewing of personal data transfer from and do non-EU countries or international organisation. A confirmation that these actions compile with national and EU legislation, together with necessary authorisations will be submitted at M18.
- Details on the materials which will be imported to/exported from the EU must be submitted as a deliverable.

Given those additional deliverables it has been agreed upon with the Project Officer that ethical clearance will be specifically covered in WP8 in detail.

7 Authorship guidelines

Authorship of EuCanImage publications is regulated by the Vancouver rules found in the recommendations of the International Committee of Medical Journal Editors. The Vancouver rules ensure that contributors who have made substantive intellectual contribution to a paper are given credit as authors, but also that contributors credites as authors understand their role in taking responsibility and being accountable for what is published.

7.1 Authors

Authorship is based on the following standardized set of criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
2. Drafting the work or revising it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged (see 7.2 Non-author contributors).

If a contributor has made such a substantial contribution to the work but only meets the first criterion for authorship, the contributor should be given the opportunity to meet the remaining criteria for authorship as well.

7.2 Non-author contributors

Contributors that do not meet all four of the above criteria should not be listed as authors, but should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding, general supervision of a research group or general administrative support, writing assistance, technical editing, language editing, and proofreading.

Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g., "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript"). Written permission to be acknowledged from all acknowledged individuals should be required.

7.3 Authorship disputes

In case authorship disagreement may arise, the involved parties should use these guidelines to solve the disagreement. If no agreement between the involved parties can be reached, it is advised to involve the PC and PM.

The following suggestions may help prevent authorship disputes:

1. Discuss the author list and the order of authors at an early stage (e.g. when planning your research) and keep discussing these issues throughout the process of writing. There should be a common understanding of what kind of work counts as authorship.
2. Authorship should be decided before you start working on the article.
3. Adress problems directly by acknowledging disagreements, setting boundaries and trying to find a common ground.
4. Be aware of journal-specific guidelines, as well as general guidelines.
5. All authors should check the last version of a publication before it is submitted and it should be possible to withdraw your name if you disagree with the interpretation of the results.

8 Summary

The presented document establishes EuCanImage internal guidelines to ensure best possible quality for deliverables, reports and other documentation.

Together with D8.2 the EuCanImage Project Handbook the documents serve as a reference during the full course of the project. If required, updates can be made and the most recent version of the document will always be accessible for all consortium partners in the shared Google Drive folder.

In case of a partner spotting any irregularities and/or wishing to suggest any changes, please contact the Project Manager and/or Project Coordinator as soon as possible.

It will be appreciated that all partners stick to the outlined guidelines, guaranteeing highest possible quality, as well as, allowing smooth project progress with minimal incidences.