EUCCC CERTIFICATION SCHEME MANUAL

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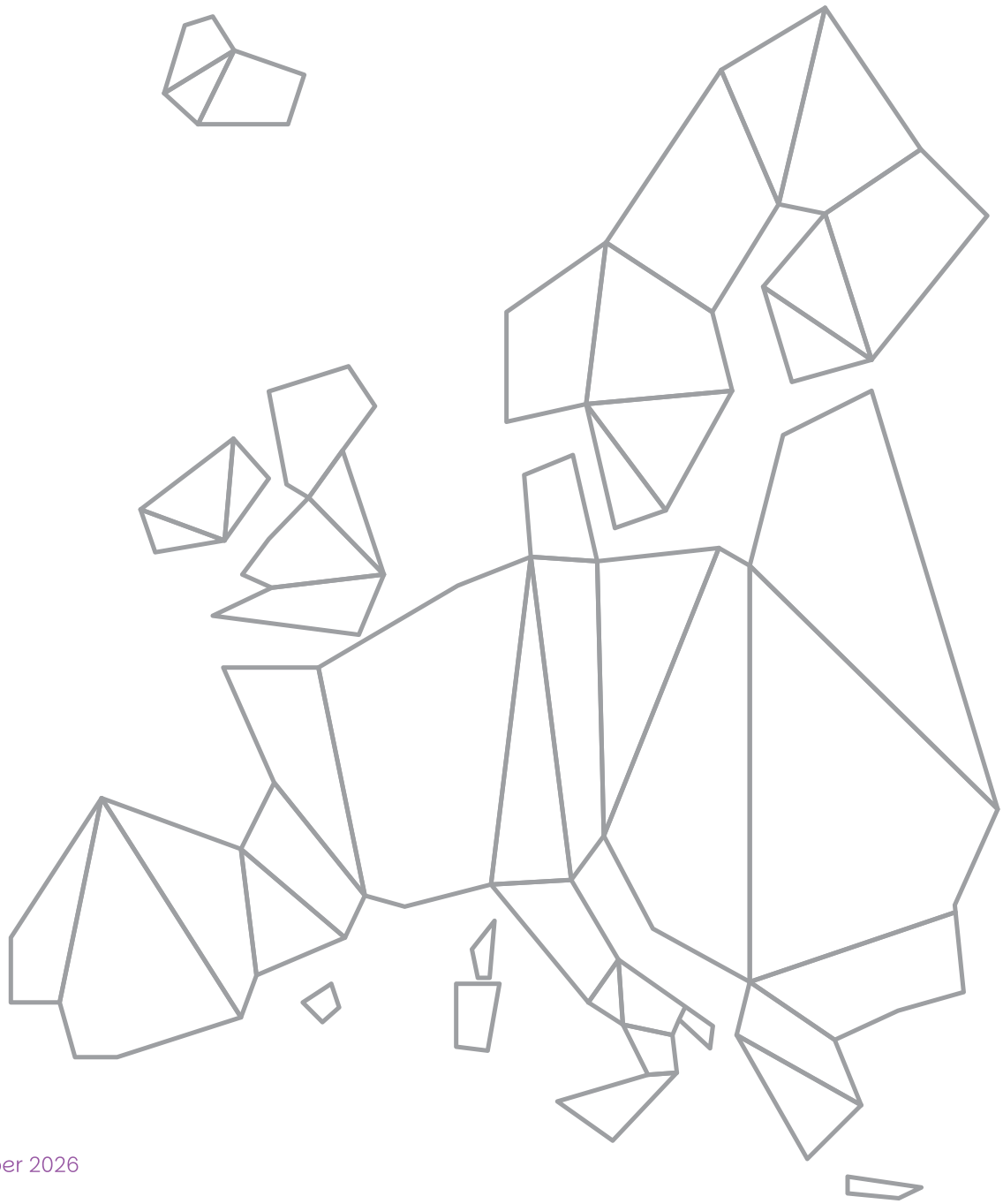


THE EUROPEAN COMPREHENSIVE CANCER CENTRE NETWORK

EUnetCCC

ONEFORALL

Co-funded by the European Union



September 2026

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FOREWORD

The establishment of a European Network of Comprehensive Cancer Centres (EUCCCs) is one of the flagship initiatives of Europe's Beating Cancer Plan (EBCP), aiming to improve equitable access to high-quality cancer care, research, education and innovation across Europe. Within this broader ambition, the development of a common European certification scheme constitutes a key milestone towards ensuring a harmonised and transparent framework for recognising Comprehensive Cancer Centres throughout the European Union.

The development of the EUCCC Certification Scheme builds upon the important work initiated during the CraNE Joint Action, which laid the conceptual foundations of a European certification framework through the development of a Set of Criteria and Standards, an initial certification process and the definition of the essential characteristics of Comprehensive Cancer Centres. While these foundations represented a major step towards the establishment of a future European certification system, they had not yet been tested under operational conditions.

Building on this legacy, the EUnetCCC Joint Action was entrusted with transforming these initial concepts into an operational and implementable certification scheme. Through an extensive programme of methodological development, field testing and stakeholder consultation, the Joint Action progressively completed, refined and consolidated the different components required for future implementation. These activities included the development of admission criteria, certification pathways, evaluation methodologies, evidence requirements, decision-making principles and supporting digital tools, together with the large-scale field testing of the certification framework in collaboration with European cancer centres and auditors.

This Certification Scheme Manual represents the outcome of this progressive development process. It establishes the governance principles, operational framework and certification processes that together define the EUCCC Certification Scheme. It forms part of a coherent architecture that also includes the EUCCC Set of Criteria and Standards, and supporting digital operational tools.

The Scheme has been designed in accordance with internationally recognised principles for accredited certification, while reflecting the specific characteristics of Comprehensive Cancer Centres and the diversity of healthcare systems across Europe. Particular attention has been given to ensuring harmonised implementation, transparency, proportionality and continuous improvement through a structured peer assessment process, whereby multidisciplinary assessment teams composed of qualified peers from Comprehensive Cancer Centres evaluate conformity with the requirements of the EUCCC Certification Scheme.

The Scheme is intended to serve all organisations participating in the certification process, including applicant centres, Certification Operators, auditors, and accreditation bodies By clearly defining roles, responsibilities and certification processes, it aims to ensure a common interpretation and consistent implementation of the EUCCC Certification Scheme throughout Europe.

The present document should therefore be understood as the operational reference describing how the EUCCC Certification Scheme functions. Together with the accompanying Set of Criteria and Standards and associated operational digital tools, it provides the foundation for the deployment, maintenance and continuous evolution of a European certification system supporting excellence and inclusivity in comprehensive cancer care, research and education.

1 INTRODUCTION TO THE EUCCC CERTIFICATION SCHEME

1.1 Background

The establishment of a European Network of Comprehensive Cancer Centres (EUCCCs) is one of the flagship initiatives of Europe's Beating Cancer Plan (EBCP). It aims to improve equitable access to high-quality cancer care across Europe by promoting excellence in patient care, research, and education.

To support the implementation of this ambition, successive EU-funded Joint Actions have progressively developed the concept of a harmonised European framework for recognising Comprehensive Cancer Centres. While certification was not an end in itself, it emerged within the projects as a practical and structured tool to define common expectations, support quality improvement, and enable the development of a coherent European network of CCCs.

The first step was undertaken through the **CraNE Joint Action[1],** which established the conceptual and methodological foundations of a future European certification system. This work resulted in the development of an Initial Certification Framework, including a common Set of Criteria and Standards, certification principles, assessment methodologies and the first elements of a European certification pathway.

Building upon this work, the **EUnetCCC Joint Action** further developed and consolidated these foundations through an extensive programme of methodological refinement and field testing involving Comprehensive Cancer Centres, auditors and experts from across Europe. The in-house and on-site field tests provided valuable evidence regarding the feasibility, consistency and operational applicability of the proposed certification framework and supported its further refinement.

The present EUCCC Certification Scheme Manual represents the outcome of this progressive development process. It establishes the governance principles, operational framework and certification processes supporting the implementation of a harmonised European certification scheme for Comprehensive Cancer Centres.

1.1.1 Objectives

The overall objective of the EUCCC Certification Scheme is to provide a harmonised European framework for the impartial assessment and independent certification of Comprehensive Cancer Centres. This objective is achieved through certification performed by accredited Certification Operators, harmonised assessment methodologies, common decision rules, harmonised auditor competence requirements and the consis-

[1] D7.2 Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centres, WP7 FRAMEWORK AND CRITERIA TO ENABLE THE IMPLEMENTATION OF COMPREHENSIVE CANCER CENTRES WITHIN AN EU NETWORK - Crane4health.eu

tent application of certification requirements across all applicant centres. More specifically, the Scheme aims to:

More specifically, the Scheme aims to:

- Foster excellence and continuous quality improvement in comprehensive cancer centres;
- Promote accessibility and inclusiveness by ensuring that the Scheme can be applied across the diversity of European healthcare systems, while maintaining a common set of certification requirements and decision rules for all applicant centres establish a common European certification framework based on internationally recognised principles for accredited certification;
- Ensure a consistent, transparent and harmonised certification process across Europe;
- Support mutual confidence between Member States through a common interpretation of certification requirements;
- Contribute to the development of a European Network of Comprehensive Cancer Centres by promoting comparable levels of quality and organisational maturity.

The Scheme has been designed to support accredited third-party certification, while respecting the diversity of healthcare systems and organisational models across Europe.

1.1.2 Purpose of the Certification Scheme Manual

The purpose of this Certification Scheme Manual is to define the governance, fundamental principles and certification processes governing the EUCCC Certification Scheme.

It describes the objectives, scope, governance arrangements, roles and responsibilities of the organisations involved in the certification process, as well as the certification pathway applicable to candidate Comprehensive Cancer Centres. It also establishes the principles ensuring the consistent implementation, integrity and continuous improvement of the Scheme across Europe.
This Manual constitutes the primary normative reference document for the implementation and operation of the EUCCC Certification Scheme. It is intended for all organisations involved in the certification process, including the Certification Operators, aspiring Comprehensive Cancer Centres, auditors and accreditation bodies

The technical requirements against which candidate Comprehensive Cancer Centres are assessed are defined in the **EUCCC Set of Criteria and Standards,** which forms an integral normative component of the EUCCC Certification Scheme and shall be read in conjunction with this Manual. Owing to its technical nature and the need for its periodic revision, the **EUCCC Set of Criteria and Standards** is maintained as a separate document.

Additional operational documents, including handy auditors and centres guidance manual, will be developed to support the implementation of the Scheme. These documents facilitate the operational delivery of certification but do not replace or modify the provisions established in this Manual.

A visual representation of the EUCCC history can be found in the figure below.

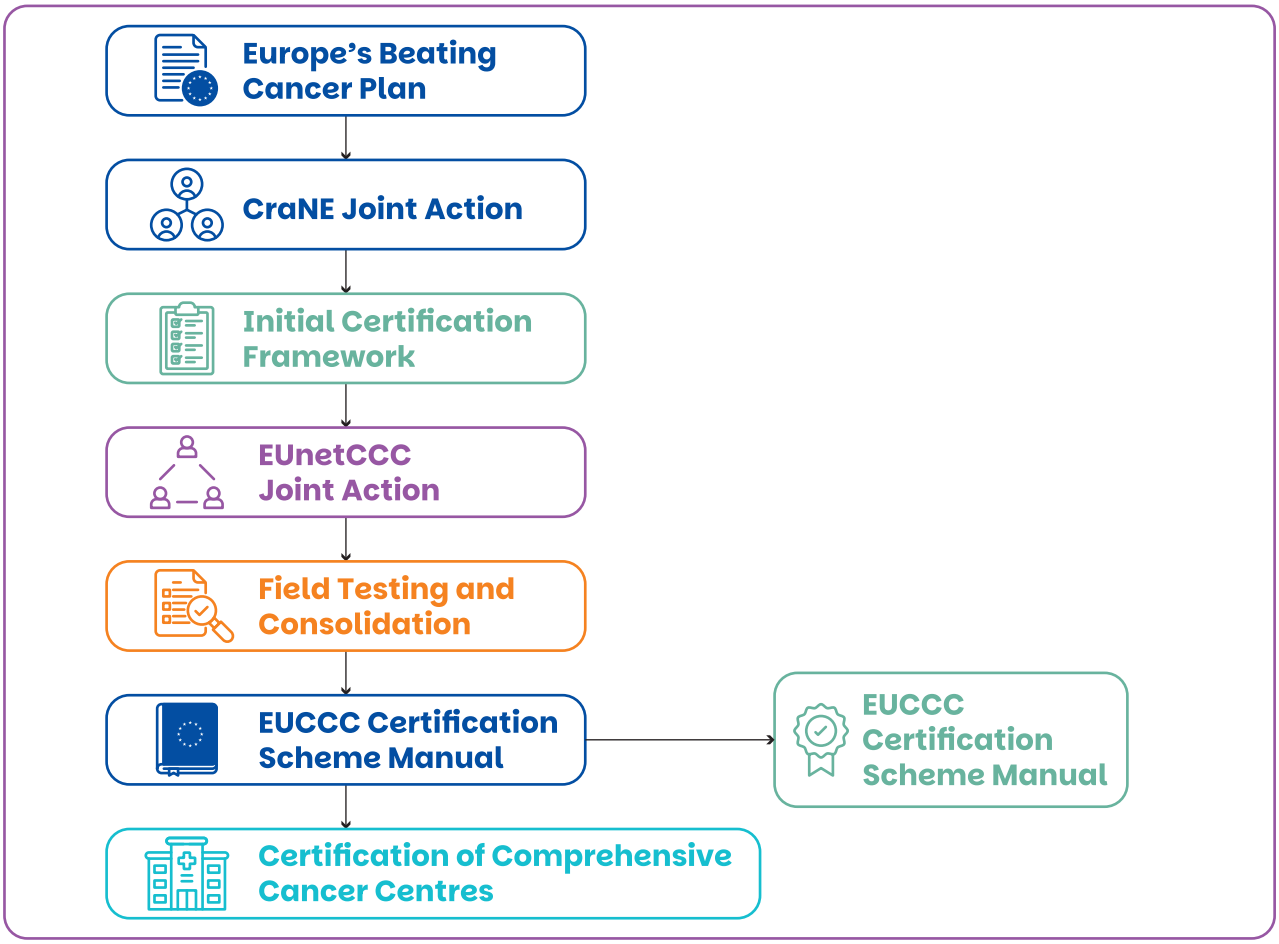


Figure 1. Development of the EUCCC Certification Scheme

1.2 Added value of the EUCCC Certification Scheme

The EUCCC Certification Scheme has been established to support the development of a harmonised European framework for excellence in comprehensive cancer care. By providing a common approach to the impartial assessment and independent certification of Comprehensive Cancer Centres, the Scheme contributes to the consistent implementation of high-quality organisational, clinical, research and educational standards across Europe.

The Scheme is intended to promote continuous quality improvement rather than to provide a one-time recognition of excellence. Through a structured peer-assessment process based on common European requirements, it enables aspiring Comprehensive Cancer Centres to evaluate their level of maturity, identify opportunities for improvement and strengthen the integration of care, research, education, prevention and innovation within their organisations.

One of the main added values of the Scheme lies in the establishment of a common European reference framework. By relying on harmonised standards, common assessment methodologies and internationally recognised certification principles, the Scheme promotes a shared understanding of excellence, while ensuring a consistent interpretation and implementation of certification requirements throughout Europe. In doing so, it facilitates mutual confidence between applicant centres, certification assessment bodies, national authorities and other stakeholders involved in the certification process.

The Scheme also provides a structured framework supporting organisational development within Comprehensive Cancer Centres. Beyond the certification decision itself, the assessment process encourages multidisciplinary collaboration, evidence-based organisational practices, performance monitoring and benchmarking, thereby fostering a culture of continuous improvement and shared learning.

For patients, the Scheme contributes to improving the quality, safety and coordination of comprehensive cancer care by promoting recognised organisational standards and integrated models of care. For Comprehensive Cancer Centres, it provides an objective framework for assessing organisational maturity and identifying priorities for future development. For healthcare professionals, it supports multidisciplinary collaboration, peer learning and the dissemination of good practices across Europe. For healthcare systems and public authorities, it contributes to greater transparency, harmonisation and mutual confidence through the implementation of a common European certification framework.

More broadly, the EUCCC Certification Scheme constitutes one of the foundations supporting the future European Network of Comprehensive Cancer Centres. By promoting common expectations, shared assessment principles and comparable levels of organisational quality, it contributes to strengthening collaboration between centres, while respecting the diversity of national healthcare systems and organisational models.

The EUCCC Certification Scheme should therefore be understood not only as a certification process, but also as a common European framework supporting excellence, continuous quality improvement and the long-term development of Comprehensive Cancer Centres across Europe.

Through a common EUCCC certification label, Europe can scale excellence, lead global cancer research, and attract the healthcare talents of tomorrow.

1.3 Scope of the EUCCC Certification Scheme

This chapter describes the scope of the EUCCC Certification Scheme, the organisations to which it applies, the defining characteristics of a European Comprehensive Cancer Centre, the guiding principles underpinning the Scheme, and the documentation supporting its implementation.

1.3.1 Scope

The EUCCC Certification Scheme applies to organisations that fulfil the European definition of a Comprehensive Cancer Centre (see section 1.3.2 below) and seek certification under the EUCCC Certification Scheme.

The Scheme is intended for organisations providing integrated cancer care, while combining clinical excellence with research, education and training, prevention and innovation within a coordinated organisational framework.

The Scheme applies equally to:

- Stand-alone Comprehensive Cancer Centres;
- Consortium-based Comprehensive Cancer Centres composed of two or more organisations operating under a formalised governance framework.

Prior to entering the certification process, all applicants shall demonstrate that they fall within the scope of the Scheme through the Admission Phase. This eligibility verification is conducted by the Scheme Owner before the conformity assessment performed by the Certification Operator.

1.3.2 Definition of a Comprehensive Cancer Centre

For the purposes of the EUCCC Certification Scheme, a Comprehensive Cancer Centre (CCC) is defined as follows:

"A European Comprehensive Cancer Centre (EU CCC) serves as a major source of clinical care, innovation and discovery into the understanding of cancer, and for the development of more effective approaches to prevention, diagnosis and therapy. It provides an extensive range of high-quality cancer diagnostics and care covering at least all major cancers, while demonstrating a substantial breadth and depth of activities in basic, translational, clinical, prevention and population-based research. It serves as the focal point of a local, regional or national network, promoting excellence in care and research, disseminating good practices, and engaging stakeholders throughout its catchment area. A Comprehensive Cancer Centre actively collaborates with institutions, networks and stakeholders involved in prevention, care, research, education and innovation, while contributing to the development of the European Network of Comprehensive Cancer Centres."

This definition was developed through the CraNE Joint Action and endorsed as the common European reference for Comprehensive Cancer Centres. It forms the basis of the EUCCC Certification Scheme.

For the purpose of the EUCCC Certification Scheme, a Comprehensive Cancer Centre shall demonstrate the following essential organisational characteristics:

- **Organisational capabilities,** including clearly defined governance arrangements, leadership, organisational infrastructure and coordination mechanisms;
- **Strategic partnerships,** demonstrating coherent collaboration between participating organisations and engagement within the catchment area;
- **Transdisciplinary collaboration and coordination,** ensuring effective integration of patient care, research, education and training, prevention and innovation throughout the patient pathway;
- **Institutional commitment to European collaboration,** including active participation in the objectives and activities of the European Network of Comprehensive Cancer Centres.

These characteristics define the scope of the EUCCC Certification Scheme and constitute the basis for the Admission Phase preceding certification.

Stand-alone Comprehensive Cancer Centres

A stand-alone Comprehensive Cancer Centre is a single organisational entity that independently fulfils the European definition of a Comprehensive Cancer Centre.

It operates under a unified governance structure and assumes full responsibility for the planning, implementation and continuous improvement of all activities covered by the EUCCC Certification Scheme, including patient care, research, education and training, prevention and innovation.

The organisation shall demonstrate that these activities are integrated within a coherent organisational framework and comply with the requirements of the EUCCC Set of Criteria and Standards.

Consortium-based Comprehensive Cancer Centres

The EUCCC Certification Scheme also applies to consortium-based Comprehensive Cancer Centres.

A consortium-based Comprehensive Cancer Centre consists of two or more organisations that collectively fulfil the European definition of a Comprehensive Cancer Centre through a formalised and demonstrable partnership.

The Scheme does not prescribe any specific legal model or organisational structure for consortium-based candidates. Different governance arrangements may therefore be eligible, provided that they demonstrate effective organisational integration and collective responsibility for the activities covered by the Scheme.

A consortium-based Comprehensive Cancer Centre shall demonstrate:
a clearly defined governance structure;

- Shared strategic objectives;
- Clearly allocated roles and responsibilities;
- Effective coordination of patient care, research, education and training, prevention and innovation;
- Common quality management arrangements across participating organisations;
- Collective accountability for compliance with the EUCCC Set of Criteria and Standards.

Certification is therefore based on the effectiveness of organisational integration rather than on the legal form of the consortium itself, in accordance with the principles established during the development and field testing of the EUCCC Certification Scheme.

1.3.3 Guiding principles of the EUCCC Certification Scheme

The EUCCC Certification Scheme is founded on a number of fundamental principles that ensure its credibility, consistency and harmonised implementation across Europe. These principles support a common European certification framework, while taking into account the specific characteristics of Comprehensive Cancer Centres and respecting the diversity of healthcare systems and organisational models across Europe.

Its implementation is based on the following fundamental principles:

- **Peer assessment,** ensuring that assessments are performed by qualified professionals with recognised expertise in comprehensive cancer care, they are acting within an independent conformity assessment process;
- **Independence and impartiality,** ensuring that certification decisions are taken objectively and free from conflicts of interest;
- **Transparency,** through clearly defined certification rules, responsibilities and decision-making processes;
- **Continuous quality improvement,** encouraging centres to strengthen their performance beyond the certification decision itself;
- **European harmonisation,** by promoting a common interpretation and consistent application of certification requirements across Europe;
- **Risk-based approach,** ensuring that certification activities are proportionate to the complexity and organisational characteristics of candidate centres while maintaining the robustness and consistency of the assessment process.

These principles underpin the governance, implementation and continuous development of the EUCCC Certification Scheme and shall be considered throughout all stages of the certification process.

1.3.4 Documentation of the EUCCC Certification Scheme

The EUCCC Certification Scheme is implemented through a coherent set of complementary documents that collectively define its governance, certification requirements, assessment methodologies and operational guidance. Together, these documents ensure the consistent implementation of the Scheme across Europe, while supporting harmonised certification practices among applicant Comprehensive Cancer Centres, Certification Operators and auditors.

This **Certification Scheme Manual** constitutes the overarching governance document of the EUCCC Certification Scheme. It establishes the governance framework, defines the roles and responsibilities of the organisations involved, describes the certification

pathway, and sets out the general rules governing the implementation, maintenance and continuous improvement of the Scheme.

The **EUCCC Set of Criteria and Standards** constitutes the normative reference against which candidate centres are assessed. It defines the certification requirements applicable to Comprehensive Cancer Centres and forms an integral part of the EUCCC Certification Scheme.

The implementation of the Scheme is further supported by a series of complementary documents providing practical guidance for its consistent application. These documents facilitate the preparation of candidate centres, support the work of Certification Operators and auditors, and promote a harmonised interpretation of the certification requirements. They do not introduce additional certification requirements beyond those defined in the EUCCC Set of Criteria and Standards.

The principal documents composing the EUCCC Certification Scheme are summarised **below.**

Documentation of the EUCCC Certification Scheme

Document	Purpose
Certification Scheme Manual	Defines the governance framework, certification pathway, roles, responsibilities and general rules governing the implementation of the EUCCC Certification Scheme.
EUCCC Set of Criteria and Standards	Defines the certification requirements applicable to Comprehensive Cancer Centres.
Seven Domain Guidelines	Provide guidance for the interpretation and assessment of the certification.
Preparatory Kit	Supports candidate centres in preparing for the certification process.
Self-Assessment Manual	Provides guidance for completing the self-assessment process and preparing supporting evidence.

2 GOVERNANCE OF THE EUCCC CERTIFICATION SCHEME

The EUCCC Certification scheme is established in accordance with the accredited certification framework set out in Regulation (EC) No 765/2009. It is designed to operate within the European accreditation system and applies the internationally recognised principles and requirements governing accredited third-party certification, in particular ISO/IEC 17065.

Under this framework, accredited Certification Operators compete in an open market and may offer certification services to eligible Comprehensive Cancer Centres (CCCs) across Europe. Comprehensive Cancer Centres that voluntarily participate in the Scheme and demonstrate compliance with its requirements are awarded an accredited certification that is recognised and accepted throughout the European Union.

The Governance Framework of the EUCCC Certification Scheme establishes the organisational structure, roles, responsibilities and interactions necessary to ensure the integrity, consistency, transparency and continuous improvement of the Scheme throughout its implementation across Europe.

Its primary objective is to ensure the harmonised implementation of the Scheme, while preserving the independence of certification activities and maintaining confidence in the certification process among candidate Comprehensive Cancer Centres, Certification Operators, accreditation bodies and other stakeholders.

The governance model is founded on a clear separation of responsibilities between the governance of the Scheme and the delivery of certification activities:

- The Scheme Owner is responsible for establishing, maintaining and continuously improving the EUCCC Certification Scheme, and for safeguarding its overall integrity.
- Accredited Certification Operators remain solely responsible for conducting conformity assessment activities and taking certification decisions in accordance with ISO/IEC 17065 and the provisions of this Manual.

This separation of responsibilities is fundamental to ensuring impartiality, transparency and the consistent application of the Scheme across Europe.

2.1 Governance framework of the EUCCC Certification Scheme

The integrity of the EUCCC Certification Scheme is maintained through complementary governance functions that collectively ensure its scientific robustness, operational consistency and continuous improvement. While several governance bodies contribute to these objectives, the overall accountability for preserving the integrity of the Scheme remains with the Scheme Owner.

Accordingly, the Governance Framework is organised around five complementary components:

- the **Scheme Owner**
- the **Certification Secretariat**
- the **Scientific Advisory Council**
- the **Certification Operators**
- the **Community of Experts and Auditors**

Together, these governance bodies ensure the effective management, implementation and continuous improvement of the Scheme, while preserving the independence of certification activities.

Their respective roles, responsibilities and interactions are described in the following sections.

2.1.1 Scheme Owner

The **Scheme Owner** is responsible for the overall governance, integrity, maintenance and continuous improvement of the EUCCC Certification Scheme. It ensures that the Scheme remains fit for purpose, aligned with internationally recognised principles governing accredited third-party certification, and consistently implemented across Europe.

The Scheme Owner establishes, maintains and periodically updates the Certification Scheme Manual and the associated normative and operational documents composing the Scheme. It ensures that certification requirements remain clear, relevant and suitable for conformity assessment, taking into account implementation experience, stakeholder feedback and scientific developments.

The Scheme Owner is also responsible for safeguarding the integrity of the Scheme. This includes ensuring the consistent interpretation and application of certification requirements, preserving the credibility and reputation of the Scheme, monitoring its imple-

mentation, collecting and analysing feedback from stakeholders, and coordinating the continuous improvement of the certification framework.

The governance of the Scheme is based on a clear separation of responsibilities between the Scheme Owner and accredited Certification Operators. While the Scheme Owner is responsible for the governance and maintenance of the Scheme, accredited Certification Operators remain solely responsible for performing conformity assessment activities and taking certification decisions in accordance with ISO/IEC 17065 and the provisions of this Manual. The Scheme Owner therefore does not conduct audits, does not participate in certification decisions, does not manage appeals or complaints related to certification decisions, and does not replace the responsibilities assigned to Certification Operators.

The Scheme Owner is supported by complementary governance structures contributing to the implementation and continuous improvement of the Scheme, including the Certification Secretariat, the Scientific Advisory Council and the Community of Experts and Auditors. These structures support the operational, scientific and technical development of the Scheme, while the overall responsibility for its governance and integrity remains with the Scheme Owner.

As part of its governance responsibilities, the Scheme Owner manages the Admission Phase, which precedes the conformity assessment process. It verifies that candidate centres fulfil the admission requirements defined by the Scheme, confirms that they fall within the scope of the EUCCC Certification Scheme and issues the Allowance to Apply. The Admission Phase is limited to the verification of the admission requirements and does not constitute a conformity assessment activity.

The Scheme Owner is also responsible for establishing and facilitating the Community of Experts and Auditors harmonisation activities and for leading the EUCCC Experts and Auditors continuous learning Programme. It coordinates familiarisation with the scheme activities, continuous development of harmonised audits methodologies and experience sharing in order to promote the shared interpretation and consistent application of the Scheme throughout Europe. Participation in these activities is recommended but remains voluntary. The appointment of auditors for individual certification activities remains the sole responsibility of accredited Certification Operators.

The main responsibilities of the Scheme Owner are summarised in **Table 2.**

Main responsibilities of the Scheme Owner

Responsibility	Description
Governance of the Scheme	Ensure the overall governance, maintenance and continuous improvement of the EUCCC Certification Scheme.
Scheme documentation	Maintain, review and periodically update the Certification Scheme Manual and associated normative and operational documents.
Integrity of the Scheme	Preserve the integrity, credibility, transparency and consistent application of the Scheme across Europe.
Admission Phase	Verify eligibility of candidate centre and issue the Allowance to Apply.
Certification Operators	Maintain relations with accredited Certification Operators and monitor the implementation of the Scheme.
Community of Experts and Auditors	Establish oversee and facilitate the EUCCC Community of Experts and Auditors continuous learning Programme.
Scientific governance	Coordinate the Scientific Advisory Council and integrate scientifically grounded developments into the Scheme.
Continuous improvement	Collect feedback, monitor implementation and coordinate periodic revisions of the Scheme.

2.1.2 Certification Secretariat

The **Certification Secretariat** provides the operational and administrative support necessary for the effective implementation of the EUCCC Certification Scheme. Acting under the responsibility of the Scheme Owner, it serves as the central operational interface for the day-to-day management of the Scheme and supports the consistent implementation of its processes across Europe.

The Certification Secretariat coordinates the operational activities associated with the Scheme, facilitates communication between the Scheme Owner and relevant stakeholders, maintains the Scheme documentation and records, and provides administrative support to the governance bodies established within the EUCCC Certification Scheme. It contributes to the efficient organisation of certification activities while ensuring consistency, traceability and operational continuity.

As part of the **Admission Phase,** the Certification Secretariat provides administrative support to the Scheme Owner. It receives the Admission Form and supporting documentation, verifies their administrative completeness, coordinates exchanges with candidate centres and organises onboarding activities where appropriate. The Secretariat supports the eligibility verification process but does not participate in decisions concerning the issuance of the **Allowance to Apply,** which remain the sole responsibility of the Scheme Owner.

Following the issuance of the Allowance to Apply, the Certification Secretariat facilitates the operational interface between candidate centres and accredited Certification Operators. It may provide procedural information and ensure the continuity of administrative exchanges where appropriate but does not intervene in the contractual relationship between the candidate centre and the Certification Operator, nor in any conformity assessment activities conducted under ISO/IEC 17065.

The Certification Secretariat also supports the activities of the Scientific Advisory Council and the Community of Experts and Auditors by coordinating meetings, preparing documentation, maintaining records and facilitating communication between the different governance bodies. It further contributes to the continuous improvement of the Scheme by collecting operational feedback, identifying implementation issues and supporting the periodic review of operational procedures.

The Certification Secretariat does not perform conformity assessment activities, does not assess compliance with the EUCCC certification requirements, does not appoint auditors, does not participate in certification decisions and does not manage appeals or complaints relating to certification activities. These responsibilities remain exclusively with accredited Certification Operators.

The main functions of the Certification Secretariat are summarised **below.**

Main functions of the Certification Secretariat	
Function	**Main activities**
Operational coordination	Coordinate the day-to-day operational implementation of the EUCCC Certification Scheme.
Admission support	Provide administrative support to the Admission Phase under the responsibility of the Scheme Owner.
Stakeholder communication	Serve as the operational contact point for candidate centres and governance bodies.
Documentation management	Maintain controlled Scheme documentation, templates and operational records.
Governance support	Provide administrative support to the Scheme Owner, Scientific Advisory Council and Community of Experts and Auditors.
Operational support	Coordinate onboarding activities and facilitate operational exchanges throughout the implementation of the Scheme.
Continuous improvement	Collect operational feedback and support the periodic improvement of Scheme procedures.

2.1.3 Scientific Advisory Council

The **Scientific Advisory Council (SAC)** is an independent advisory body established to provide scientific and technical advice to the Scheme Owner. Through its recommendations, the Council contributes to maintaining the scientific credibility, robustness and continuous evolution of the EUCCC Certification Scheme, ensuring that it remains evidence-based and aligned with scientific, organisational and methodological developments relevant to Comprehensive Cancer Centres and the certification framework.

The Scientific Advisory Council provides independent advice to the Scheme Owner on matters relating to the scientific and technical development of the Scheme. It contributes to the periodic review of the EUCCC Set of Criteria and Standards and associated guidance documents, identifies emerging evidence, innovations and good practices, and provides recommendations to support the continuous improvement of the Scheme. Where appropriate, the Council may also advise on scientific or technical matters relevant to the evolution of the certification framework.

The Scientific Advisory Council operates solely in an advisory capacity and does not exercise executive or decision-making responsibilities within the governance of the Scheme. It does not participate in conformity assessment activities, appoint auditors, or take certification decisions. The governance, maintenance and continuous improvement of the Scheme remain the responsibility of the Scheme Owner, while conformity assessment activities remain exclusively under the responsibility of accredited Certification Operators.

The Scientific Advisory Council shall comprise members with recognised expertise covering the different dimensions of Comprehensive Cancer Centres and the EUCCC Certification Scheme, including clinical care, research, education and training, prevention, quality management, organisational governance and patient perspectives. Members shall act independently, declare any actual or potential conflicts of interest and perform their duties in accordance with the conflict-of-interest policy established by the Scheme Owner. The members of the Scientific Advisory Council shall be appointed by the Scheme Owner in accordance with transparent selection procedures and defined terms of reference.

Through its scientific advice and recommendations, the Scientific Advisory Council contributes to the long-term sustainability, scientific credibility and continuous evolution of the EUCCC Certification Scheme, supporting its harmonised development and implementation across Europe.

The main functions of the Scientific Advisory Council are summarised **below.**

Main functions of the Scientific Advisory Council	
Function	**Main activities**
Scientific advice	Provide independent scientific and technical advice to the Scheme Owner.
Scientific review of the Scheme	Contribute to the periodic review of the EUCCC Certification Scheme, including the Set of Criteria and Standards and associated guidance documents.
Scientific monitoring	Identify emerging scientific evidence, innovations and developments relevant to the Scheme.
Scientific recommendations	Provide recommendations supporting the scientific and technical evolution of the Scheme.
Continuous improvement	Contribute to the long-term scientific credibility and continuous improvement of the EUCCC Certification Scheme.

2.1.4 Certification Operators

Certification Operators are independent conformity assessment bodies accredited by the National Accreditation Body of the Scheme Owner country to implement the EUCCC Certification Scheme and perform certification activities under the Scheme. They operate in accordance with the provisions of this Certification Scheme Manual and the applicable accreditation requirements and retain sole responsibility for conformity assessment activities and certification decisions.

Certification Operators shall establish, implement and maintain documented procedures governing all certification activities performed under the EUCCC Certification Scheme. They shall ensure that conformity assessment activities are conducted consistently, impartially and competently, in accordance with the certification requirements, evaluation methodologies and governance arrangements established by the Scheme.

Certification Operators shall be responsible for:

- reviewing certification applications;
- establishing contractual arrangements with candidate centres;
- planning, organising and performing conformity assessment activities;
- appointing competent audit teams;
- reviewing assessment results;
- taking certification decisions;
- performing surveillance and recertification activities, where applicable;
- managing appeals and complaints relating to certification activities.

Certification Operators retain full responsibility for the selection, qualification, appointment, monitoring and continuous training and professional development of the auditors performing certification activities under the EUCCC Certification Scheme. They shall ensure that audit teams collectively possess the competence required for the scope of the assessment, that auditors remain impartial and independent throughout the certification process, and that actual or potential conflicts of interest are identified, managed and documented.

The competence requirements established by the Scheme Owner and the activities of the EUCCC Community of Auditors support the harmonised implementation of the Scheme. These arrangements do not replace or limit the responsibility of Certification Operators for the selection, qualification, appointment, monitoring and continual competence of their auditors.

Certification Operators implement the EUCCC Certification Scheme but do not participate in its governance. They shall not modify the certification requirements, evaluation methodologies or governance arrangements established by the Scheme. Likewise, the Scheme Owner governs and maintains the Scheme but does not participate in conformity assessment activities, certification decisions or the management of auditors, which remain the sole responsibility of Certification Operators.

Certification Operators shall contribute to the continuous improvement of the EUCCC Certification Scheme by providing implementation feedback, operational experience and recommendations to the Scheme Owner through the governance and feedback mechanisms established within the Scheme.

The main functions and responsibilities of Certification Operators are summarised **below.**

Functions and responsibilities of Certification Operators	
Function	**Main responsibilities**
Application management	Review certification applications and establish contractual arrangements with candidate centres.
Conformity assessment	Plan, organise and perform conformity assessment activities in accordance with the EUCCC Certification Scheme.
Audit management	Appoint competent audit teams and ensure their competence, impartiality and independence.
Certification decisions	Review assessment results and take independent certification decisions.
Surveillance	Perform surveillance and recertification activities, where applicable.
Appeals and complaints	Manage appeals and complaints relating to certification activities.
Auditor management	Select, qualify, appoint, monitor and maintain the continuous training and professional development of auditors.
Continuous improvement	Provide implementation feedback and operational experience supporting the continuous improvement of the Scheme.

2.1.5 Community of Experts and Auditors

The **Community of Experts and Auditors** is established to support the harmonised implementation of the EUCCC Certification Scheme across Europe. It provides a structured framework for sharing experience, promoting a common understanding of the Scheme, and supporting consistency in the interpretation and application of certification requirements.

The Community of Experts and Auditors is based on the peer-assessment culture underpinning the EUCCC Certification Scheme. Auditors and experts involved in certification activities are expected to contribute to a shared understanding of the standards, evaluation methodologies and underlying principles of the Scheme, while respecting the responsibilities of Certification Operators for conformity assessment activities and certification decisions.

The Community of Experts and Auditors shall not be understood as an auditor pool managed by the Scheme Owner. Participation in the Community does not replace or limit the responsibility of Certification Operators for the selection, qualification, appointment, training, monitoring and management of auditors performing certification activities under the EUCCC Certification Scheme. Certification Operators remain responsible for ensuring that audit teams collectively possess the competence required for the scope and complexity of each assessment. To facilitate the establishment of the Community of Experts and Auditors, the Scheme Owner will publish a call for expressions of interest inviting eligible auditors to participate on a voluntary basis.

The role of the Scheme Owner is to facilitate the Community of Experts and Auditors as a community of practice supporting the consistent and high-quality implementation of the Scheme. This may include the organisation of information sessions, exchanges of experience, methodological workshops, feedback mechanisms and discussions on the interpretation and application of certification requirements.

The Community of Experts and Auditors contributes to the continuous improvement of the EUCCC Certification Scheme by enabling structured feedback from audit experience. Lessons learned from certification activities, recurring interpretation issues, operational difficulties and methodological questions may be collected and analysed through the governance mechanisms established by the Scheme. Such feedback supports the periodic review of the Scheme and the continuous refinement of its methodologies and guidance documents.

The Community of Experts and Auditors also supports the European dimension of the Scheme. It promotes shared learning among auditors and experts from different Member States, contributes to the development of a common certification culture, and supports the consistent application of the Scheme across diverse healthcare systems and organisational contexts.

The Community of Experts and Auditors shall bring together a diversity of expertise reflecting the scope of the EUCCC Certification Scheme, including governance, clinical care, research, education and training, prevention, quality management, innovation, patient perspectives and consortium-based organisational models. This diversity of

expertise supports robust peer-assessment-based assessments and contributes to the credibility of the Scheme.

Participation in the Community of Experts and Auditors may support continuous professional development by enabling auditors and experts to remain informed of updates to the Scheme, methodological clarifications, lessons learned from implementation and developments relevant to Comprehensive Cancer Centres. These activities complement, but do not replace, the competence management responsibilities of Certification Operators.

The main functions of the Community of Experts and Auditors are summarised **below.**

Main functions of the Community of Experts and Auditors

Function	Main activities
Peer-assessment culture	Support a shared peer-assessment approach based on professional expertise, structured judgement and quality improvement.
Common understanding of the Scheme	Promote a consistent understanding of EUCCC standards, evaluation methodologies and certification principles.
Harmonisation of practices	Support consistency in the interpretation and application of certification requirements across Europe.
Exchange of experience	Facilitate exchanges between auditors, experts and certification stakeholders on lessons learned from certification activities.
Feedback to the Scheme	Provide structured feedback supporting the continuous improvement of the Scheme and associated guidance documents.
European coverage and diversity	Bring together expertise from different countries, healthcare systems and domains covered by the Scheme.
Continuous professional development	Support auditors and experts in maintaining awareness of Scheme updates, methodological clarifications and good practices.

2.2 Governance framework and functional interactions

The governance of the EUCCC Certification Scheme is based on clearly defined responsibilities and structured interactions between the different governance bodies involved in the development, implementation and continuous improvement of the Scheme. While each body fulfils distinct functions, their coordinated interactions contribute to ensuring the scientific robustness, operational consistency and long-term integrity of the EUCCC Certification Scheme.

As illustrated in **Figure 2,** the governance framework is organised around three complementary dimensions:

- **Strategic governance,** provided by the **Scheme Owner,** with independent scientific advice from the **Scientific Advisory Council;**
- **Operational coordination,** ensured by the **Certification Secretariat,** including the facilitation of the **Community of Experts and Auditors** as a European community of practice;
- **Independent conformity assessment activities,** performed by **Certification Operators,** which remain solely responsible for certification activities in accordance with the requirements of this Certification Scheme.

The governance framework preserves a clear separation between the governance of the Scheme and conformity assessment activities. The governance framework also incorporates structured feedback mechanisms. Scientific developments, implementation experience and lessons learned from certification activities contribute to the monitoring, periodic review and continuous improvement of the EUCCC Certification Scheme, ensuring that it remains scientifically robust, operationally effective and consistently implemented across Europe.

EUCCC CERTIFICATION SCHEME

Governance and Operational Interactions

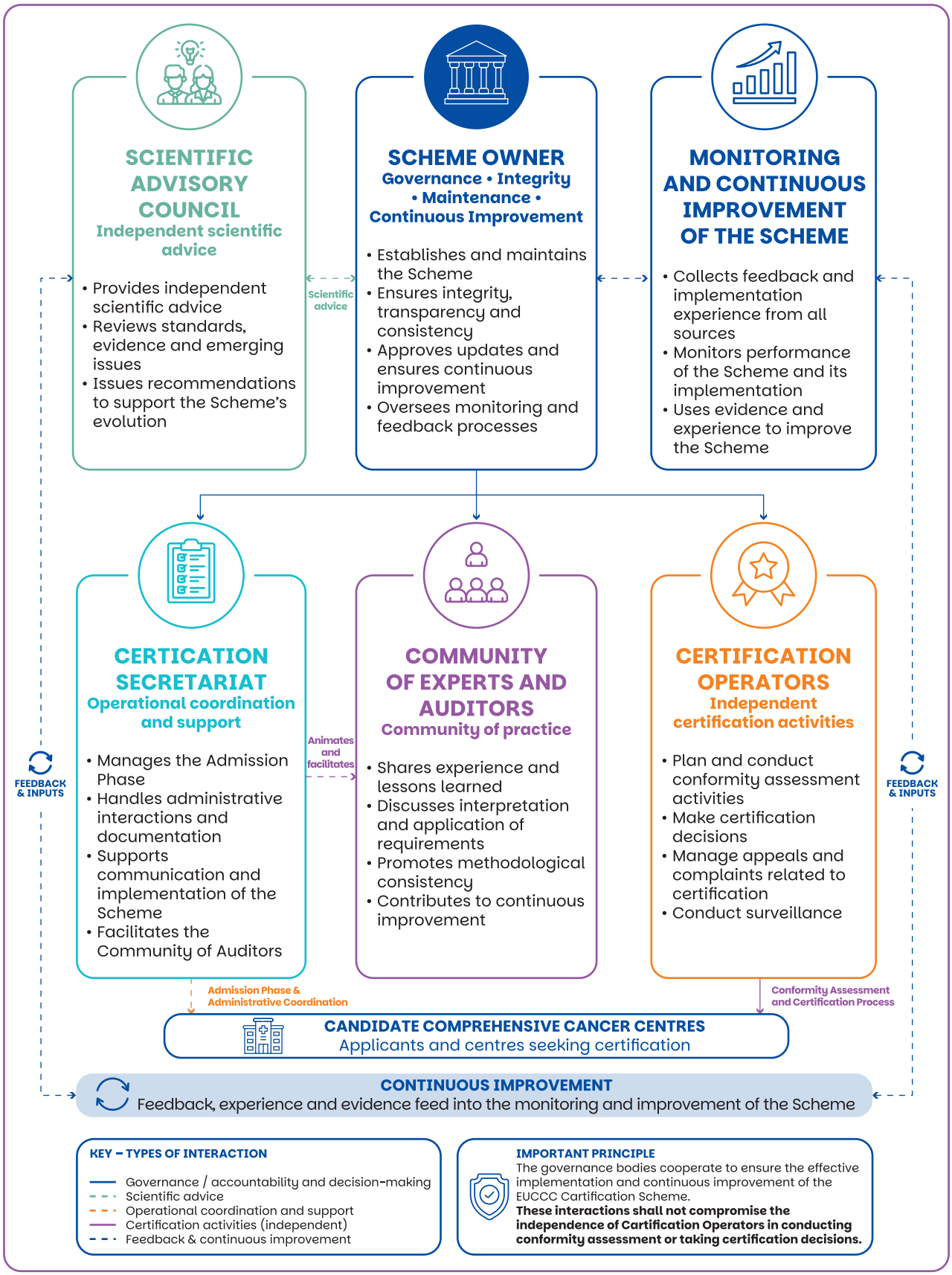


Figure 2. Governance framework and functional interactions within the EUCCC Certification Scheme.

3 EUCCC CERTIFICATION PROCESS

The EUCCC Certification Scheme is implemented through a structured certification pathway designed to ensure a consistent, transparent and harmonised assessment of candidate Comprehensive Cancer Centres across Europe.

The certification pathway is composed of clearly defined phases, each with specific objectives, responsibilities, inputs and outputs. Together, these phases provide a coherent framework for assessing conformity with the requirements of the EUCCC Certification Scheme, while ensuring impartiality, consistency and transparency throughout the certification process.

The certification pathway begins with an **Admission Phase,** during which it is confirmed that the candidate centre falls within the scope of the EUCCC Certification Scheme and fulfils the Admission Requirements established by the Scheme. This preliminary phase precedes all conformity assessment activities and provides the basis for entering the certification process.

Following admission, certification activities are performed by an accredited **Certification Operator** and include the application review, self-assessment review, audit preparation, on-site audit, audit reporting, certification decision, surveillance and re-certification, where applicable. Each phase is described in the following chapters together with its purpose, responsibilities, associated documentation and expected outputs.

Figure 3 EUCCC Certification Pathway

EUCCC CERTIFICATION PATHWAY

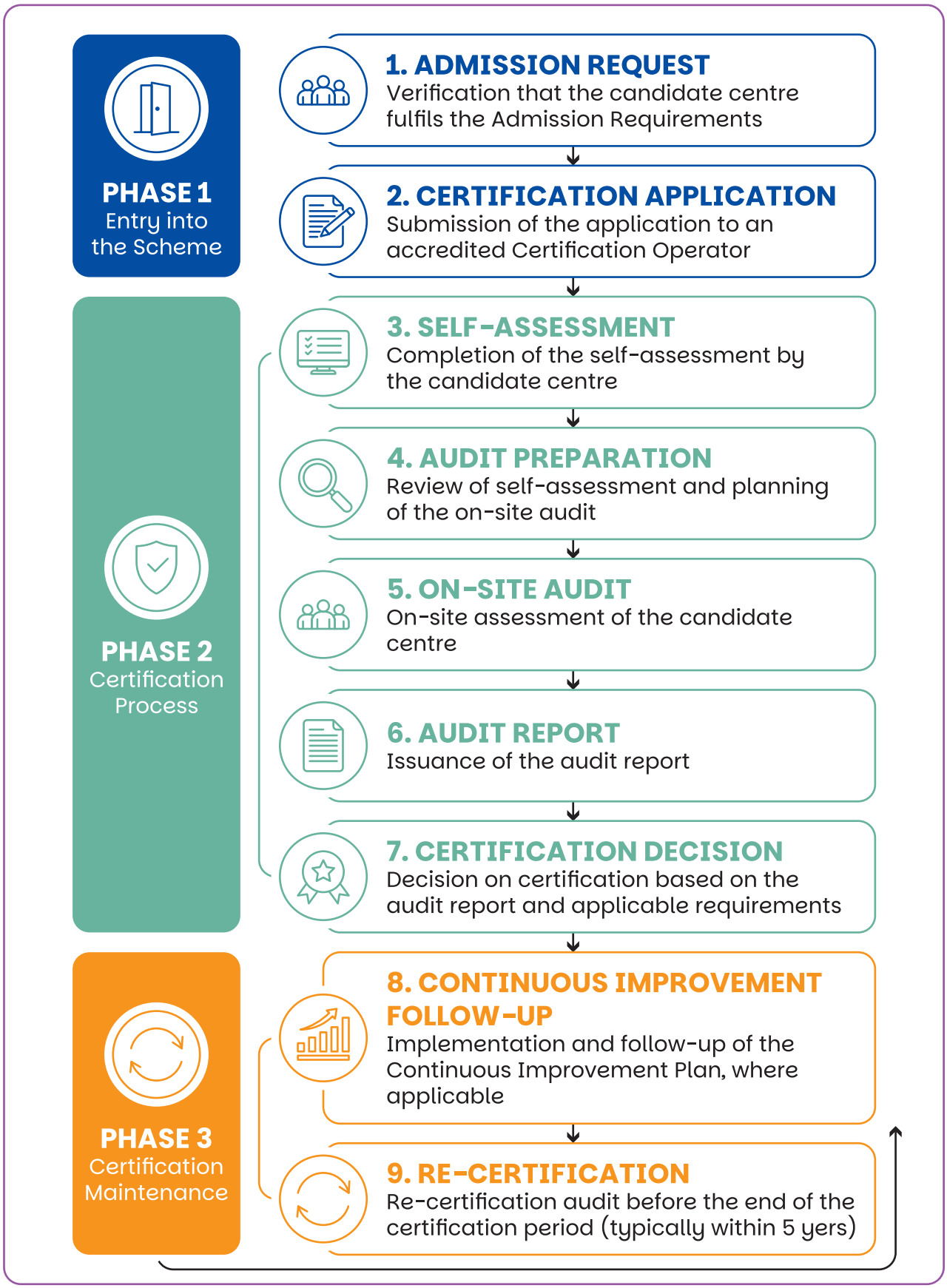


Figure 3. EUCCC Certification Pathway

ADMISSION PHASE

The **Admission Phase** constitutes the entry point to the EUCCC Certification Scheme. Overseen by the Scheme Owner, with operational support from the Certification Secretariat, it provides a harmonised process for determining whether a candidate centre or consortium may enter theEUCCC certification process or whether further preparation is needed before proceeding to certification.

During this phase, the Scheme Owner develops an initial understanding of the candidate's organisational configuration, principal activities, territorial context and proposed scope of certification. This enables the Scheme Owner to verify that the candidate falls within the scope of the EUCCC Certification Scheme and fulfils the applicable Admission Requirements. The Admission Phase also helps candidates understand the expectations of EUCCC certification, structure the information needed throughout the certification pathway and identify areas that may require further development or Capacity Building.

As the organisation and planning of healthcare remain the responsibility of the Member States, the Admission Phase also provides for the involvement of the national health authorities or, where relevant, the competent regional authorities. Through a Letter of Endorsement, they are invited to express their support for candidates applying for EUCCC certification and acknowledge the applicant's compliance with the Admission Requirements defined by the Scheme Owner.

Upon successful completion of the Admission Phase, the Scheme Owner issues an **Allowance to Apply,** enabling the candidate centre to enter the EUCCC Certification Process and to submit an application to an accredited Certification Operator.

As such, **the Admission Phase does not form part of the conformity assessment process,** and the Allowance to Apply does not constitute certification or demonstrate compliance with the EUCCC Set of Criteria and Standards. Conformity assessment activities and certification decisions remain the sole responsibility of the accredited Certification Operator.

From the date on which the Allowance to Apply is issued, however, the candidate is granted the temporary status of Designated Comprehensive Cancer Centre (Designated CCC) and may use this designation for a maximum period of two years, pending completion of the certification process.

Transition during the Joint Action EUCCC 2024–2028

During the implementation period of the EUnetCCC Joint Action, the Framework for Designation of Comprehensive Cancer Centres fulfils the function of the Admission Phase described in this Certification Scheme and constitutes the entry mechanism for participating centres. Candidate centres participating in the Joint Action shall first undergo the designation process coordinated by the Designation Advisory Committee (DAC), in accordance with the Framework for Designation. Following a positive designation decision, centres are deemed to have fulfilled the Admission Requirements and may proceed directly to the next phase of the EUCCC Certification Process. No additional admission review is required during the Joint Action. This transitional arrangement applies exclusively during the implementation of the Joint Action. Following completion of the Joint Action, the Admission Phase described in this Certification Scheme shall constitute the standard entry point to the EUCCC Certification Process for all candidate centres.

3.1.1 Admission Process

STEP 1 – Applying for EUCCC Certification

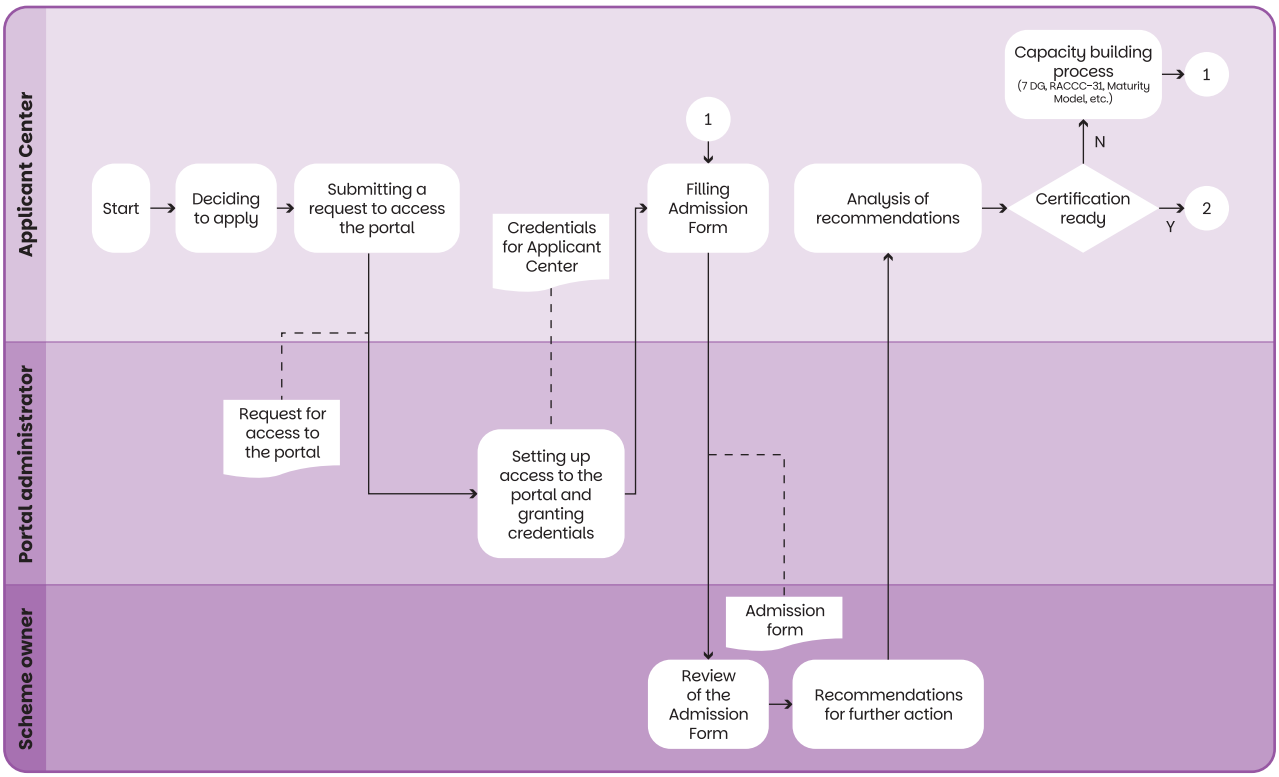


Figure 4. Step 1 Admission process

The Admission Process consists of a sequence of activities designed to ensure a consistent, transparent and harmonised admission of candidate centres to the EUCCC Certification Scheme.

Request for national or regional endorsement

As a first step, the candidate centre or consortium should request a **Letter of Endorsement** from the competent national health authority or, where responsibility for the organisation of cancer care is exercised at regional level, from the relevant regional authority. Through this letter, the competent authority confirms its support for the application, acknowledges the applicant's compliance with the European definition of a Comprehensive Cancer Centre and the admission requirements of the EUCCC certification scheme.

Access to the EUCCC Certification Portal

Once the Letter of Endorsement has been requested, the candidate requests access to the EUCCC Certification Portal. The Portal Administrator grants access and provides the credentials and information necessary to initiate the Admission Phase.

Completion of the required information

The candidate then completes the two online forms required for admission, the Admission Form and the Contextual Information Form. The candidate also provides the Letter of Endorsement issued by its national health authority or regional authority. The information collected through the forms and the respective purposes of each form are described in Section 3.1.2. At this stage, the information provided through the forms is declarative, and no supporting evidence is required other than the Letter of Endorsement.

Admission review

The Scheme Owner, with operational support provided by the Certification Secretariat, verifies that the admission dossier is complete and reviews the information provided to determine whether the requirements established by the Scheme have been fulfilled.

Clarification and further preparation

Where necessary, additional information, clarification, or revisions to the forms may be requested before the admission review can be completed.

Where improvements are required, the Scheme Owner provides recommendations for further action. The candidate centre analyses these recommendations and determines whether it is ready to proceed with the certification process.

If additional preparation is required, the applicant may access the Capacity Building materials and tools available through the EUCCC Certification Portal, revise the forms accordingly, and resubmit them for review.

This iterative process continues until the admission requirements have been satisfactorily fulfilled.

Allowance to apply

Once the Scheme Owner determines that the candidate fulfils the admission requirements and is ready to proceed to certification, it issues the Allowance to Apply.

The candidate may then formally apply to an accredited Certification Operator, which assumes sole responsibility for the conformity assessment and certification decision.

3.1.2 Admission requirements

The Admission Phase is based on a set of information, documentation and administrative requirements that enable the Scheme Owner to determine whether an Allowance to Apply may be issued.

These requirements are fulfilled through the submission of two complementary documents by the candidate centre:

Admission Form

The Admission Form is an online form available on the EUCCC Certification Portal through which the candidate centre or consortium formally applies for admission and provides the information required by the Scheme Owners.

It collects:

- general and administrative information about the applicant;
- information on the organisation included in the application, where relevant;
- initial information on the proposed scope of certification; and
- structured information on the candidate's territorial, organisational, clinical and scientific characteristics (see list of questions in section 3.1.3 below).

Where necessary, the Scheme Owner may request additional information or clarification before completing the Admission Phase.

Contextual Information Form

The Contextual Information Form is an online form available on the EUCCC Certification Portal. It complements the Admission Form by collecting more detailed and descriptive information on the candidate's organisation and operating context. It enables the Scheme Owner to understand the organisational model presented by the applicant and to prepare the subsequent certification process.

For consortium-based applications, the Contextual Information Form shall additionally include an overview of the consortium identifying the coordinating organisation, the participating organisations, the principal governance arrangements and the proposed certification scope. This overview provides the basis for the detailed organisational mapping that will be further developed during the Self-Assessment Phase using the EUCCC Set of Criteria and Standards.

3.1.3 Indicative targets for candidate centres

Part of the Admission Form is structured around seven domains covering the main dimensions of a Comprehensive Cancer Centre. For each domain and its associated questions, the section below specifies the information expected from candidate centres or consortia and, where appropriate, proposes indicative benchmarks to support their self-assessment and help them determine their readiness to enter the certification process.

These indicative benchmarks are provided for guidance purposes only. They shall not be interpreted as mandatory Admission Requirements, conformity assessment requirements or certification criteria, nor do they constitute minimum thresholds for entering the certification process. Their purpose is to promote a common understanding of the expected profile of a Comprehensive Cancer Centre, while allowing sufficient flexibility to accommodate differences in national healthcare systems, institutional organisation and territorial contexts.

Domain 1 – Population Catchment Area

Objective
This criterion aims to assess the geographical and demographic scope of the candidate centre and its strategic positioning within its territory.

Information requested	
Information	**Description**
Territories covered	Description of the regions, cities or administrative areas served by the centre.
Estimated population served	Approximate number of inhabitants within the catchment area.
Annual patient flow	Number of patients treated annually, based on the most recent available data.
Map of the area	Visual representation of the catchment area.
Evidence of service activity	Documentation demonstrating actual service delivery, including: • Origin of patients • Referral patterns • Existing collaborations with local or regional institutions

Indicative benchmark

Catchment area between 3 and 5 million inhabitants (adaptable depending on the national context).

Domain 2 – Organisation and Governance

Objective
This criterion assesses the governance structure and inter-institutional coordination mechanisms supporting the operation of the Comprehensive Cancer Centre.

Information requested	
Information	**Description**
Steering Committee	Formal governance body established to oversee strategic and operational decisions.
Inter-institutional Agreement	Signed or ongoing agreement formalising collaboration between institutions involved in the CCC.
Shared Platforms	Common data or project management platform supporting coordination.
Governance Documentation	Governance Charter or equivalent document supporting transparency and accountability.

Domain 3 – Strategic Positioning

Objective
This criterion assesses the strategic positioning of the candidate centre and its contribution to national and European cancer control objectives.

Information requested	
Information	**Description**
Motivation for candidacy	Brief narrative describing the centre's ambitions, strengths and added value.
Strategic priorities	One or more priorities may be identified: • Strengthening regional structuring of cancer care • Promoting equitable access to innovation • Integrating care, research and training • Enhancing international visibility and collaboration • Reducing inequalities in cancer outcomes

Domain 4 – Clinical Capacity

Objective
This criterion assesses the centre's capacity to deliver comprehensive, multidisciplinary and high-quality cancer care.

Information requested	
Information	**Description**
New cancer cases treated per year	Total number of newly diagnosed and treated cancer cases annually.
Cancer types covered	Coverage across the five major cancer types.
Medical oncology staff	Number of Full-Time Equivalent (FTE) professionals in medical oncology.
Territorial coordination mechanisms	Description of regional coordination mechanisms, including shared multidisciplinary tumour boards, regional care pathways, mobile oncology teams and integration of supportive care.
Operational clinical data platform	Status of implementation (Yes / Ongoing / No).
Monitoring of median waiting time	Monitoring between diagnosis confirmation and first treatment (Yes / Ongoing / No).
Monitoring of post-surgical mortality	Monitoring of 30- or 90-day mortality rates (Yes / Ongoing / No).

Indicative benchmark

≥ 2,500 new cancer cases treated annually.

Domain 5 – Research and Clinical Trials

Objective
This criterion assesses the centre's research activity and its integration into clinical practice.

Information requested

Information	Description
Active oncology clinical trials	Number of ongoing oncology clinical trials.
Patient enrolment	Percentage of treated patients enrolled in clinical trials.
Annual cancer research budget	Total budget allocated to oncology research.
Scientific output	• Percentage of publications in Q1 journals. • Cumulative publication score (number of publications × average journal impact factor).
Participation in research consortia	Involvement in European or international research networks (Yes / No, with list if applicable).
Minimum thresholds	At least one of the following: • 100 FTEs involved in cancer care. • 1,000 new cancer cases treated annually.
Relative research output	Number of peer-reviewed cancer-related publications per year, adjusted for population or institutional size.

Indicative benchmark 1

5% of diagnosed and/or treated patients within the candidate centre should be recruited for clinical trials, including patients enrolled through formal agreements with consortia and/or associated care providers, as well as through cross-border collaborations.

This benchmark is intended as a progressive objective and shall not be interpreted as a mandatory requirement for initial certification. Candidate centres are expected to demonstrate transparency regarding their clinical research activities and a clear commitment to progressively strengthening their research capacity towards this objective.

Indicative benchmark 2 – Balanced and Scalable Evaluation Framework

Candidate centres should also provide information on their scientific output using the following bibliometric indicators:

- Relative Research Output (publications adjusted per 100 FTEs involved in cancer care or per 1,000 new cancer cases treated annually);
- Percentage of publications published in Q1 journals;
- Cumulative Publication Score (number of publications × average journal impact factor).

The following indicative ranges support candidate centres in positioning their scientific activity.

Performance level	Publications (per 100 FTE or 1,000 new cancer cases/year)	Q1 journals	Publication score
Excellent	≥ 30	≥ 40%	≥ 1,000
Satisfactory	20–30	≥ 25%	500–999
Minimum	10–20	≥ 15%	300–499
Below minimum	< 10	< 15%	< 300

Domain 6 – Integration of Functions

Objective
This criterion assesses the centre's ability to integrate care, research and innovation within a unified patient pathway.

Information requested	
Information	**Description**
Clinical trial enrolment from first consultation	Patients are considered for clinical trials early in their care pathway.
Trial availability assessment	Access to information on available clinical trials is integrated into the patient pathway.
Innovation action plan	Documented strategy for fostering innovation in care, research and services.
Access to advanced technologies	Availability of: • Sequencing platforms • Artificial intelligence tools • High-end imaging systems • Precision radiotherapy • Other advanced technologies (to be specified).

Domain 7 – Prevention, Training and Patient Engagement

Objective
This criterion assesses the centre's contribution to prevention, education, training and participatory governance.

Information requested	
Information	**Description**
Participation in screening programmes	Participation in: • National screening programmes • Local screening initiatives
Role in screening	• Screening unit • Referral centre • Both
Involvement in education and training	Activities targeting students, interns, nurses, patients or other groups.
Patient engagement	Involvement of patients or patient representatives in governance structures.
Collaborations in training and education	Partnerships with training centres, research institutions, community organisations or patient groups.

3.2 Certification application

This step marks the beginning of the preparation phase for the EUCCC certification process. The applicant centre establishes the organisational structure and project management arrangements necessary to conduct the self-assessment in a structured and effective manner.

The applicant centre establishes a governance structure to oversee the certification process by appointing a Steering Committee and a Project Team. The Steering Committee consists of senior managers with the authority to support and oversee the implementation of the certification activities and may subsequently evolve into the CCC Governing Body. The Project Team comprises personnel with the expertise required to address the different thematic areas covered by the EUCCC Certification Scheme and is responsible for coordinating the self-assessment activities.

The applicant centre prepares a project plan defining the activities, responsibilities, timelines, and resources required to perform the self-assessment and, where necessary, implement improvements to the centre's operations. Throughout this phase, applicants may use the guidance documents and supporting materials provided by the EUCCC Certification Scheme to facilitate the planning and preparation process.

The established scope of the consortium when applying for certification cannot be changed during the certification journey.

The Certification application is illustrated in **Figure 5.**

STEP 2 – Core team set-up and planning

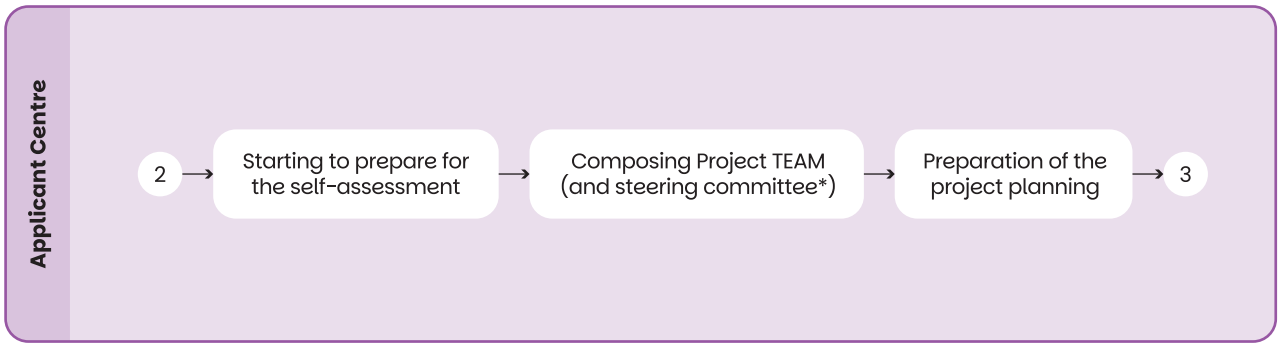


Figure 5. Core team set-up and planning

3.3 Self-Assessment

3.3.1 Purpose of the Self-Assessment

The purpose of the **Self-Assessment** step is to enable the applicant centre to evaluate its level of compliance with the EUCCC Set of Criteria and Standards before proceeding to the external certification audit. Through a structured internal assessment, the applicant centre shall identify the extent to which the certification requirements have been implemented, provide objective evidence demonstrating compliance, and identify areas requiring further improvement.

The self-assessment shall be conducted using the EUCCC Self-Assessment Tool embedded within the EUCCC Certification Portal. The tool provides a structured and standardised environment for assessing all certification standards, documenting supporting evidence, and automatically calculating compliance scores according to the EUCCC scoring methodology.

This step comprises five main components:

- familiarisation with the Self-Assessment Tool and its functionalities;
- application of the EUCCC criteria weighting guidelines and scoring methodology;
- completion and internal validation of the self-assessment by the Project Team and Steering Committee;
- specific arrangements for conducting an integrated self-assessment for consortium-based candidate centres; and
- an administrative completeness check performed by the Scheme Owner to verify that the submitted self-assessment complies with the requirements of the EUCCC Certification Scheme before the applicant centre proceeds to the external conformity assessment.

Successful completion of this step confirms that the applicant centre has submitted a complete and internally validated self-assessment, supported by appropriate documentary evidence, and is ready to continue the certification process with an accredited Certification Operator.

3.3.2. Overview of the Self-Assessment Phase

STEP 3 – Detailed self-assessment

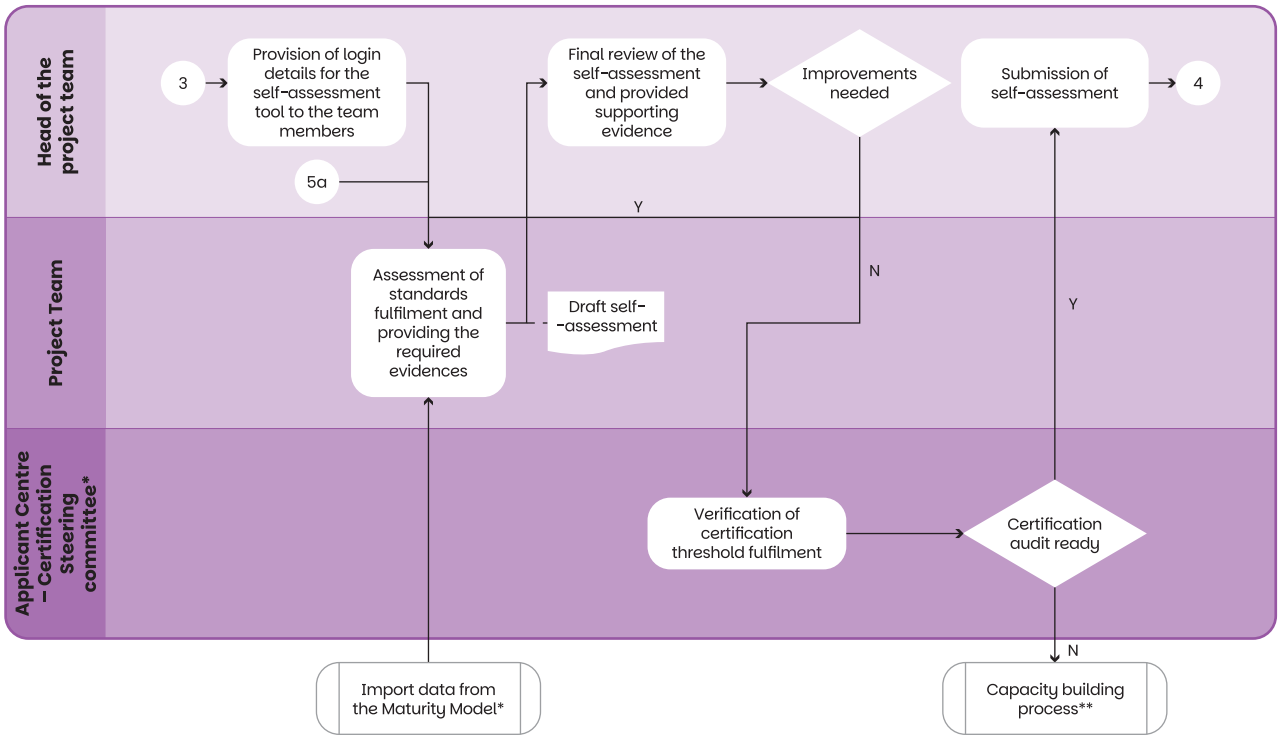


Figure 6. Detailed self-assessment

STEP 4 – Self-assessment check

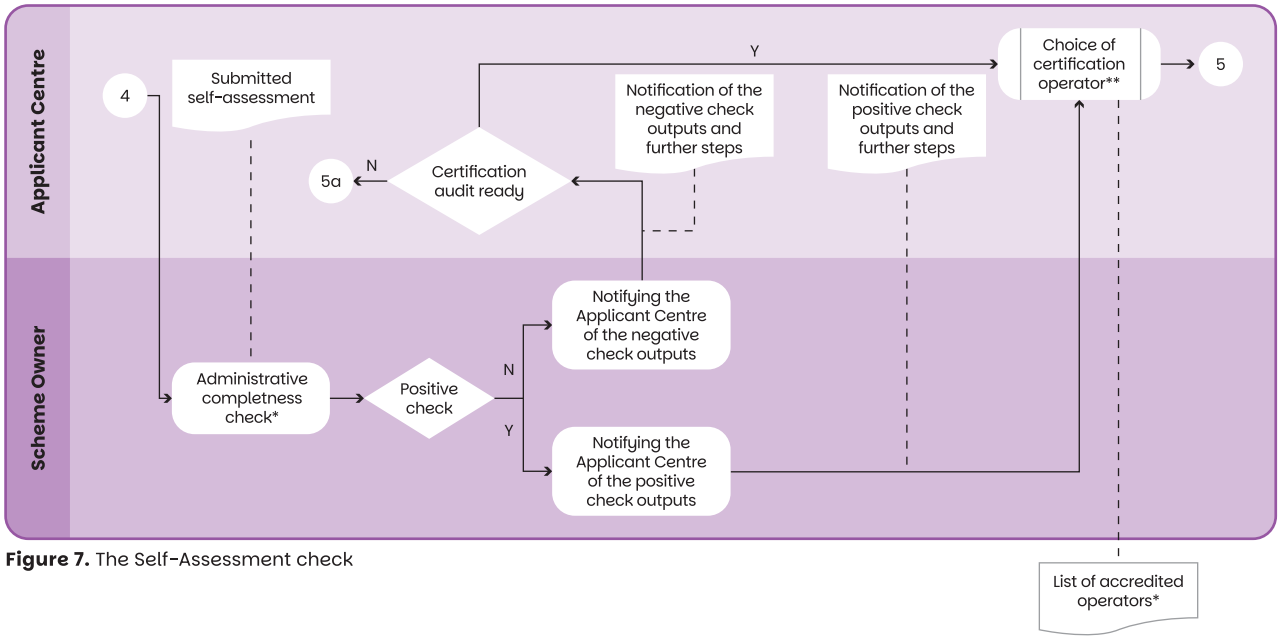


Figure 7. The Self-Assessment check

3.3.3. Self-Assessment Tool

The Self-Assessment Tool has been developed to provide the technological infrastructure supporting the certification process of European Comprehensive Cancer Centres. Its primary purpose is to enable applicant centres to perform a structured assessment against the EUCCC Set of Criteria and Standards, identify strengths and areas requiring improvement, and prepare for the subsequent external certification audit.

The tool follows the hierarchical structure of the certification framework, allowing users to navigate through domains, topics, criteria, and individual standards. For each standard, users may record the degree of fulfilment, provide narrative descriptions explaining how the requirement has been implemented, and upload supporting documentation demonstrating compliance.

The Self-Assessment Tool supports standardised data collection across applicant centres and incorporates an automated scoring mechanism that calculates performance against the certification thresholds. The information entered into the tool shall form the basis for the subsequent administrative review and external certification audit.

The user manual of the Self-Assessment Tool is provided as a separate document available for applicant centres.

3.3.4. Criteria Weighting Guidelines and Scoring System

Before proceeding to completing the Self-Assessment, it is important to understand the weighting guidelines and scoring system used in the EUCCC Certification Scheme. The scheme applies a standardised scoring methodology to evaluate compliance with the Set of Criteria and Standards. The methodology is intended to provide a transparent, objective, and comparable assessment across applicant centres while recognising both the comprehensiveness and excellence expected of a Comprehensive Cancer Centre.

The certification framework distinguishes between **core** and **non-core standards.** Core standards represent essential requirements that underpin multiple elements of the certification framework, receive particular attention during certification, require more robust supporting evidence, and are prioritised during external review. Where deficiencies are identified in core standards, the applicant centre shall prepare and implement appropriate corrective actions before certification can be granted.

Each standard shall be assessed using the following four-level scale:

- **100%** – Standard fulfilled: the standard is fully implemented, documented, and consistently applied throughout the organisation.
- **65%** – Standard mostly fulfilled: the standard is substantially implemented, with only minor gaps that do not significantly affect performance.
- **35%** – Standard partially fulfilled: important elements of the standard have been implemented, but several critical components remain incomplete or are only partially operational.
- **0%** – Standard not fulfilled: the standard has not been implemented.

For each assessment theme, the fulfilment score shall be calculated as the average of all standards within that theme. To satisfy the certification requirements, the applicant centre shall achieve an average score of at least 70% in each of the seven assessment themes.

In addition to the thematic scores, a Core Standards Indicator shall be calculated across all themes. This indicator reflects performance in the most critical areas of the certification framework. The applicant centre shall achieve an average score of at least 80% across all core standards to proceed within the certification process.

The integrated scoring mechanism within the Self-Assessment Tool shall automatically calculate these indicators, enabling the applicant centre to monitor progress throughout the self-assessment and determine its readiness for external certification.

3.3.5. Conducting the Self-Assessment

The Self-Assessment shall be conducted collectively by the Project Team set up in the previous step. The Head of the Project Team shall assign login credentials to the members of the Project Team and, where appropriate, to members of the Steering Committee to provide access to the Self-Assessment Tool.

The Project Team shall assess each standard using the prescribed assessment scale, prepare narrative evidence describing the implementation of the standard, and upload supporting documentation to the Self-Assessment Tool. Where the applicant centre has previously completed the Maturity Model as part of the Capacity Building process, the Project Team may reuse the available information to facilitate completion of the self-assessment. Supporting documents submitted through the tool should be provided in English whenever possible.

Upon completion of the draft self-assessment, the Head of the Project Team shall review the preliminary scoring, narrative descriptions, and supporting documentation to ensure their completeness and consistency. Where deficiencies or inconsistencies are identified, the Project Team shall revise the self-assessment before it is submitted for further review.

The Steering Committee shall review the completed self-assessment and verify whether the certification thresholds established by the Scheme have been achieved. To proceed to the next stage of the certification process, it is recommended that the applicant centre achieves an average score of at least **80%** across all core standards and an average score of at least **70%** across all standards within each of the seven assessment themes. Where these thresholds are not met, the applicant centre may implement the necessary improvements, including, where appropriate, the use of Capacity Building materials and tools, before updating and repeating the self-assessment.

When the applicant centre has confirmed its readiness to proceed, the Head of the Project Team shall submit the completed self-assessment through the Self-Assessment Tool.

3.3.6. Self-Assessment for Consortium-Based Candidate Centres

The self-assessment process for consortium-based candidate centres shall follow the same Set of Criteria and Standards and the same evaluation methodology as those applicable to single-entity applicant centres. However, the process shall be adapted to reflect the distributed organisational structure of the consortium and the allocation of activities and responsibilities across multiple participating entities.

The consortium shall conduct **one integrated self-assessment** covering the entire certification perimeter rather than separate self-assessments for each participating entity. Before initiating the assessment, the consortium coordinator shall define the certification perimeter and identify all participating entities included within the certification application.

As an initial step, the consortium shall prepare a structured mapping matrix identifying, for each standard included in the EUCCC Certification Scheme:

- whether the standard is applicable to the consortium;
- which participating entity or entities are responsible for implementing the standard;
- whether evidence is expected at consortium level, entity level, or both; which entity will be responsible for providing the supporting documentation; and
- which entity will coordinate the completion of the corresponding section of the self-assessment.

An illustrative example of such a mapping matrix is presented below.

Standards / Activities	Entity 1	Entity 2	Entity 3	Entity 4
Criterion 1.1.1	Yes	No	Yes	Yes
Criterion 1.1.2	Yes	No	Yes	Yes
Criterion 1.1.3	Yes	No	Yes	Yes

The purpose of this mapping is to ensure that responsibilities for evidence collection are clearly assigned before the self-assessment begins and to facilitate both the subsequent external audit and the development of an appropriate sampling strategy.

The assessment shall subsequently be performed according to the organisational level at which each standard is implemented. Certain standards may be demonstrated through common consortium-wide governance arrangements, policies, procedures or shared services, whereas other standards require evidence of operational implementation within individual participating entities.

Although all seven domains of the Set of Criteria and Standards shall be assessed across the consortium, the approach to scoring may differ according to the nature of the standards.

For standards within the **Care** domain, implementation shall normally be demonstrated by each participating healthcare entity delivering clinical services. Since patient care is provided locally, evidence shall be collected and assessed at the level of each relevant entity. For **core standards** within this domain, the consortium score shall correspond to the **lowest score achieved by any participating entity** included within the certification perimeter. This principle ensures that essential clinical requirements are consistently fulfilled throughout the consortium and prevents deficiencies at one site from being compensated by stronger performance at another.

A similar approach should be considered for other domains where standards relate directly to activities that are expected to be implemented consistently across all participating entities.

Conversely, some standards relate to functions that may legitimately be organised according to the principle of complementarity between consortium members. This may include, for example, specialised research infrastructures, innovation platforms, educational programmes, prevention activities or other functions that are intentionally concentrated within one or several entities serving the consortium as a whole. Where such organisational arrangements are formally established and effectively implemented, compliance may be demonstrated by the entity responsible for performing the function on behalf of the consortium. In these cases, the consortium score may reflect the performance of the responsible entity, provided that the arrangement is supported by formal

governance mechanisms and that all participating entities have effective access to the relevant services or activities.

Throughout the self-assessment process, the consortium coordinator or another formally designated contact point shall oversee the collection of evidence from all participating entities, ensure consistency of scoring across the consortium, coordinate the resolution of discrepancies, and consolidate the final self-assessment before submission through the EUCCC Self-Assessment Tool.

The adapted self-assessment methodology is intended to ensure that the certification process accurately reflects both the collective performance of the consortium and the effective implementation of standards at the level where the corresponding activities are performed. It also provides the basis for planning a proportionate, risk-based external audit, allowing auditors to focus their onsite assessment on the entities responsible for implementing the applicable standards while evaluating the consortium as a single Comprehensive Cancer Centre.

3.3.7. Administrative Completeness Check

The purpose of the Administrative Completeness Check is to verify that the self-assessment submitted by the applicant centre is complete and complies with the administrative requirements of the EUCCC Certification Scheme before the external certification process is initiated.

Following submission of the self-assessment, the Scheme Owner shall perform an administrative completeness check to verify that all required sections of the Self-Assessment Tool have been completed, that the necessary supporting documentation has been provided, and that the submission complies with the administrative and documentary requirements of the EUCCC Certification Scheme.

The Administrative Completeness Check shall **not** include an evaluation of the applicant centre's compliance with the EUCCC Set of Criteria and Standards, nor an assessment of the centre's readiness for certification. The decision to proceed with the certification process following completion of the self-assessment remains the responsibility of the applicant centre. The verification of compliance with the certification standards and the determination of whether the requirements for certification have been fulfilled are performed exclusively by the selected Certification Operator during the external conformity assessment.

Where deficiencies relating to the completeness of the submission are identified, the Scheme Owner shall notify the applicant centre and request that the self-assessment be revised and resubmitted. The applicant centre shall address the identified deficiencies before resubmitting the self-assessment for review.

Following a successful administrative completeness check, the Scheme Owner shall notify the applicant centre that the self-assessment has been accepted for further processing.

3.4. Selection of the Certification Operator, Contractualisation and Payment

3.4.1. Purpose

The purpose of this step is to establish the contractual relationship between the applicant centre and an accredited Certification Operator, thereby initiating the independent external conformity assessment required by the EUCCC Certification Scheme.

The EUCCC Certification Scheme is based on the principle that certification decisions shall be made independently from the Scheme Owner. Consequently, conformity assessment activities shall be performed exclusively by independent Certification Operators that have been accredited to operate the EUCCC Certification Scheme in accordance with its governance and accreditation requirements.

The Scheme Owner is responsible for maintaining the Certification Scheme, and publishing the list of accredited operators through the EUCCC Certification Portal. However, once the applicant centre has successfully completed the administrative completeness check, the Scheme Owner shall not intervene in the contractual relationship, commercial arrangements, or conformity assessment activities carried out between the applicant centre and the selected Certification Operator.

The applicant centre shall independently select a Certification Operator from the list of accredited operators available through the EUCCC Certification Portal. From this point onwards, all activities related to contractualisation, financial arrangements, audit planning and the execution of the certification audit shall be managed directly between the applicant centre and the selected Certification Operator.

Overview of the actions in this step is illustrated in **Figure 8** below.

STEP 5 – Contractualisation & Payment

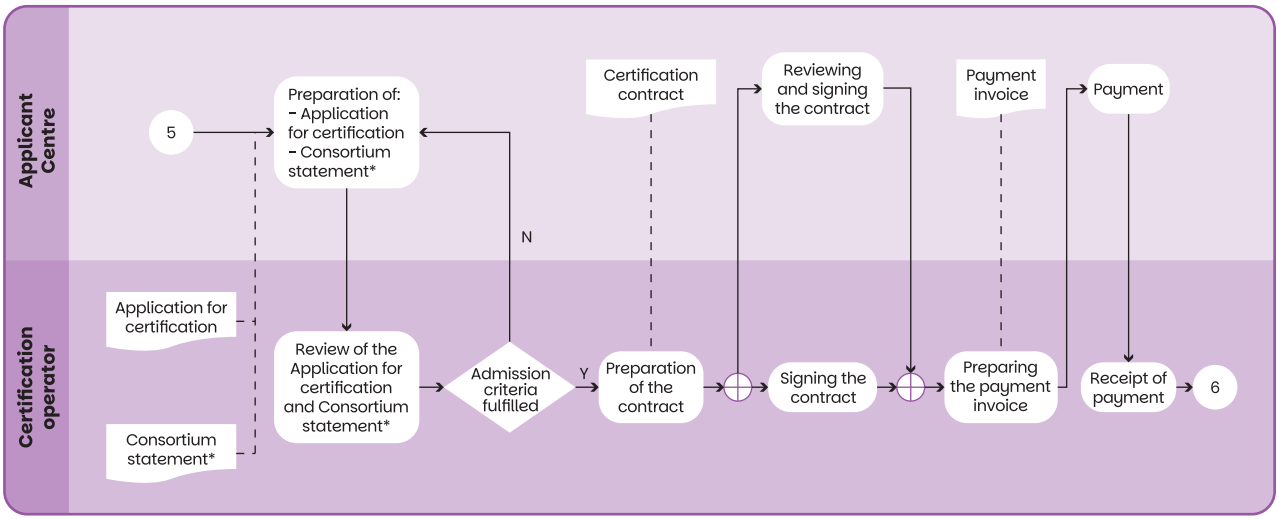


Figure 8. Contractualisation & Payment

3.4.2. Selection of the Certification Operator

The applicant centre shall review the list of accredited Certification Operators published in the EUCCC Certification Portal.

The applicant centre may select any Certification Operator accredited to perform assessments under the EUCCC Certification Scheme. The selection shall be made independently by the applicant centre, taking into consideration its own organisational needs and any practical considerations relevant to the certification process.

Once selected, the Certification Operator shall become responsible for all subsequent conformity assessment activities conducted under the EUCCC Certification Scheme.

3.4.3. Submission of the Application for Certification

The applicant centre shall prepare a formal Application for Certification and submit it to the selected Certification Operator.

Where the applicant centre is organised as a consortium consisting of multiple independent legal entities, the application shall be accompanied by the Consortium Statement defining the certification perimeter, governance arrangements, participating entities and authorised representatives of the consortium.

The Application for Certification and, where applicable, the Consortium Statement shall be submitted directly to the selected Certification Operator.

3.4.4. Review of the Application

Upon receipt of the application, the Certification Operator shall review the submitted documentation to verify that the admission requirements for initiating the conformity assessment have been fulfilled.

Where applicable, the Certification Operator shall also review the Consortium Statement to verify that the consortium structure, governance arrangements and certification perimeter have been clearly defined.

The purpose of this review is to verify that the information necessary to initiate the certification process has been provided. It does not constitute the certification audit nor an assessment of compliance with the EUCCC Set of Criteria and Standards.

Where deficiencies or omissions are identified, the Certification Operator shall notify the applicant centre and request that the Application for Certification and, where applicable, the Consortium Statement be revised and resubmitted. The review process shall continue until the required documentation has been satisfactorily completed.

3.4.5. Contractualisation

Once the Certification Operator has confirmed that the application requirements have been fulfilled, the Certification Operator shall prepare the certification contract and submit it to the applicant centre.

The applicant centre shall review the contractual documentation and, where acceptable, sign the contract.

For consortium-based applicant centres, the contract shall be signed by the authorised representative(s) designated in the Consortium Statement and empowered to act on behalf of all participating entities within the certification perimeter.

The Certification Operator shall subsequently countersign the contract. Upon signature by both parties, the contractual relationship shall enter into force and the certification process may proceed.

3.4.6. Payment of Certification Fees

Following execution of the certification contract, the Certification Operator shall prepare and issue the invoice for the certification activities in accordance with the contractual agreement.

The applicant centre shall pay the applicable certification fees directly to the Certification Operator within the timeframe specified in the contract.

Upon receipt of the payment, the Certification Operator shall confirm that the financial requirements for initiating the certification assessment have been fulfilled.

Completion of the contractualisation and payment process authorises the Certification Operator to proceed with the preparation of the external certification audit, including the appointment of the audit team and the detailed planning of the onsite assessment.

Additional funding for centres engaged in certification activities during the EUnetCCC Joint Action (2024–2028)

The following arrangements apply exclusively to centres participating in the EUnetCCC Joint Action and do not constitute permanent provisions of the EUCCC Certification Scheme.

Additional funding for centres engaged in certification activities.

Additional funding may be made available to support centres participating in the certification scheme, in particular to cover the recruitment of project managers, travel costs, and certification/auditing fees. The certification audit itself is estimated at approximately €50,000 for standalone centres and €75,000 for consortium centres, due to the additional complexity and coordination required.

Access to this additional budget is subject to the fulfilment of two criteria: (i) the centre must be designated and commit to undergoing the certification process, and (ii) the centre must have consumed at least 60% of its previously allocated periodic budget. Once these conditions are met, the centre may request additional funding and will be eligible to receive an initial 40% pre-financing payment of the additional budget allocated. Subsequent payments will be based on the actual declaration of eligible costs incurred by the centre.

The amount of additional funding will be calculated based on the number of project months (PMs) allocated to each centre. The allocation will range between 12 and 24 PMs, depending on the configuration and level of involvement of the centre. Centres involving a higher number of affiliated entities will be eligible for a higher number of PMs, reflecting the additional coordination and management efforts required. The total amount of additional funding will be calculated by multiplying the number of allocated PMs by the applicable country-specific monthly rate.

3.5. Audit Preparation.

3.5.1 Purpose

The purpose of the audit preparation phase is to ensure that the on-site audit is appropriately planned and organised to enable an independent, consistent and evidence-based assessment of the Applicant Centre against the requirements of the EUCCC Certification Scheme.

The EUCCC Certification Scheme is based on a peer-assessment approach. On-site audits shall therefore be conducted by multidisciplinary audit teams composed of qualified auditors with recognised experience in Comprehensive Cancer Centres or equivalent organisations.

Audit preparation aims to:

- confirm the scope of certification;
- appoint an appropriately competent audit team;
- review the Applicant Centre's self-assessment and supporting documentation;
- prepare the audit activities;
- establish the audit programme and agenda;
- agree the organisational and logistical arrangements necessary for the conduct of the on-site audit.

The extent of audit preparation shall be proportionate to the scope, complexity and organisational configuration of the Applicant Centre.

The audit preparation process comprises three successive stages: (i) appointment and preparation of the audit team, (ii) development of the on-site audit agenda, and (iii) final preparation of the on-site audit. These stages are illustrated in Figures 9.1 to 9.3.

STEP 6 – Composing and preparing the Audit team

Overview of the activities leading to the appointment of the audit team and the allocation of roles and responsabilities for the preparation of the on-site audit.

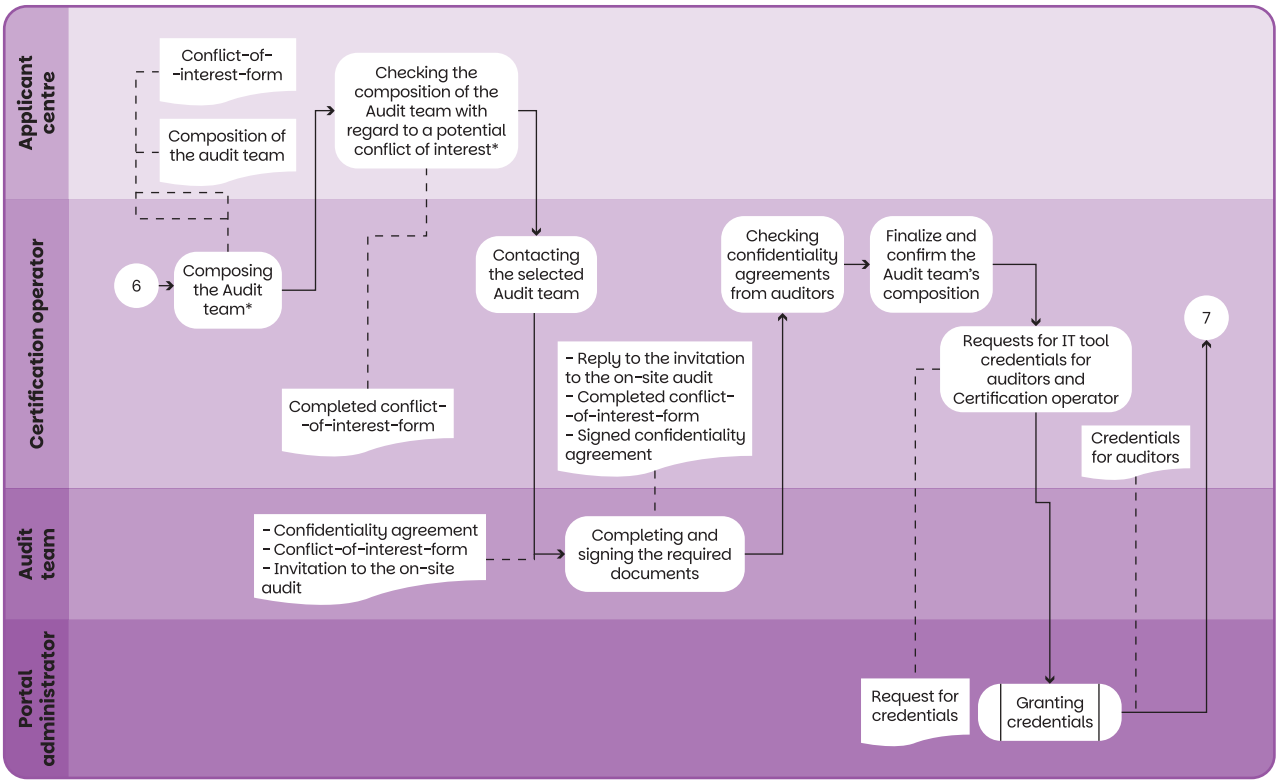


Figure 9.1 Illustrates the main steps of the audit preparation process.

STEP 7 – Composing the on-site audit agenda

Overview of the collaborative planning process between the Chairperson and the Applicant Centre to establish the audit agenda and confirm the organisational arrangements required for the on-site audit.

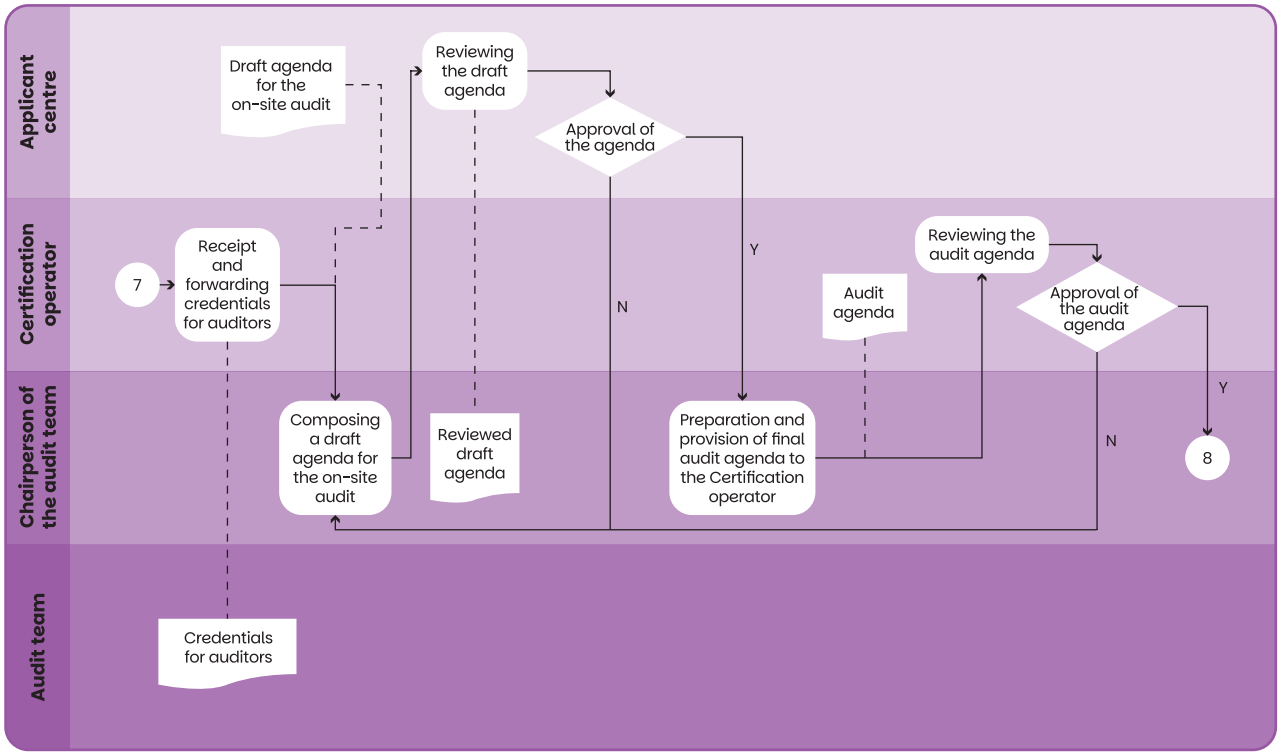


Figure 9.2 Preparation of the On-site Audit Agenda

STEP 8 – Preparation of the on-site audit

Overview of the final preparation activities undertaken before the on-site audit, including document review, interview preparation, confirmation of logistical arrangements and finalisation of the audit agenda.

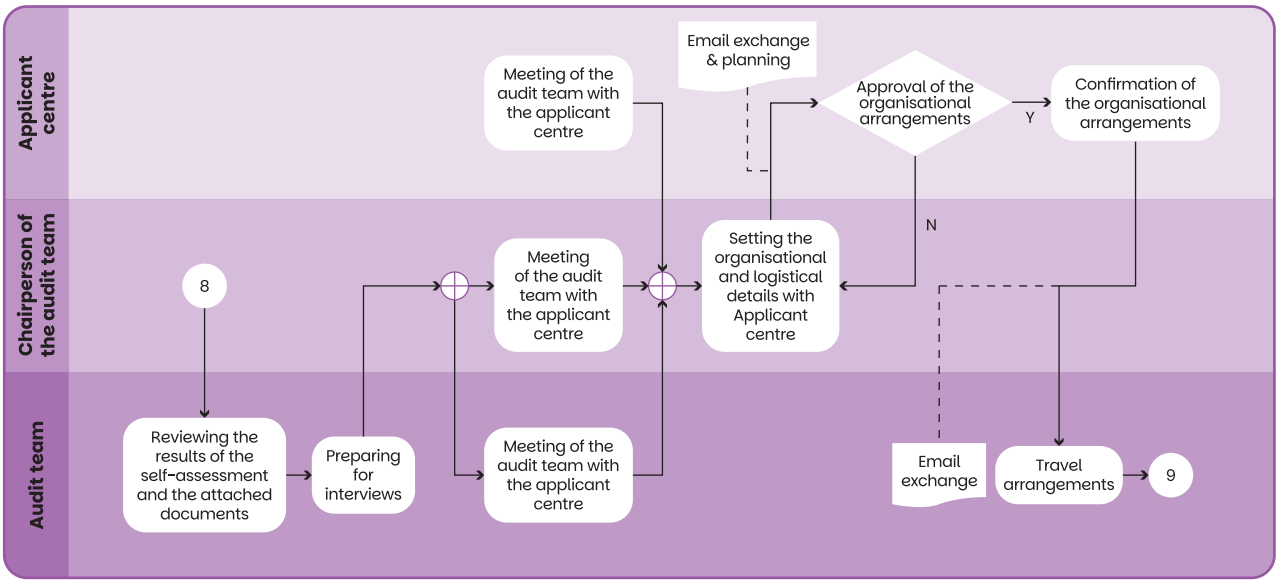


Figure 9.3 Preparation of the On-site Audit

STEP 9 – On-site audit

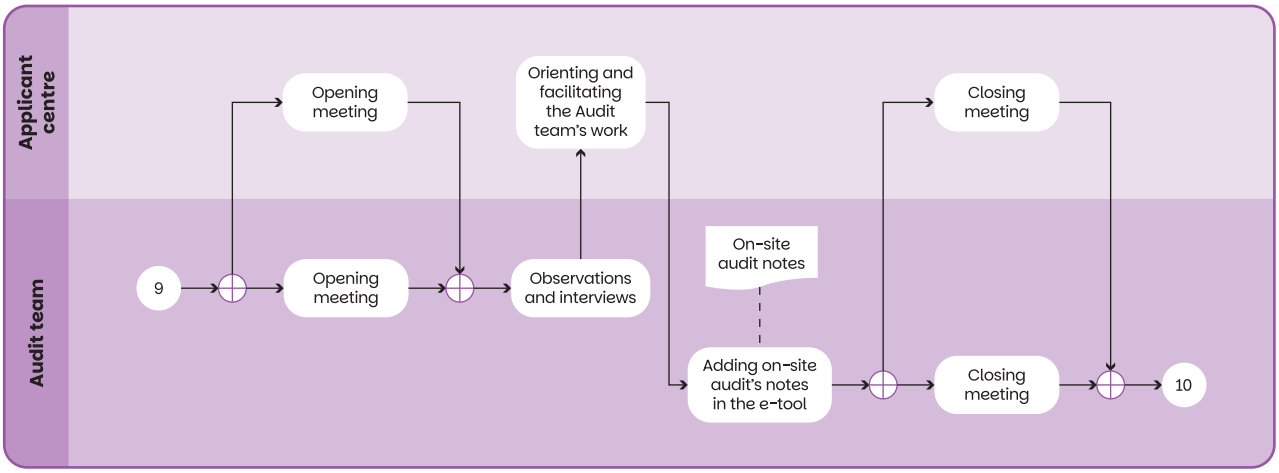


Figure 10. On-site audit

3.5.2 Audit Team

The Certification Operator shall appoint an audit team possessing the collective competence necessary to assess the scope of certification.

Auditors shall be experienced professionals working in Comprehensive Cancer Centres or equivalent organisations and shall collectively possess the expertise required to assess conformity with the EUCCC Certification Scheme.
One auditor shall be appointed as Chairperson of the Audit Team.

The Chairperson shall be responsible for coordinating the preparation of the audit, ensuring effective communication with the Applicant Centre, facilitating coordination within the audit team, overseeing the development of the audit plan and ensuring the consistency of the conformity assessment throughout the on-site audit.

Indicative Audit Team Composition

Candidate configuration	Typical audit team composition
Stand-alone Comprehensive Cancer Centre	Chairperson + **3–4 auditors**
Large single-site Comprehensive Cancer Centre	Chairperson + **4–6 auditors**
Consortium-based Comprehensive Cancer Centre (limited complexity)	Chairperson + **5–7 auditors**
Large multi-site consortium	Chairperson + **6–8 auditors**

Note
The figures presented above are indicative only and shall not be regarded as mandatory requirements. The Certification Operator shall determine the final composition of the audit team based on the scope of certification, organisational complexity, number of participating entities and sites, audit duration, identified risks, sampling strategy and the competences required to perform the assessment.

Factors Influencing Audit Planning

Complexity factor	Potential influence on audit planning
Number of participating sites	Increased audit resources and coordination
Geographical dispersion	Longer audit duration and logistical planning
Identified risks	Risk-based allocation of audit resources

The Certification Operator shall document the rationale used to determine the audit team composition and the overall audit planning.

3.5.3 Review of the Self-Assessment and Supporting Documentation

Before the on-site audit, the audit team shall review the documentation submitted by the Applicant Centre.

The review shall normally include:

- the completed self-assessment;
- supporting evidence;
- organisational and governance documentation;
- documentation relevant to the certification scope;
- any additional information requested by the Certification Operator.

The purpose of the document review is to prepare the on-site assessment.

The audit team shall, in particular:

- understand the organisational context;
- verify the completeness of the submitted documentation;
- identify areas requiring clarification;
- identify standards requiring further verification during the on-site audit;
- prepare interviews, observations and site visits.

Document review shall support, but shall not replace, the on-site assessment.

3.5.4 Audit Planning and Coordination

Following completion of the document review, the Chairperson shall prepare a draft audit plan.

The draft audit plan shall normally include:

- the proposed audit dates and duration;
- the audit agenda;
- allocation of responsibilities within the audit team;
- proposed interviews;
- planned observations and site visits;
- opening and closing meetings;
- daily coordination meetings of the audit team.

To ensure that the audit can be conducted efficiently, the draft audit plan shall be discussed with the Applicant Centre.

The purpose of this planning phase is to confirm the organisational feasibility of the audit while preserving the independence of the conformity assesment.

Discussions shall normally address:

- the proposed audit schedule;
- availability of key personnel;
- sequencing of interviews and site visits;
- access to departments, facilities and documentation;
- practical and logistical arrangements;
- organisational constraints that may affect the conduct of the audit.

Where appropriate, one or more preparatory meetings may be organised between the Chairperson, members of the audit team and representatives of the Applicant Centre. These meetings may be conducted remotely.

Following these discussions, the Chairperson shall finalise the audit agenda and communicate it to the Applicant Centre sufficiently in advance of the on-site audit.

Indicative Timeline for Audit Preparation

The indicative timeline presented in Table reflects recognised good practice for the preparation of an on-site audit. Certification Operators may adapt these indicative timeframes according to the size, scope and organisational complexity of the Applicant Centre, provided that sufficient time is allowed for document review, audit planning and the effective preparation of the on-site audit.

Indicative Timeline for Audit Preparation

Activity	Typical timing
Appointment of the Chairperson and audit team	Normally **3–4 months** before the on-site audit
Self-assessment report and supporting documentation made available to the audit team	Normally **2–3 months** before the on-site audit
Documentary review by the audit team	Normally completed **6–8 weeks** before the on-site audit
Preliminary audit programme communicated to the Applicant Centre	Normally **4–6 weeks** before the on-site audit
Audit planning meeting between the Chairperson and the Applicant Centre	Normally **3–4 weeks** before the on-site audit
Finalisation and communication of the detailed audit agenda	Normally **1–2 weeks** before the on-site audit
Confirmation of organisational and logistical arrangements	During the **week preceding** the on-site audit

The audit preparation process should include planning discussions between the Chairperson and the Applicant Centre to facilitate the organisation of the on-site audit. These discussions shall focus on practical and organisational arrangements, including the audit programme, availability of key personnel, scheduling of interviews, multidisciplinary meetings, site visits and logistical arrangements.

Following these discussions, the audit agenda and organisational arrangements may be refined where necessary. However, the Certification Operator shall retain sole responsibility for determining the audit scope, audit methodology, audit plan, sampling strategy and composition of the audit team.

3.5.5 Logistical Arrangements

The Applicant Centre shall designate a contact person responsible for coordinating practical arrangements with the Certification Operator throughout the preparation phase.

Logistical arrangements shall normally include:

- access to facilities;
- working facilities for the audit team;
- access to documentation and information systems where appropriate;
- arrangements for site visits;
- security requirements;
- local practical arrangements.

3.5.6 Specific Provisions for Consortium-Based Candidate Centres

For consortium-based candidate centres, audit preparation shall additionally ensure that the audit programme reflects the organisational configuration and governance arrangements of the consortium.

Before the on-site audit, the audit team shall review:

- the consortium governance arrangements;
- the certification scope;
- the distribution of activities across participating entities;
- the mapping of applicable standards;

- responsibilities assigned to each participating entity;
- operational coordination mechanisms;
- documentation demonstrating organisational integration.

The audit programme shall distinguish:

- consortium-level assessment activities;
- site-level assessment activities;
- participating entities selected for on-site assessment.

Where multiple participating entities are involved, the planning process shall ensure appropriate coordination between the consortium coordination body and the participating entities to facilitate efficient conduct of the audit.

3.6. On-Site Audit

3.6.1 Purpose

The on-site audit constitutes the principal conformity assessment activity of the EUCCC Certification Scheme.

Its purpose is to determine, through peer assessment and the collection of objective evidence, whether the Applicant Centre conforms to the requirements of the EUCCC Certification Scheme. The on-site audit shall verify the effective implementation of the applicable Certification Standards within the organisational context of the Applicant Centre and, where appropriate, confirm the information provided during the self-assessment phase.

Figure 10.1 illustrates the sequence of activities performed during the on-site audit, from the opening meeting through interviews, observations, evidence collection, daily coordination and the closing meeting.

OVERVIEW OF THE ON-SITE AUDIT PROCESS



Figure 10.1 Overview of the On-site Audit Process

3.6.2 General Audit Methodology

The on-site audit shall be conducted using a structured, evidence-based and peer--assessment methodology designed to ensure a consistent, proportionate and transparent assessment of conformity with the applicable certification requirements of the EUCCC Certification Scheme, while allowing sufficient flexibility to reflect the organisational characteristics of the Applicant Centre.

The audit methodology is based on the following principles.

Peer-assessment approach

The audit shall be carried out by highly experienced experts and auditors with substantial professional expertise in oncology, including leadership, clinical practice, research, and nursing.

The multidisciplinary composition of the audit team shall ensure that the assessment benefits from practical experience and professional judgement across the different areas included within the scope of certification.

Evidence-based assessment

Audit findings shall be based exclusively on objective evidence obtained during the conformity assessment. Conclusions shall be supported by verifiable information collected through appropriate evaluation techniques.

Risk-based approach

The audit team shall allocate audit effort according to the complexity, scope and risk profile of the Applicant Centre. Areas presenting greater organisational or clinical complexity, or greater potential impact on patient care, may receive increased audit attention.

Multidisciplinary assessment

The audit shall evaluate the Comprehensive Cancer Centre as an integrated organisation. Assessment activities shall therefore consider the interactions between governance, patient care, research, prevention, education, innovation and quality management rather than assessing these areas independently.

Organisation through Auditable Blocks

To promote an integrated assessment, the on-site audit shall normally be organised through thematic **auditable blocks** grouping together related certification standards according to organisational functions, clinical processes or patient pathways.

Each auditable block brings together standards that are operationally interconnected, allowing the audit team to assess multiple related requirements through a coherent sequence of interviews, observations and review of objective evidence.

The organisation of the audit into auditable blocks facilitates:

- evaluation of organisational processes rather than isolated requirements;
- multidisciplinary discussions involving several professional groups;
- efficient organisation of interviews and site visits;
- assessment of interfaces between organisational functions;
- evaluation of the effective integration of care, research, education, prevention and innovation.

The organisation of auditable blocks remains the responsibility of the Certification Operator. Depending on the scope, organisational characteristics and complexity of the Applicant Centre, auditable blocks may be organised in different ways, provided that all applicable standards are assessed.

Illustrative examples of auditable blocks and their typical assessment focus

Illustrative Auditable Block	Typical assessment focus
Governance, Leadership and Organisational Structure	Governance arrangements, leadership and organisational responsibilities.
Cancer Strategy, Governance Processes and Internal Coordination	Strategic planning, governance processes and organisational coordination.
Governance Model for High-Quality Patient Care	Clinical governance, quality of care and patient safety.
Patient Participation in Governance and Educational and Support Activities	Patient participation, engagement and support.
External Collaboration and Networks	External partnerships, referral pathways and network collaboration.
Common Quality and Coordination Systems	Quality management, performance monitoring and continuous improvement.
Shared Policies and Procedures	Organisation-wide policies, procedures and harmonised practices.
Multidisciplinary Tumour Boards (MDTs)	Multidisciplinary clinical decision-making and coordination of care.
Systemic Therapies and Medication Safety	Delivery and safety of systemic anticancer therapies.

Illustrative examples of auditable blocks and their typical assessment focus	
Illustrative Auditable Block	**Typical assessment focus**
Surgery and Radiotherapy Activities	Organisation and delivery of surgical and radiotherapy services.
Radiology and Nuclear Medicine	Diagnostic imaging and nuclear medicine services.
Survivorship and Prevention	Survivorship, supportive care and prevention.
Professional Education and Training Programmes	Education, training and professional competency development.
Research Strategy and Leadership	Research governance, leadership and strategic direction.
Research Comprehensiveness	Breadth and integration of research activities.
Clinical Trials Capacity and Management	Organisation and management of clinical trials and patient access.
Innovation Strategy and Culture	Innovation governance and implementation.
Structural Arrangements for Integration	Integration of care, research, education, prevention and innovation.

Table below provides illustrative examples of auditable blocks and their typical assessment focus.

The organisation and sequencing of auditable blocks may be adapted according to the organisational characteristics of the Applicant Centre, provided that all applicable certification standards remain covered by the conformity assessment. Auditable blocks are intended solely to facilitate the organisation and conduct of the on-site audit and shall not replace the assessment of individual standards, for which conformity shall be determined independently.

Consistency and proportionality

The audit methodology shall be applied consistently by all Certification Operators while remaining proportionate to the size, scope and complexity of the Applicant Centre, thereby ensuring a comparable level of confidence in the conformity assessment irrespective of the organisational model of the Applicant Centre.

The relationship between certification standards, evaluation techniques, objective evidence and audit findings is illustrated in **Figure 10.2.**

FROM CERTIFICATION STANDARDS TO AUDIT FINDINGS

On-site Audit Process

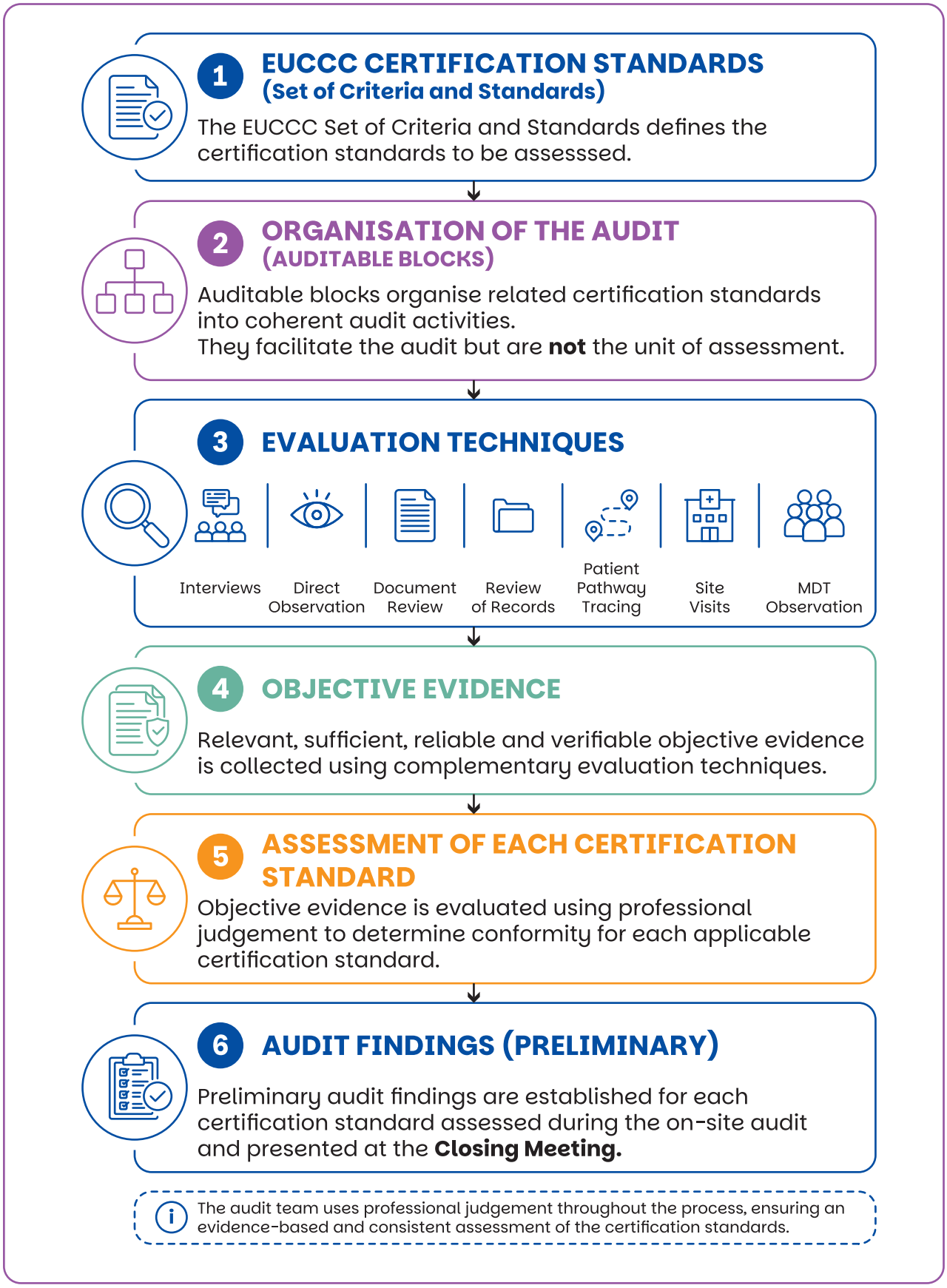


Figure 10.2 From Certification Standards to Audit Findings – On-site Audit Process

3.6.3 Opening Meeting

The on-site audit shall commence with an Opening Session involving the audit team and representatives of the Applicant Centre.

The purpose of the Opening Session is to establish a common understanding of the audit objectives, methodology, scope and programme before commencing the assessment activities.

The Opening Session shall normally include:

- introduction of participants;
- presentation of the audit methodology;
- confirmation of the audit scope;
- confirmation of the audit agenda;
- communication arrangements;
- health and safety information where appropriate;
- final organisational clarifications.

The Applicant Centre provides a short introductory presentation describing its organisational structure, governance arrangements and any significant developments since submission of the application.

3.6.4 Conduct of On-site Audit Activities

The on-site audit shall be conducted in accordance with the approved audit plan and the audit methodology described in this Scheme Manual.

Audit activities shall be organised through the auditable blocks established during the audit planning phase. The audit team shall conduct the assessment in a systematic and coordinated manner to ensure that all applicable standards are evaluated within the agreed scope of certification.

Audit activities shall normally be conducted by **one or two experts and auditors,** depending on the nature of the auditable block, the competences required and the complexity of the assessment. This approach is intended to facilitate open discussions, optimise the use of audit resources and minimise disruption to the activities of the Applicant Centre. Audit activities should normally be organised to maximise the availability of relevant professionals while minimising disruption to patient care and routine clinical activities.

The Chairperson shall ensure the effective coordination of audit activities throughout the on-site audit. Where justified by observations made during the audit, operational constraints or emerging audit findings, the Chairperson may adapt the sequence of audit activities or modify the audit agenda, provided that the audit objectives, scope and overall integrity of the conformity assessment are maintained.

The conduct of the audit shall combine complementary evaluation techniques appropriate to the certification requirements being assessed. Depending on the purpose of the assessment, audit activities may include:

- structured interviews with managers, healthcare professionals, researchers, patients or other relevant stakeholders;
- direct observation of clinical, organisational or support activities;
- review of documented information, records and performance data;
- patient pathway tracing to assess the continuity, coordination and integration of care across organisational interfaces;
- observation of multidisciplinary tumour boards or other governance meetings, where appropriate;
- visits to clinical departments, research facilities and other relevant locations;
- any other evaluation activity considered necessary to obtain sufficient and reliable audit evidence.

The selection and combination of evaluation techniques shall remain proportionate to the scope and complexity of the Applicant Centre and shall enable the audit team to obtain sufficient objective evidence to support the conformity assessment.

Throughout the audit, the audit team shall maintain effective internal communication to coordinate assessment activities, ensure a consistent interpretation of the Certification Standards, identify any additional objective evidence required and facilitate the consistent development of audit findings.

3.6.5 Evaluation Methodology

The conformity assessment shall be based on the systematic collection, verification and evaluation of objective evidence to determine conformity with the applicable certification requirements of the EUCCC Certification Scheme.

To achieve this objective, the audit team shall apply evaluation techniques appropriate to the standards being assessed. The selection and combination of evaluation techniques shall remain proportionate to the objectives of the assessment, the level of risk, the organisational context and the evidence available.

The selection of evaluation techniques shall take into consideration the **Suggested Evidence** associated with each certification standard. The Suggested Evidence included in the EUCCC Set of Criteria and Standards is intended to assist the audit team in identifying potential sources of evidence and shall neither be regarded as exhaustive nor mandatory. The audit team shall remain responsible for determining the most appropriate evaluation techniques and sources of evidence according to the circumstances encountered during the audit.

The evaluation methodology aims to verify both the documented arrangements established by the Applicant Centre and their effective implementation and effectiveness in practice. No single evaluation technique is sufficient to assess all standards. The selection and combination of evaluation techniques shall therefore be determined according to the nature of the certification standards being assessed and the evidence necessary to support the conformity assessment.

Professional judgement shall be exercised by the audit team in an impartial, evidence--based and consistent manner throughout the conformity assessment. The collective deliberation of the audit team shall contribute to ensuring the consistency and robustness of the conformity assessment. Conformity shall be determined independently for each applicable Certification Standard on the basis of evidence collected during the audit. Audit conclusions shall be supported exclusively by objective evidence obtained through the conformity assessment. Such evidence shall be:

- relevant;
- sufficient;
- reliable;
- verifiable.

Where reasonably practicable, audit conclusions shall be supported by evidence obtained through more than one evaluation technique. No audit finding should normally rely solely upon a single source of evidence where additional corroboration from other sources is reasonably available.

Typical evaluation techniques are presented **table below.**

Typical Evaluation Techniques	
Evaluation technique	**Typical objective**
Structured interviews	Assess governance, responsibilities, implementation and effectiveness through discussions with managers, healthcare professionals, researchers, patients, patient representatives or other relevant stakeholders, as appropriate.
Direct observation	Assess the implementation and effectiveness of organisational processes, clinical practices and support activities under routine operating conditions.
Review of documented information	Verify documented policies, procedures, protocols, governance arrangements and other documented information relevant to the certification standards.
Review of records	Confirm the consistent implementation and effectiveness of organisational processes through the review of records, performance indicators and other documented evidence.
Patient pathway tracing	Assess the continuity, coordination and integration of care across organisational interfaces by following one or more representative patient pathways.
Observation of multidisciplinary meetings	Assess multidisciplinary decision-making, coordination and collaboration between healthcare professionals.
Site visits	Assess the organisation, infrastructure and operational implementation of clinical, research, educational and support activities.

The audit team may combine these evaluation techniques, or apply other appropriate evaluation methods where justified, in order to obtain sufficient objective evidence to determine conformity with each applicable certification standard and to support reliable audit findings.

3.6.6 Sampling Methodology

Sampling shall be designed to provide a representative and reliable basis for determining conformity with the applicable certification standards, while maintaining the operational feasibility of the audit.

The Certification Operator shall establish, document and justify a sampling strategy appropriate to the Applicant Centre. The sampling strategy shall be based on a risk-based and proportionate approach, taking into consideration the scope of certification, organisational complexity, patient safety considerations, clinical activities, organisational risks and the results of the document review and self-assessment.

Sampling may include, where appropriate:

- organisational functions and governance processes;
- clinical departments and support services;
- multidisciplinary tumour boards;
- patient pathways;
- patient records;
- research and innovation activities;
- education and training activities;
- quality management processes and performance indicators.

The Certification Operator shall ensure that the selected sample provides sufficient objective evidence to support a reliable conformity assessment, while remaining proportionate to the size, scope and complexity of the Applicant Centre. The sampling strategy may be refined during the on-site audit where emerging audit findings indicate that additional assessment activities are necessary to support the conformity assessment.

Specific provisions for consortium-based Applicant Centres

For consortium-based Applicant Centres, the sampling methodology has been developed taking into account internationally recognised approaches for the assessment of multi-site organisations, including the relevant internationally recognised methodologies for multi-site assessment (International Accreditation Forum's "Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization"), adapted where necessary to the specific characteristics of Comprehensive Cancer Centres.

These principles have been adapted to reflect the specific characteristics of Comprehensive Cancer Centres, particularly the importance of patient safety, clinical complexity, heterogeneity of activities and the need to assess operational integration across consortium

entities. Consequently, the sampling strategy shall combine methodological robustness, operational feasibility and risk-based considerations in order to ensure representative and meaningful conformity assessments across consortium configurations.

All entities formally included within the certification scope shall participate in the self-assessment process according to the activities they perform and the structured mapping of consortium activities established during the application phase. However, on-site audit activities may be limited to a representative sample of participating entities, where this remains compatible with the level of risk, organisational complexity and audit objectives.

The sampling strategy shall combine:

- targeted selection based on risk, activities and organisational complexity;
- a proportion of random sampling intended to ensure diversity of assessed situations and organisational configurations across the consortium.

As an indicative methodological principle for **initial certification audits,** the minimum number of participating sites selected for direct on-site assessment may be determined using the following approach:

$$y = \checkmark x$$

Where:

x = total number of participating sites included within the certification scope;

y = minimum number of participating sites selected for direct on-site assessment.

The calculated value shall be rounded up to the nearest whole number.

As a general principle, **at least 25% of sampled sites should be selected randomly.** However, the sampling methodology shall remain adaptable according to:

- patient safety considerations;
- distribution of patient care activities;
- specialised or high-risk activities;
- maturity of governance and coordination mechanisms;
- the level of operational integration across consortium entities.

Priority should normally be given to:

- sites involved in high-risk or high-complexity care activities;
- major patient pathways across the consortium;
- organisational areas presenting significant operational importance within the consortium model.

The Certification Operator may increase the number of sampled sites where this is justified by the level of risk, organisational complexity, uncertainties arising from the document review or self-assessment, or observations made during the audit.

The sampling strategy adopted for each consortium-based Applicant Centre shall be documented and justified within the audit plan.

3.6.7 Daily Coordination of the Audit Team

The audit team shall maintain effective communication and coordination throughout the on-site audit to ensure the consistent application of the audit methodology and the efficient conduct of audit activities.

The Chairperson shall coordinate the daily activities of the audit team and ensure that information obtained by individual auditors is appropriately shared and considered during the conformity assessment. This meeting does not replace the individual professional judgement of each auditor but provide a structured forum to ensure consistency of interpretation and coordination across the audit team. Daily coordination meetings shall normally be organised at the end of each audit day. The purpose of these meetings is to:

- review the audit activities completed during the day;
- consolidate the objective evidence collected;
- discuss preliminary audit observations and areas requiring further investigation;
- ensure a consistent interpretation of the certification requirements;
- identify any additional evidence or interviews required;
- review the audit programme and, where necessary, adapt the audit plan for the following day;
- ensure appropriate coordination between auditors responsible for different auditable blocks.

Where appropriate, brief coordination meetings may also be organised during the audit day to address operational issues or to facilitate coordination between auditors.

The daily coordination meetings are internal working sessions of the audit team and are not intended to communicate audit conclusions to the Applicant Centre.

Any significant modification to the audit programme shall be communicated to the Applicant Centre by the Chairperson as soon as reasonably practicable.

The audit team shall maintain confidentiality regarding audit observations and preliminary findings throughout the on-site audit. Audit conclusions shall only be formally communicated during the Closing Meeting.

3.6.8 Closing Meeting

The on-site audit shall conclude with a **Closing Meeting** involving the audit team and the representatives of the Applicant Centre.

The purpose of the Closing Meeting is to formally conclude the on-site audit, provide a factual summary of the audit activities performed and present the preliminary audit findings observed during the conformity assessment.

The Closing Meeting shall normally be chaired by the Chairperson of the audit team. Representatives of the Applicant Centre, including members of the management team and other relevant personnel, should normally participate.

The Closing Meeting shall normally include:

- confirmation that the on-site audit has been completed in accordance with the agreed audit plan, including any significant deviations where applicable;
- summary of the audit activities performed;
- presentation of the preliminary audit findings, including identified strengths, opportunities for improvement and potential non-conformities, where applicable;
- clarification of any factual issues raised during the audit;
- opportunity for the Applicant Centre to request clarification regarding the audit findings;
- presentation of the subsequent stages of the certification process, including preparation of the audit report, factual accuracy review, certification decision and, where applicable, submission of a corrective action or improvement plan.

The audit team shall clearly explain that the observations presented during the Closing Meeting are **preliminary** and remain subject to the internal review and certification decision-making processes of the Certification Operator.

The Closing Meeting shall not result in a certification decision, nor shall the audit team provide any commitment or indication regarding the outcome of the certification process.

Following the Closing Meeting, the Certification Operator shall proceed with the preparation of the audit report in accordance with Chapter 3.7 of this Scheme Manual.

3.7. Audit Report

3.7.1. Purpose

The purpose of the Audit Report is to document the findings of the external conformity assessment and provide a comprehensive, objective and evidence-based evaluation of the applicant centre's compliance with the EUCCC Set of Criteria and Standards.

The Audit Report constitutes the formal outcome of the certification audit and forms the basis for the subsequent certification decision. It presents the auditors' evaluation of each certification standard, summarises the evidence collected during the external assessment, identifies strengths and examples of good practice, records observations and opportunities for improvement, and documents any non-conformities identified during the audit.

The report shall reflect the collective judgement of the audit team and shall be prepared following the principles of impartiality, consistency, transparency and consensus. The report shall accurately represent the evidence collected during the audit and shall provide sufficient justification for the scores assigned to each standard.

The overview of the actions in the Audit Report phase is illustrated in **Figure 11** below.

STEP 10 – Finalising the audit report

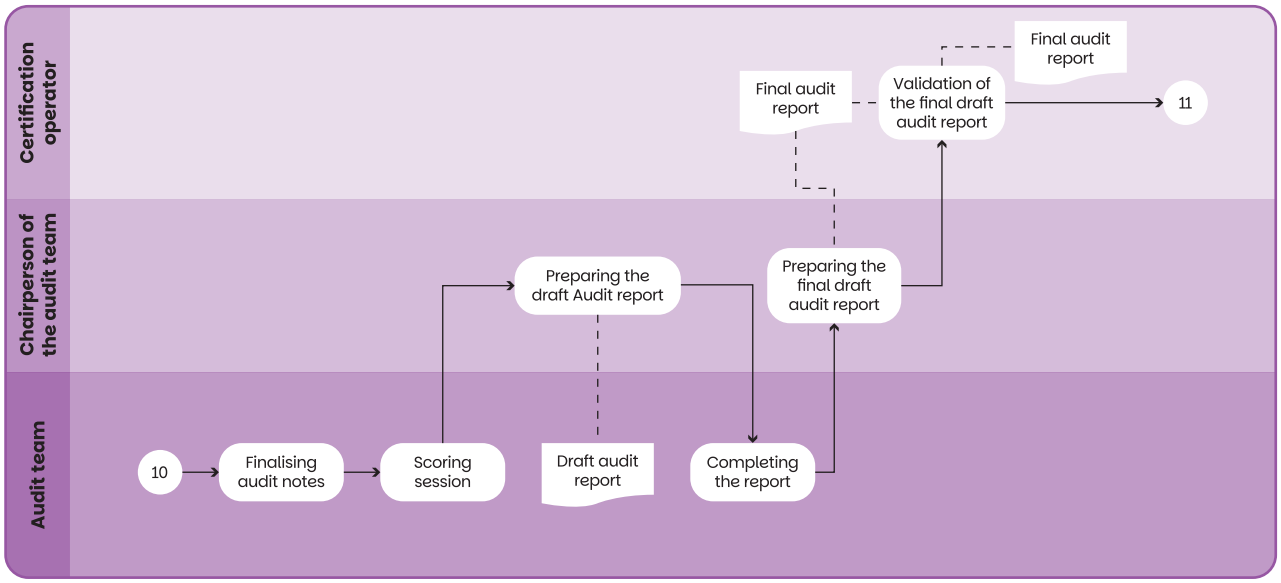


Figure 11. Finalising the audit report

3.7.2 Audit Report

The Audit Report shall constitute the official record of the external conformity assessment performed under the EUCCC Certification Scheme. It shall accurately document the results of the on-site audit and provide a clear, objective and evidence-based account of the audit findings.

The Audit Report shall present the evaluation of each applicable Certification Standard based on the objective evidence collected during the conformity assessment. It shall provide sufficient information to support the subsequent certification decision and shall be prepared in a clear, consistent and understandable manner.

The Audit Report shall include:

- identification of the Applicant Centre;
- scope of certification;
- dates of the on-site audit;
- composition of the audit team;
- summary of the audit activities performed;
- evaluation and scoring of each Standard;
- audit findings supported by objective evidence;

- identified strengths and examples of good practice;
  opportunities for improvement and non-conformities, where applicable;
- thematic results and overall scoring outcomes;
- overall audit conclusions.

The Audit Report shall be prepared in accordance with the requirements of the EUCCC Certification Scheme and shall provide the basis for the subsequent certification decision.

3.7.3. Audit Scoring Methodology

The external certification audit shall apply the same four-level scoring methodology used during the applicant centre's self-assessment. However, unlike the self-assessment, which reflects the applicant centre's own evaluation of its level of implementation, the audit scores shall be assigned exclusively on the basis of objective evidence verified by the audit team during the conformity assessment.

Audit scores shall reflect the level of implementation demonstrated by the Applicant Centre and shall be assigned exclusively on the basis of objective evidence obtained through the evaluation techniques described in Chapter 3.6 of this Scheme Manual. The assigned score shall reflect the auditors' professional judgement regarding the actual level of implementation demonstrated by the evidence available at the time of the audit.

Each standard shall be assessed using the following scale:

- **100% – Standard fulfilled:** the standard is fully implemented, appropriately documented, and consistently applied throughout the organisation.
- **65% – Standard mostly fulfilled:** the standard is substantially implemented, with only minor deficiencies or inconsistencies that do not significantly affect its effectiveness.
- **35% – Standard partially fulfilled:** important elements of the standard have been implemented, but significant components remain incomplete or are inconsistently applied.
- **0% – Standard not fulfilled:** the standard has not been implemented or there is insufficient objective evidence to demonstrate compliance.

The scores assigned to individual Certification Standard shall be used to calculate the thematic indicators and the Core Standards Indicator in accordance with the EUCCC Certification Scheme. These verified scores shall constitute the basis for the subsequent certification decision.

3.7.4. Approval and Issue of the Audit Report

The Certification Operator shall review the Draft Audit Report to verify its completeness, consistency, clarity and compliance with the requirements of the EUCCC Certification Scheme.

Where necessary, the Certification Operator may request clarifications from the audit team to ensure that the audit findings are adequately supported by objective evidence and that the report provides a reliable basis for the certification decision.

Where applicable, the Applicant Centre may be invited to review the Draft Audit Report solely for the purpose of identifying factual inaccuracies. Any comments submitted by the Applicant Centre shall be limited to factual corrections and shall not affect the audit findings, audit scores or the subsequent certification decision.

Once the review process has been completed, the Certification Operator shall approve and issue the final Audit Report. The final Audit Report shall constitute the official record of the conformity assessment and shall provide the basis for the subsequent certification decision.

3.8. Certification Process Results

3.8.1. Purpose

The purpose of this step is to reach the formal certification decision based on the results of the external conformity assessment and to conclude the certification process.

In accordance with the principle of independence underpinning the EUCCC Certification Scheme, the certification decision shall be made exclusively by the Certification Operator. Neither the Scheme Owner nor the applicant centre shall influence the certification decision. The Certification Operator shall evaluate the audit outcomes against the certification requirements and shall determine whether the applicant centre has demonstrated sufficient conformity with the EUCCC Set of Criteria and Standards to be awarded certification.

Once the certification decision has been made, the Certification Operator shall communicate its decision simultaneously to the applicant centre and to the Scheme Owner. Where the decision is positive, the applicant centre shall be awarded the EUCCC Certificate and may proceed to the Continuous Improvement Follow-Up phase.

The overview of the actions in the Certification Phase is illustrated in Figure 12 below.

STEP 11 – Certification decision

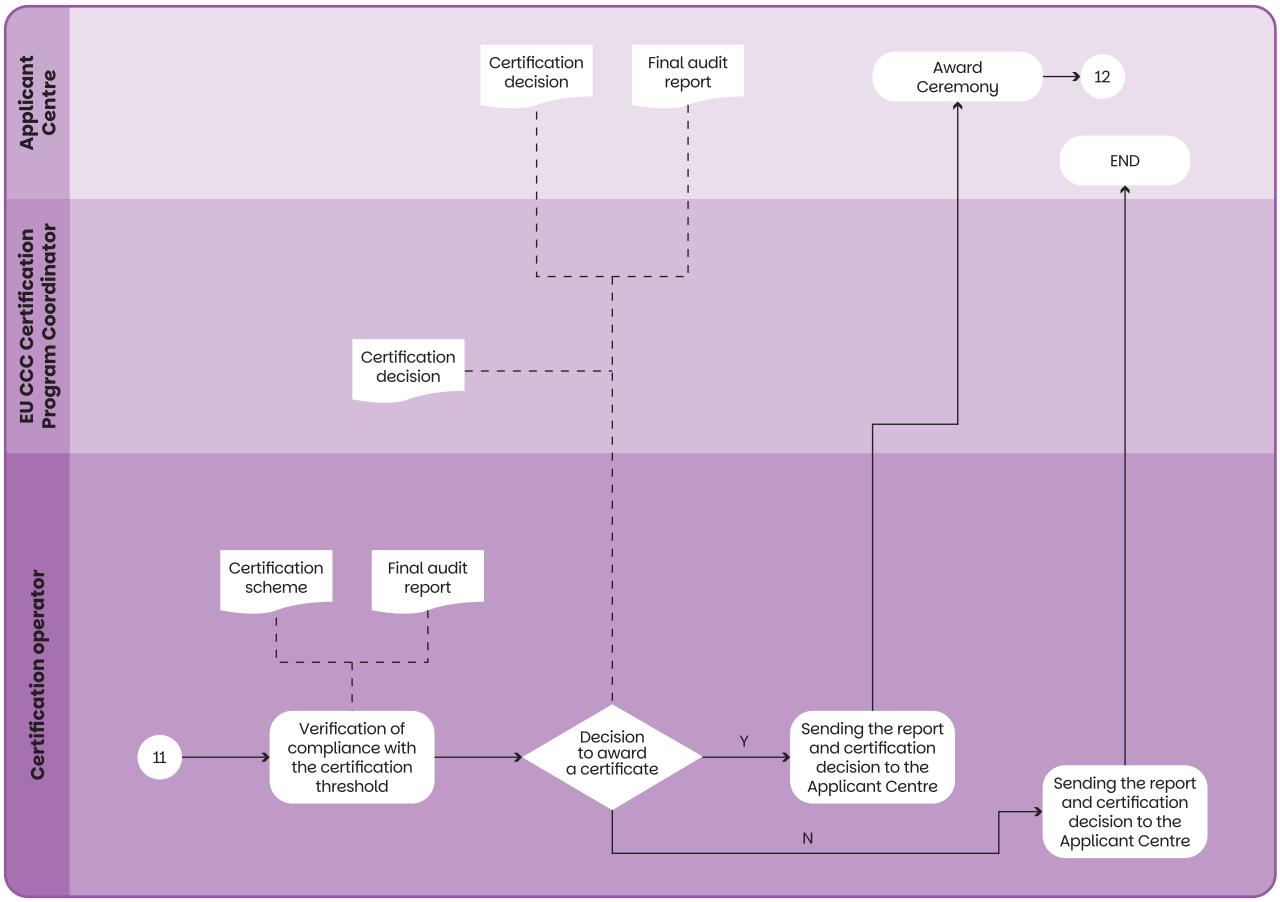


Figure 12. Certification decision

3.8.2. Verification of Compliance with the Certification Thresholds

Following validation of the Audit Report, the Certification Operator shall verify that the final audit scores satisfy the certification thresholds established by the EUCCC Certification Scheme.

The certification decision shall be based on the verified audit scores determined during the external conformity assessment. To be eligible for certification, the applicant centre shall achieve:

- an average score of at least 80% across all core standards; and
- an average score of at least 70% across all standards within each of the seven assessment domains.

The Certification Operator shall verify the calculated thematic indicators and the Core Standards Indicator before proceeding to the certification decision.

3.8.3. Certification Decision

Where the Applicant Centre satisfies the certification requirements, the Certification Operator shall issue a positive certification decision. The certification shall be valid for a period of five (5) years from the date of the certification decision.

Where the Applicant Centre does not satisfy the certification requirements, the Certification Operator shall issue a negative certification decision. The Applicant Centre shall be informed of the reasons supporting the decision.

The Certification Operator shall communicate the certification decision to the Applicant Centre and shall notify the Scheme Owner for registration within the EUCCC Certification Scheme.

3.8.4. Issuance of the EUCCC Certificate

Following a positive certification decision, the Certification Operator shall issue an EUCCC Certificate to the Applicant Centre.

The EUCCC Certificate shall identify at least:

- the name of the certified Applicant Centre;
- the scope of certification;
- the date of issue;
- the period of validity of the certificate;
- the unique certificate identification number;
- the version of the EUCCC Certification Scheme against which certification has been granted;
- the name and identification of the Certification Operator.

Where applicable, the certificate shall clearly identify any limitations or conditions associated with the scope of certification.

For consortium-based certifications, the certificate shall clearly identify the coordinating organisation and the participating organisations included within the certified scope. Where appropriate, an annex forming part of the certificate may identify the participating organisations and sites covered by the certification.

The Certification Operator shall notify the Scheme Owner of the certification decision and the issuance of the certificate for registration within the EUCCC Certification Scheme.

3.9 Continuous Improvement Follow-Up and Re-Certification

3.9.1. Purpose

The purpose of the Continuous Improvement Follow-up and Re-certification phase is to ensure that certification represents the beginning of a continuous organisational improvement cycle rather than the conclusion of the conformity assessment process.

EUCCC certification is granted for a period of five (5) years. Throughout this period, certified centres are expected to maintain continued conformity with the EUCCC Set of Criteria and Standards, while pursuing continuous organisational improvement through the implementation of a Continuous Improvement Plan developed following the external conformity assessment.

The EUCCC Certification Scheme adopts a proportionate follow-up approach centred on continuous organisational improvement rather than periodic surveillance audits. This approach is intended to support the sustained development of certified Comprehensive Cancer Centres, while ensuring that certification remains a dynamic process throughout the five-year certification cycle.

At the end of the certification cycle, certified centres shall undergo re-certification in order to demonstrate continued conformity with the EUCCC Certification Scheme and maintain their certification status.

The Continuous Improvement Follow-up and Re-certification phase therefore serves two complementary objectives:

- to support continuous organisational improvement throughout the five-year certification cycle; and to prepare the certified centre for re-certification.

The overview of the Continuous Improvement Follow-up and Re-certification phase is illustrated in **Figure 13.**

STEP 12 – Continuous Improvement Follow-Up

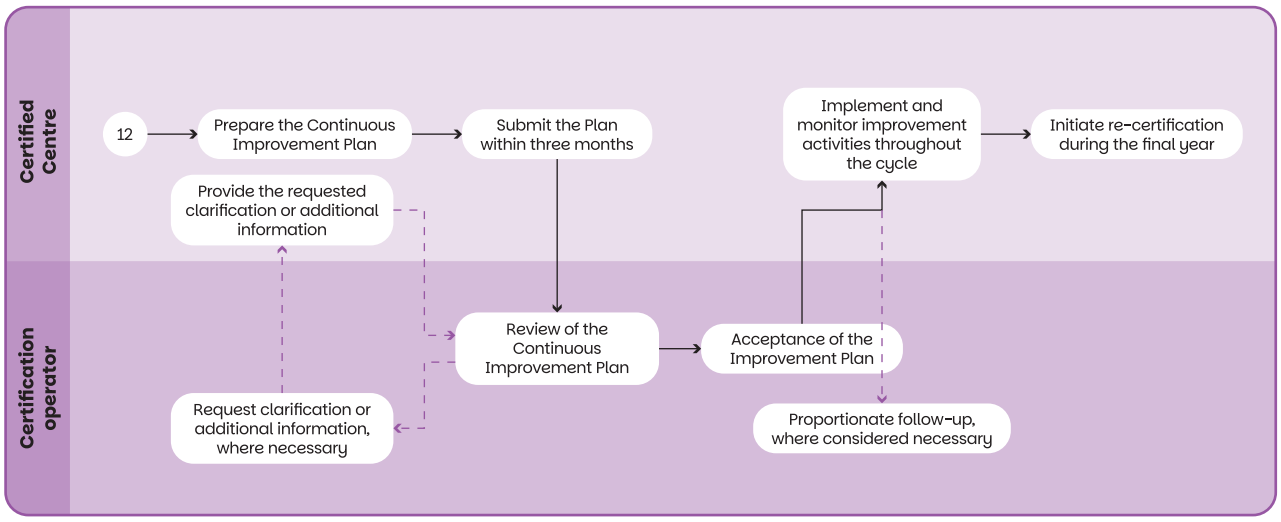


Figure 13. Continuous Improvement Follow-Up ⟶ Required step - - -→ Where considered necessary

3.9.2 Continuous Improvement Plan

Following a positive certification decision, the certified centre shall prepare a **Continuous Improvement Plan** based on the findings, recommendations and opportunities for improvement identified during the external conformity assessment.

The purpose of the Continuous Improvement Plan is to support the centre's organisational development throughout the five-year certification cycle and to demonstrate its commitment to maintaining and further strengthening conformity with the EUCCC Set of Criteria and Standards.

The Continuous Improvement Plan shall be submitted to the Certification Operator within **three (3) months** of the certification decision.

The Continuous Improvement Plan shall be proportionate to the findings of the external conformity assessment and shall give particular consideration to recommendations relating to **CORE Standards,** while also addressing the opportunities for improvement identified during the audit.

The Continuous Improvement Plan shall identify, where appropriate:

- the improvement objectives;
- the planned improvement actions;
- the persons or functions responsible for implementation;
- the indicative implementation timetable;
- the arrangements established to monitor progress.

The Certification Operator shall review the Continuous Improvement Plan to verify that it appropriately addresses the findings, recommendations and opportunities for improvement identified during the external conformity assessment.

Where necessary, the Certification Operator may request clarification or additional information before accepting the Continuous Improvement Plan.

Acceptance of the Continuous Improvement Plan shall not constitute a new conformity assessment nor modify the certification decision. Its purpose is to establish an appropriate framework for continuous organisational improvement throughout the certification cycle.

3.9.3 Continuous Improvement Follow-up

Following acceptance of the Continuous Improvement Plan, the certified centre shall implement the planned improvement activities throughout the five-year certification cycle.

The certified centre shall monitor the implementation of the Continuous Improvement Plan and maintain continued conformity with the EUCCC Set of Criteria and Standards throughout the period of certification.

The Continuous Improvement Follow-up is intended to support the sustained organisational development of the certified centre throughout the certification cycle. It shall focus on the implementation of the Continuous Improvement Plan and the centre's commitment to maintaining and, where appropriate, further strengthening conformity with the EUCCC Set of Criteria and Standards.

Unlike certification schemes based on periodic surveillance audits, the EUCCC Certification Scheme adopts a proportionate follow-up approach. Consequently, no routine surveillance audit shall be required during the validity of the certificate.

Where considered necessary, the Certification Operator may request information regarding:

- the implementation of the Continuous Improvement Plan;
- significant organisational changes that may affect the scope or validity of certification.

Such information may be provided through one or more appropriate follow-up mechanisms. For example, the Certification Operator may request a progress report, organise a mid-cycle progress review or use other proportionate follow-up arrangements appropriate to the organisational context of the certified centre.

Such follow-up activities shall remain proportionate to the objectives of the EUCCC Certification Scheme and shall neither constitute a new conformity assessment nor modify the validity of the certification decision.

3.9.4 Re-Certification

EUCCC certification is valid for a period of five (5) years from the date of the certification decision.

To maintain certification under the EUCCC Certification Scheme, certified centres should initiate the re-certification process during the final year of the certification cycle. Where the certification period expires before a new certification decision has been issued, the centre shall cease to claim or represent itself as an EUCCC-certified Comprehensive Cancer Centre until certification has been renewed.

Re-certification shall consist of a new conformity assessment conducted against the version of the EUCCC Certification Scheme, including the EUCCC Set of Criteria and Standards, in force at the time of the re-certification. The conformity assessment shall take account of any revisions to the certification requirements, assessment methodology or certification process adopted since the previous certification cycle.

The Admission process applicable to initial certification shall not be repeated. However, the certified centre shall provide updated information necessary to support the re-certification process, including any changes to its organisation, governance, activities or scope of certification.

The conformity assessment shall evaluate all applicable Certification Standards within the approved scope of certification and shall be conducted with the same level of independence, impartiality, consistency and rigour as the initial certification assessment.

When planning and conducting the re-certification assessment, the Certification Operator shall take into consideration the certified centre's certification history, including previous Audit Reports, the Continuous Improvement Plan and the actions implemented since the previous certification cycle. Particular attention may be given to the implementation of previous recommendations, the resolution of findings identified during earlier certification

cycles and the centre's organisational development. Such information shall support the planning and effectiveness of the assessment but shall not replace the independent evaluation of conformity with the applicable certification requirements.

Where re-certification is undertaken by a different Certification Operator, the certification records from the previous certification cycle, including the validated Audit Report, the Continuous Improvement Plan and any other relevant certification records, **shall be transferred** to the Certification Operator responsible for the re-certification assessment. The Scheme Owner shall establish the necessary arrangements to ensure the secure transfer of certification records between recognised Certification Operators, in accordance with the applicable requirements relating to confidentiality and data protection.

The re-certification process shall conclude with a new certification decision issued by a Certification Operator recognised under the EUCCC Certification Scheme.

3.10 Appeals and Complaints

3.10.1 Principles

Certification Operators shall establish, implement and maintain documented procedures for the handling of appeals and complaints in accordance with the applicable requirements of EN ISO/IEC 17065. Appeals and complaints shall be handled in an impartial, timely and confidential manner.

3.10.2 Appeals

An appeal is a request by an Applicant Centre for reconsideration of a certification decision taken by the Certification Operator.

Appeals shall be submitted and handled in accordance with the documented appeal procedure established by the Certification Operator.

Where an Applicant Centre considers that an appeal has not been handled in accordance with the applicable accreditation requirements, the matter may be referred to the relevant National Accreditation Body.

3.10.3 Complaints

Complaints relating to certification activities shall be managed by the Certification Operator in accordance with its documented complaint procedure.

Where a complainant considers that a complaint has not been handled in accordance with the applicable accreditation requirements, the matter may be referred to the relevant National Accreditation Body.

3.10.4 Responsibilities and interaction with the Scheme Owner

Appeals and complaints relating to certification activities shall be managed by the Certification Operator in accordance with its documented procedures.

The Scheme Owner shall not intervene in the investigation or resolution of individual appeals or complaints and shall not act as an appeal body.

The Scheme Owner may use information arising from appeals and complaints, where appropriate, to support the monitoring and continuous improvement of the EUCCC Certification Scheme.

4 SPECIFIC CERTIFICATION PROVISIONS

4.1 Auditor Independence, Impartiality and Conflict of Interest Management

4.1.1 Principles

The credibility, integrity and consistency of the EUCCC Certification Scheme rely upon the independence, impartiality and professional judgement of auditors involved in certification activities. Maintaining confidence in certification outcomes requires certification activities to be conducted free from undue influence and that risks to impartiality are effectively identified, assessed and managed throughout the certification process.

The EUCCC Certification Scheme establishes the common principles governing auditor independence, impartiality and the management of conflicts of interest. Their implementation remains the responsibility of each Certification Operator through its accredited management system and in accordance with the applicable accreditation requirements.

4.1.2 Declaration of Interests and Assessment of Risks

Prior to each certification assignment, auditors are expected to complete a Declaration of Independence, Impartiality and Interests in accordance with the documented procedures established by the Certification Operator. This declaration provides the basis for identifying interests, relationships or circumstances that may create a risk to impartiality in relation to the Applicant Centre.

When assessing potential conflicts of interest, Certification Operators are expected to consider, as a minimum, the following recognised threats to impartiality:

- **Self-interest,** where personal, professional or financial interests may influence objective judgement.
- **Self-review,** where an auditor would be required to assess work to which they have previously contributed, including consultancy, advisory or preparatory activities provided to the Applicant Centre.
- **Familiarity,** where close or longstanding professional, organisational or personal relationships may impair independent judgement or create undue trust.
- **Intimidation,** where commercial, organisational or personal pressures may influence certification activities.

These categories provide a common framework for assessing risks to impartiality but are not intended to constitute an exhaustive list. Certification Operators remain responsible for identifying and evaluating any other circumstance that could compromise the independence, objectivity or credibility of certification activities.

4.1.3 Appointment of Audit Teams

When appointing audit teams, Certification Operators are expected to balance competence, independence and diversity while considering any professional, organisational, personal or other circumstances that could increase the risk to impartiality. The objective is to appoint audit teams capable of conducting independent, objective and credible certification activities.

Prior to confirming the audit team, the Applicant Centre should be informed of its proposed composition and may raise justified concerns regarding the independence or impartiality of one or more proposed auditors. The Certification Operator is responsible for assessing such concerns and documenting the outcome before confirming the audit team.

Where risks to impartiality are identified, the Certification Operator is expected to determine and implement appropriate measures to preserve the integrity of the certification process, including modification or replacement of auditors where necessary.

4.1.4 Responsibilities and Records

Certification Operators are expected to maintain appropriate records relating to declarations of interests, conflict-of-interest assessments, decisions taken and measures implemented. These records should demonstrate that risks to impartiality have been systematically considered and appropriately managed throughout the certification process.

The EUCCC Certification Scheme establishes the common principles applicable across all Certification Operators. The detailed assessment criteria, declaration process, operational procedures and record retention arrangements remain the responsibility of each Certification Operator, provided they remain consistent with the principles and objectives of the EUCCC Certification Scheme.

4.2. Facilitation of use of evidence from existing certifications

4.2.1 General Principle

The EUCCC Certification Scheme is a certification scheme based on its own requirements, assessment methodology and certification decision-making process. Existing assessments or certifications delivered under other national or international schemes shall not be regarded as equivalent to EUCCC certification and cannot replace or shortcut the EUCCC certification process.

Nevertheless, in order to avoid unnecessary duplication, while maintaining full compliance with EN ISO/IEC 17065 and applicable accreditation requirements, existing assessments may be considered as supporting evidence. Their consideration remains at the discretion and under the responsibility of the Certification Operator.

4.2.2 Use of Existing Assessments

Existing assessments, certification reports, accreditation reports or other documented evaluation results may be considered as supporting evidence during the conformity assessment process where they are relevant to the scope and requirements of the EUCCC Certification Scheme.

Such evidence may contribute to the evaluation of specific requirements, where considered relevant, reliable and applicable by the Certification Operator. When determining the suitability of existing assessments as supporting evidence, the Certification Operator should consider their scope, date, continued validity and relevance to the specific EUCCC requirements under evaluation. However, the use of such evidence shall neither replace nor reduce the independent evaluation, scoring and certification decision-making processes established by the EUCCC Certification Scheme.

4.2.3 Responsibility of Certification Operators

The decision to consider existing assessments remains entirely at the discretion and under the responsibility of the Certification Operator. Certification Operators remain responsible for determining the relevance, scope, reliability, continued validity and applicability of existing assessments, and for demonstrating that all requirements of EN ISO/IEC 17065 together with the additional requirements established by the EUCCC Certification Scheme have been fulfilled before issuing a certification decision.

4.2.4 Illustrative Examples

Existing supporting evidence may originate from different types of quality assessment, accreditation or certification schemes. The manner in which such evidence is considered shall depend on its scope, relevance, reliability, continued validity and, where applicable, its accreditation status. The following examples are provided for illustrative purposes only and do not constitute an exhaustive list.

Cancer-specific quality assessment or certification schemes

- from the OECI Accreditation and Designation Programme, which may provide supporting evidence relating to governance, multidisciplinary cancer care, quality management systems, research activities, education and patient-centred care;
- from the German Comprehensive Cancer Centre Programme (DKH), which may contribute supporting evidence relating to multidisciplinary cancer care, governance, tumour-specific organisation and quality assurance processes.
- findings from other recognised national or international cancer-specific quality assessment programmes (e.g. DKG Certification, JRC Quality Assurance) covering areas addressed by the EUCCC Certification Scheme.

National external healthcare assessment programmes

- findings from national external healthcare assessment or accreditation programmes (e.g. HAS Certification), which may provide supporting evidence relating to organisational governance, quality and safety management, patient-centred care, care coordination and other organisational requirements addressed by the EUCCC Certification Scheme.

Accredited conformity assessment activities

- reports resulting from accredited certification or accreditation activities (e.g. ISO 9001 certification, ISO 15189 laboratory accreditation or other accredited conformity assessment activities), where relevant to specific EUCCC requirements.

The consideration of such evidence shall not imply equivalence with, or automatic recognition of, EUCCC certification and shall not replace the independent conformity assessment, scoring or certification decision-making processes established by the EUCCC Certification Scheme.

The EUCCC Certification Scheme supports the reciprocal use of evidence between quality assessment and certification schemes. Accordingly, existing assessments may be considered within the EUCCC Certification Scheme and, conversely, EUCCC certification may itself be considered as supporting evidence by other quality assessment, certification or accreditation schemes, where permitted under their own rules and procedures.

4.3. Information Management, Confidentiality and Publication

4.3.1 Confidentiality, Information Use and Release

By applying for EUCCC certification, the Applicant Centre authorises the Scheme Owner and the selected Certification Operator to use the information provided solely for the operation of the EUCCC Certification Scheme, including conformity assessment activities, certification decision-making, surveillance activities and, where applicable, sanction procedures.

All information provided during the certification process shall be treated as confidential.

The Scheme Owner may publish limited information relating to recognised Certification Operators and certified centres for the purpose of ensuring transparency of the EUCCC Certification Scheme. Such information may include the name of the organisation, certification status, scope of certification and, where applicable, the validity of the certification.

Audit reports, detailed assessment results, scoring information and other information obtained during the certification process shall remain confidential and shall not be released without the written consent of the Applicant Centre.

4.3.2 Access to the EUCCC Certification Scheme and Document Control

The current version of the EUCCC Certification Scheme and other official scheme documents shall be made available through the EUCCC Portal.

The Scheme Owner shall ensure that only the latest approved versions of normative documents are used within the certification process and shall communicate any revisions through official channels.

Where applicable, the Scheme Owner shall maintain publicly available information on recognised Certification Operators and certified centres.

4.3.3 Data Protection

Access to the EUCCC Portal and its certification tools shall be restricted to authorised users.

Prior to receiving user credentials, users shall acknowledge and accept the applicable data protection and confidentiality conditions governing the use of the EUCCC Portal.

Personal data processed within the EUCCC Certification Scheme shall be handled in accordance with the applicable data protection legislation.

4.3.4 Public Use of Certification Information

The Scheme Owner may publish limited information relating to certified centres in accordance with the publication policy of the EUCCC Certification Scheme.

Certified centres may refer to their EUCCC certification only in relation to the certified scope and shall not make false or misleading claims regarding their certification status or scope.

Detailed rules governing the public use of the EUCCC Certificate and, where applicable, any certification mark or logo shall be established by the Scheme Owner in separate operational documentation.

The Scheme Owner shall establish and maintain documented procedures for handling complaints relating to the misuse of the EUCCC Certificate and, where applicable, any certification mark.

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