D7.2 Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centres

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Project Information

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Abbreviations and Acronyms

AI	Artificial Intelligence
CCB	Cancer Centre Board
CCC	Comprehensive Cancer Centre
CCCN	Comprehensive Cancer Care Network
CPD	Continuous Professional Development
EBCP	EU Beating Cancer Plan
EHR	Electronic health record
ERN	European Reference Network
EU	European Union
EUCCC	European Union Comprehensive Cancer Centre
GA	Grant Agreement
GDPR	General Data Protection EU Regulation
ICT	Information and communication technology
IT	Information Technology
JA	Joint Action
KPI	Key Performance Indicator
MD	Doctor of Medicine
MDT	Multidisciplinary Team
MRI	Magnetic resonance imaging
MS	Member State
MTB	Molecular Tumour Board
NGO	Non-governmental organization
PDCA	Plan-do-check-act
PI	Principal Investigator
R&D	Research and development
RT	Radiation therapy
SAB	Scientific Advisory Board
SOP	Standard operating procedure
TTO	Technology Transfer Office
WHO	World Health Organization

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Executive summary

Background for and structuring of the document

The CraNE project is a key component of Flagship Initiative 5 of the EU Beating Cancer Plan (EBCP), aimed at establishing a network of Comprehensive Cancer Centres (CCCs) across Europe. The grant agreement emphasizes the primary goal of CraNE: "to establish the criteria for the creation of an EU network of CCCs throughout all Member States on a consistent basis." This objective requires a unified understanding of the requirements for being a CCC, as stated in Objective 4 of CraNE: "to develop a consensus model for CCCs, both standalone centres and those that are part of university or general hospitals." In the grant agreement it is further expressed in this way: “The work of CraNE JA will be built on reaching a consensus in order to define the organisational and operational framework for the EU Network of CCCs. Most of the deliverables and the central deliverable of the establishment of the EU Network of CCCs will be developed within the framework, which is the main and key product of the entire CraNE”.

Enabling the development and implementation of CCCs will then be a core building block of the EU network of CCCs. As a part of this CraNE will be providing a general definition of CCCs. The content of what we will understand as CCC will be explained in a most complete way by the sum of the criteria and standards that apply to the concept of CCCs. Added to this will be the requirement set for the process of certification according to these standards. This deliverable will be a crucial input for the follow-up project and the implementation of the EU network of CCCs.

This introduction outlines the work processes undertaken so far and highlights important aspects that need to be considered when interpreting and applying our proposals. The criteria and standards are organized into seven themes considered as covering a comprehensive set of dimensions necessary to be assessed to be a comprehensive cancer centre.

Each topic opens with a general comment explaining how this specifically should be placed in the framing of CCCs. The presentation of each topic is organized in chapters indicating which aspect of the CCC it is covering. Each chapter and criteria then have a short explanation with the ambition to build a joint understanding of the precise meaning and role of it. The standards are presented in a schematic format with standardized set of alternative scoring. Arguments and evidence for scoring should be provided and an overview over relevant types of evidence referred. To support the full and equal understanding of expressions and concepts applied in this set of standards a specific list of explanations is added.

The proposed certification system with its criteria and standards, following further discussions and refinements, will be tested and subsequently implemented on a broad scale as the EUCCC certification in the follow-up Joint Action of EUnetCCC.

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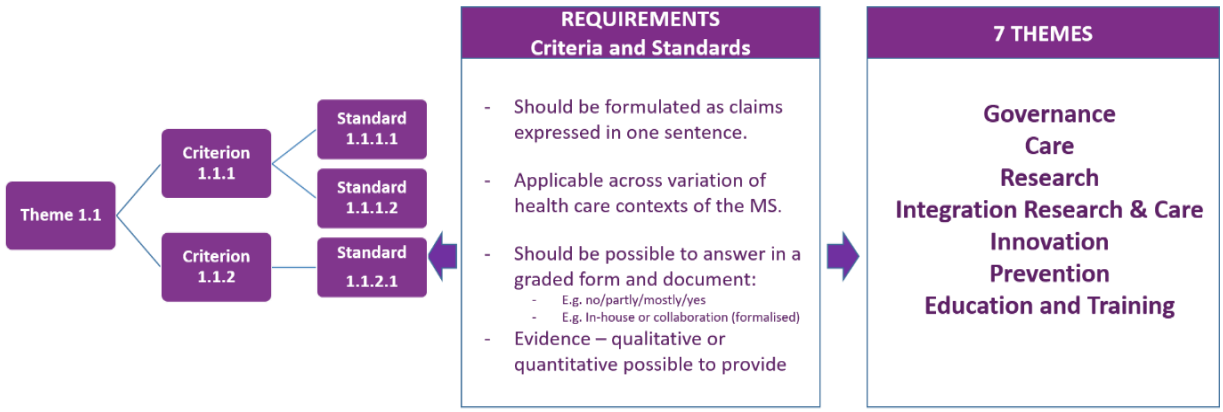

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Figure 1 The overall structure, design and requirements of the criteria and standards.

Methodology and working process of developing the standards

This proposal for criteria and standards has been developed through a process involving broad participation from the partners in CraNE. The process began with a kick-off conference in Paris in January 2023. At this conference worked out criteria through a brain-storming method involving lots of experts from the partners involved. Many of them had extensive experience from certification processes, quality audits and quality improvement. The WP lead-group summarized the outcome of the conference. Based on this, the kick-off conference was the followed by two virtual workshops for each theme focused on defining their criteria. Lots of proposals and improvements was circulated on e-mail between the meetings and edited by the lead-team. These discussions continued at a WP7 partner seminar in Paris in April. This hybrid seminar also marked the start of designing standards for each criterion. To facilitate the further work with the standards, six writing groups were established, each focusing on one of the initial six themes. These groups completed their tasks through three virtual conferences and feedback loops, negotiation and editing on e-mail between meetings. In total during the processes of development, the first draft of criteria and standards 45 CraNE partners contributed coming from 25 European participating countries contributed to the development of the first draft of Criteria and Standards.

A joint document on criteria and standards was developed by merging contributions from the six topic-based groups, with consolidation and harmonization provided by an editorial board. This consisted of six leading experts on standards and certification processes within the CraNE consortium. The entire joint document was then discussed at a workshop in Oslo in December 2023. Special attention was given to the initial draft of care standards since this had not been included in the initial draft document on criteria and standards. 17 Member States and associated countries and 51 institutions was represented at the workshop in Oslo. Throughout

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the process, existing relevant standards from ongoing certification schemes were used as reference points.

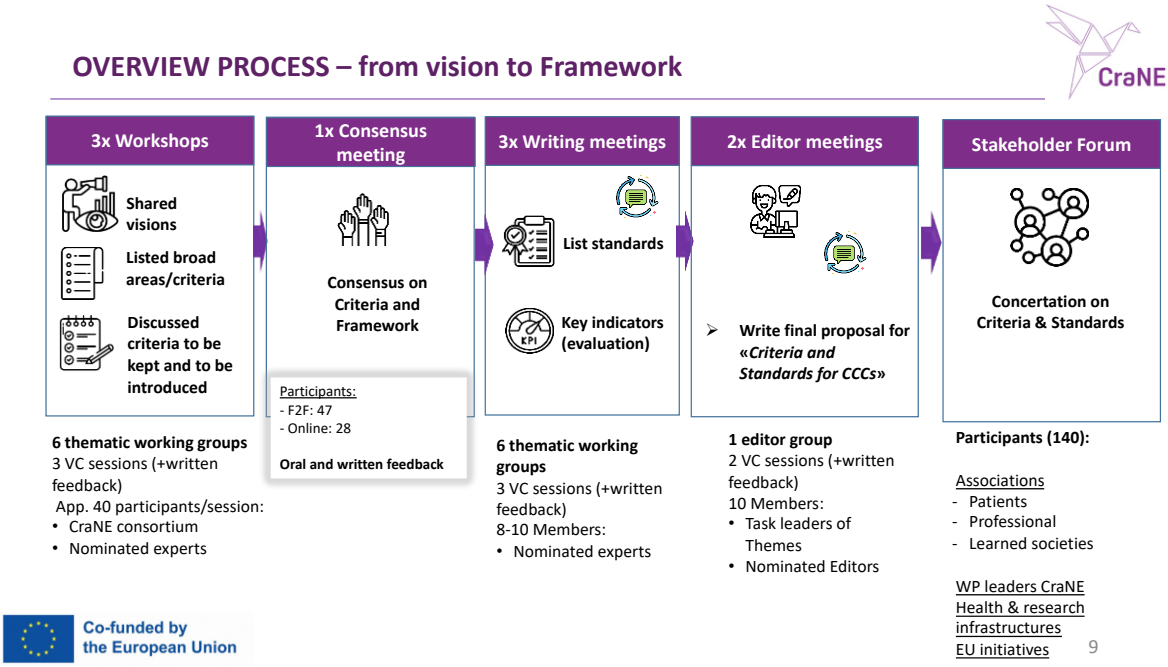

Figure 2. An overview on the phases of development of the proposed "Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centres".

In the spring of 2024, it was decided to extend the WP7 work to further draft the necessary context for the standards. This extension aimed to address the main items related to applying the standards in a certification scheme, motivated by the need for a swift transition from CraNE to implementation, in order to fulfil the ambition of having a network of CCCs and reach 90% of eligible patients by 2030. The extension also allowed for additional time and involvement to ensure the quality of the care standards and that consistent formatting was applied across all standards. In addition, we completed a collaboration between WP7 and WP6 leads on defining the interface between the CCCs and CCCNs (Comprehensive Cancer Care Network)

The WP7 lead group, consisting of representatives from Institute National du Cancer (INCa, France), and Oslo University Hospital Comprehensive Cancer Centre (OUS, Norway), has remained stable throughout the process, including during the extension of WP7. In this final phase, the lead group consulted an extended WP7 team, including other main actors in CraNE, and a focus group of ten representatives with direct affiliations to European cancer centres. These representatives were chosen on the requirements of their experience and knowledge on certification processes or themselves being trained auditors, or knowledge on local capacity of reaching and evidencing the proposed standards. They were asked to assess the feasibility of the operationalization of the proposal on criteria, standards and processes, and further refine these. These developments were next also presented and discussed in the extended WP7 team, also named the Advisory Board. The purpose for this was to make secure their resilient character also was able to tackle local or regional variations and provide advice on unsolved, strategic questions. A final two-day meeting in Oslo in June secured significant

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involvement and contribution of core partners in CraNE regarding both criteria and standard and the stepwise certification scheme. Together this will cover the deliverable D7.2 “Set of criteria, standard, their application in a certification process for CCCs”, with an ambition to enable the creation of a full European network of CCCs.

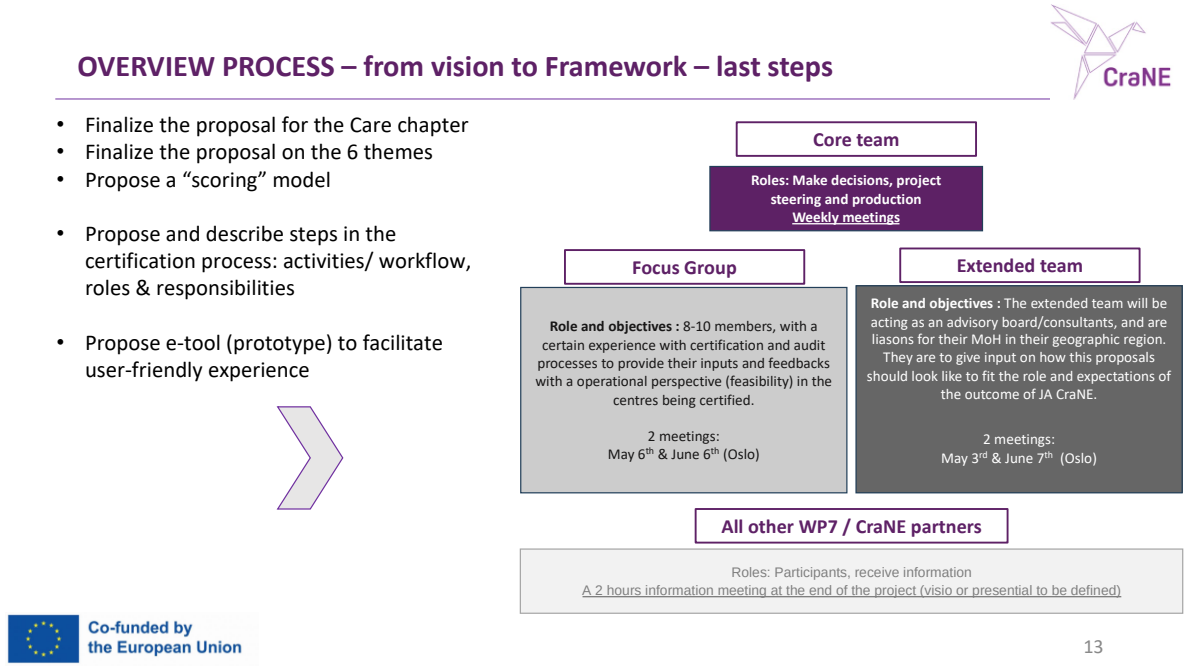

Figure 3 An overview on the last steps of the development of the proposed “Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centres”.

Content and structuring of the document/deliverable

In this document, we are presenting a complete proposal on an integrated and straightforward set of criteria and standards for CCCs covering all aspects of Governance, Research, Education, Innovation, Prevention, Care and relation Research and Care. Care standards was added to the initial six themes for standards to make the set of standards for EUCCCs complete. It is adding up to be 65 criteria and 319 standards. Criteria are expressing ambitions and standards are statements describing specific conditions that are required to be present. The criteria and standards are contextualized and explained through the framing made in the presentations during the document. There are certainly interconnections and dependences between lots of criteria and standards but as they are expressed they are all addressing distinct different aspects that EUCCC.

The development of criteria and standards have been developed with a reference to their application in a certification process of EUCCCs. The main principles for such a certifications scheme have been as follows:

The standards and certification scheme should

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1) Require and encourage process of continuous improvement involving relevant management, key-professionals and stakeholders
2) Combine a self-assessment approach with external auditing passed on the assessment from peers

To complete the proposal of measures that are required for the design of the certification process of EUCCCs the remaining descriptions have been added during the final part of the WP7. This total packaged now contains these elements:

a) the document on criteria and standards for the seven themes – **PART I**,

b) the list of required additional information on context, activity and performance (covering information/data/indicators on 11 topics related to context of the EUCCC, eight topics on activity and three topics on performance) – **PART II**

c) the description of the steps in the certification process with its functions and roles present, each step of actions, and alternative tracks depending on the outcome of the actions – **PART III**

d) a joint glossary for these documents with definitions of expressions and concepts applied and which are dependent of clear and unambiguous understanding by the users and stakeholders of these standards and certification scheme – **PART IV**

General framing comments

Criteria and standards for Comprehensive Cancer Centres (CCCs) must be considered within the context of their practical application and the organizational framework that manages these standards. This is crucial for ensuring that the criteria and standards are relevant and effective. Therefore, this document includes considerations on how these elements are linked to the EU Network of CCCs and the goals of Europe's Beating Cancer Plan (EBCP).

The CraNE grant agreement (GA) and the ambition of the Flagship no. 5 of the Europe's Beating Cancer Plan (EBCP) assume that the EU concept of CCCs should be applicable across the diverse contextual conditions found in different European countries. This applies to the following contextual variations:

a) Healthcare System:

- **Financing Mechanisms**: Differences in how healthcare systems are financed, whether through taxation or insurance, with variations within these groups.
- **Referral Systems:** Variations in referral systems, including the presence or absence of specific catchment areas and rules for overriding these borders.
- **Private Sector Involvement:** The degree of presence and funding from private actors.
- **ICT Integration**: The extent and type of integrated ICT systems.
- **Coordination Between Care Levels:** The degree and type of coordination mechanisms between primary and secondary care.
- **Integration with Research and Education:** The type and degree of integration between healthcare institutions and research and education institutions.

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- **Funding for Research and Education:** The sources and mechanisms of funding for relevant research and education.

b) Size and Comprehensiveness of the Country or Region:

- Smaller administrative units may need compensatory mechanisms to achieve comprehensiveness within their borders.

c) Type of Hospital:

- Variations exist between specialized cancer hospitals and general hospitals, with further distinctions based on whether they are university hospitals.

d) Legal Organizational Structure:

- Differences in the degree to which core activities required for comprehensiveness are included within a single legal organizational structure, with many cancer centers relying on cross-organizational collaborations.

By understanding and addressing these contextual and definitional variations, the criteria and standards for CCCs can be effectively operationalized and applied across different European countries, ensuring high-quality and comprehensive cancer care and research.

Criteria and Standards Based on Definition and Process

The criteria and standards are brought to life through the processes by which they are governed, managed, and applied. This involves several embedding clarifications and processes:

a) Comprehension and Expression of Criteria and Standards:

- A criterion is a general ambition to be fulfilled. Standards are more specific statements that allow for assessing whether this ambition is met. They represent an institutional state that can be compared to the reality in a cancer centre.

b) Definition of Comprehensiveness:

- Comprehensiveness is defined by the institutional quality of a cancer centre, emerging through the sum of all criteria and standards, both individually and collectively. It involves ensuring completeness in meeting certification standards and the added value from the interaction of these standards.

Comprehensiveness in CCCs involves four key institutional dimensions:

1. **Access to Diagnostics and Treatments:**
    - Ensure all relevant diagnostic and treatment modalities are available as routine services at the center.
2. **Treatment for All Tumor Groups:**
    - Provide access to treatment options across all tumor groups.
3. **Broad Spectrum of Research:**

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- Connect to a wide range of cancer-related research, from clinical to basic research, including healthcare and implementation research.

4. **Education and Training:**
   - Integrate education and training for all major stakeholders involved in the care and research process.

In addition to being comprehensive in these four dimensions, there is a crucial requirement for coordination within and between these dimensions. This coordination is essential for ensuring the standards are effectively implemented and managed. These approaches to governance support the core role of governance in the standards framework, highlighting its importance in creating synergies and necessary coordination across different areas of activities. Governance is closely related to organization and leadership, making it the foundational topic in the set of standards, influencing all other areas indirectly.

The concept of comprehensiveness also includes the need for continuous improvement, adaptation, and development. Since cancer care and research are constantly evolving fields, CCCs must have the capability to stay comprehensive by continually improving and adapting. This dynamic nature of comprehensiveness impacts the requirements for leadership and governance, emphasizing the need for proactive and adaptive management.

c) The governance process of the EU CCCs

The governance standards require the establishment of a board for the EU CCC, responsible for coordinating the comprehensive set of activities within the cancer centre. The leadership and governance dynamics facilitated by this board are crucial for the effective implementation and maintenance of CCC criteria and standards. This importance extends beyond the periods of certification and recertification, ensuring that the centre adheres to the standards throughout its entire operational life.

d) The certification process

The standards are assessed through a combined self-assessment and peer review process, involving both document reviews and on-site visits with interviews. The self-assessment involves key personnel in the relevant operations, with the centre's board responsible for the conclusions. This approach ensures ownership by the centre's leadership and staff. Peer reviewers are selected from relevant positions in other cancer centres, preferably those with certification experience. Final certification conclusions are drawn from a dialogue between the centre board and the reviewers. Certification processes and assessment reports are conducted by peers with first-hand relevant experience, supplemented by specific training, rather than by external auditors or professional audit organizations. The stepwise design of this certification process in more detail described in appendix 3.

e) The role of core standards

This presentation of criteria and standards for a CCC defines some standards as core standards. Core standards are characterized by the following:

- **Essential for Other Standards:** Necessary requirements to achieve a satisfactory level on several other standards.

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- **Special Focus During Certification:** Given specific attention regarding status and performance in preparation for certification.
- **Higher Quality of Evidence:** Require better-documented and more thoroughly argued evidence than other standards.
- **Priority in Peer Review:** More closely followed during the peer review process.
- **Improvement Plan Requirements:** Subject to higher requirements for an improvement plan if the self-assessment and peer review do not provide convincing evidence of satisfactory performance.

A higher tolerance for deviation is accepted for non-core standards, though they still require improvement measures if they do not meet satisfactory levels during the certification process.

f) The scoring applied by the self-assessment and the peer audit

The assessment process comparing the realities at the EUCCC with the required state set by the standards should apply a scale with four alternative scores: *yes, mostly, partially or no*. In addition an alternative of "not applicable" should be considered. Arguments for the chosen score is then supposed to be added together with possible relevant documents. Together these will constitute the evidence. Together this, in the light of the reference information on context, activity and performance is then what will be investigated into and discussed by the peer audit.

g) The requirement of evidence

In this presentation, a separate column at each criterion mentions relevant evidence for that standard. This is not yet completed and ought to be addressed as a part of the testing and implementation in the next phase of establishing the EU Network of CCCs. The level of detail and specificity of evidence required will also be discussed further. Evidence for these standards can take various forms, including qualitative descriptions of processes, diagrams, organizational charts, legal documents, procedural documents, quantitative indicators, and statistics. In some cases, specific types of evidence will be required, while in others, the cancer centre can choose the best representative evidence. More specifically the categories or types of evidence could be as examples:

- Written protocols document -and their availability
- Written guidelines and their availability
- Standard Operating Procedure - SOP and their availability
- Meetings minutes
- Meetings agendas: trainings, MDT meetings
- Systems (graphs, numbers extracted, KPIs)
- Organogram
- Strategic plans (ex: research strategy)
- Documentation confirming organization of training, workshop sessions
- List of participants at meetings/workshops
- Annual reports from centers
- Legal agreements

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- Formal agreements/ contracts (collaboration as an example)
- Materials on clinical trials (brochures, websites, public events)
- Patient Pathway written procedures and their availability
- List of members for different iniatives/research groups/programs
- Publications

h) The entrance gate – thresholds to be set?

Some certification schemes require institutions to meet certain threshold values before they can begin the certification process. For CCCs, typical variables might include the relative number of patients included in clinical studies, the number of papers published with an impact factor above a certain level, the number of newly referred patients each year, and so on. These metrics may be required as evidence for certain standards or as information according to the required additional information (context, activity and performance – appendix 2) but without a specific threshold level necessary for admission into the certification process.

The application of such threshold values for admission has been discussed, but a conclusion has not yet been reached. This topic should be further explored, concluded and tested in the subsequent implementation program of Joint Action EUnetCCC. One challenge in establishing absolute threshold values is that they could create barriers for some regions and countries to establish a CCC within a foreseeable time.

i) Mandatory additional information.

In addition to the information provided through the self-assessment process applying the standards for EUCCCs, there are requirements for supplementary sets of information connected to the certification process (appendix 2). The purpose of collecting this additional information is twofold:

Supporting the Audit Process:

The additional information helps interpret the self-assessment data, supports the quality of the audit and interviews, and aids in preparing the improvement plan. These types of information and data fall into three categories:

- **Contextual Data:** Relevant data on the context of a EUCCC.
- **Administrative Data:** Information on the activities and resources of a EUCCC.
- **Performance Development Data:** Data on the performance development of a EUCCC over recent years.

The focus on performance development data aligns with the certification's goal of continuous improvement. It is important to have data on key performance variables over recent years, rather than just a snapshot of a specific reference year.

Building a Comprehensive EUCCC Database:

Collecting additional information also contributes to building a database describing the EU landscape of CCCs. This data could include information on joint activities organized by the EU Network of CCCs.

The role of this information and data is discussed more in detail in the introduction of appendix 2).

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To minimize the administrative burden, it is essential to standardize data collection and encourage measures to improve data quality. Organizing this process could be a task for the EU Network of CCCs.

j) The dynamic system required.

The premises given by the Grant Agreement require that certification and standards are part of dynamic processes for continuous improvement, not static measures. This reality is reflected through the following processes:

- **Process Evaluation Combined with State and Outcome Evaluation:**

The assessment of a centre considers its current performance and delivered outcomes. A EUCCC gains its status through its ability to improve and develop, recognized through process evaluation. This includes the centre's capability to define and execute activities according to action and improvement plans related to the certification process and the centre's cancer strategy. The centre's action capabilities can compensate for lower scores on some standards during certification.

- **Moving Targets:**

The standards are designed as moving targets. Experience from certification practice and developments in relevant areas lead to regular revisions of criteria and standards. This ensures that centres understand certification is not permanent and requires ongoing improvement and adaptation. Certification is valid for a limited period (4 or 5 years) reinforcing this dynamic nature.

- **Peer-Based Development:**

The revision process for criteria and standards ought to be conducted through peer processes, organized by the future EU Network of CCCs, rather than by any EU administrative unit. This approach ensures that the standards remain relevant and continuously improve based on practical experience and evolving knowledge.

k) The management of certification schemes

There will be a managerial distinction between organizing and conducting certification processes and managing the specification of criteria, standards, and certification processes. The EU Network of CCCs will play a crucial role in organizing and conducting certification processes but will not be responsible for building the organizational facilities needed for the external part of the certification. This new distinction, compared to the current stage of CCC certification, requires developing effective processes at the system level between the institution defining and managing the assignment and the providers.

l) The network processes – activities and a common language

The EU Network of CCCs will use similar criteria, standards, and certification processes as a fundamental common frame of reference. This shared framework will serve as a common language, establishing a reference for institutional qualities within the European cancer centre community. The criteria and standards will also provide a common reference for various activities and improvement efforts within the centres. These shared challenges and experiences will inform activities initiated or facilitated by the EU Network, particularly

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through the activities in EU Net CCC, which focuses on supporting the development and improvement of cancer centres along the seven themes of this certification scheme.

m) From CraNE proposal to practical application

The document of standards, part I, and the document on additional information, part II, when implemented into a e-tool will get a design more appropriate than in the current version for application as a tool in the self-assessment and peer-review/audit process.

An overview of the certification process

On the next page there is an overview of the total certification process to be applied for EUCCC certification in part III of this document.

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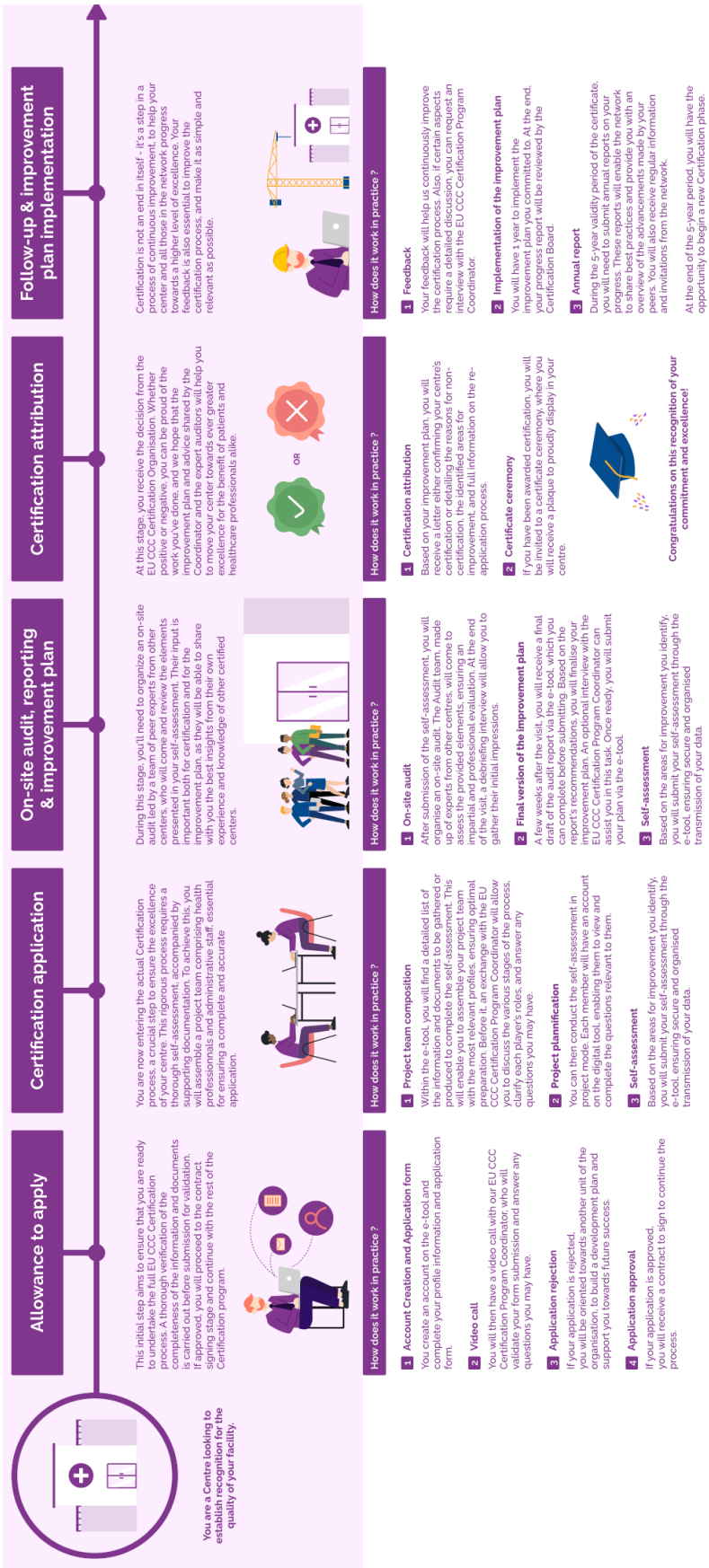

Figure 4. An illustration of the overall proposal on the certification process for members of the EU network of CCCs.

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PART I: Set of Criteria and Standards for *European Comprehensive Cancer Centres*

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1 Governance

Objective: To establish a robust governance framework for Comprehensive Cancer Centers, underpinned by evaluative standards that assess the efficacy of governance structures and processes. This framework will be tailored to the unique characteristics of Cancer Centers affiliated with University Hospitals and in collaboration with academic institutions.

The landscape of cancer care has evolved significantly with advancements in survival rates, paralleled by an escalation in the intricacy of care pathways. The integration of diverse diagnostic modalities, treatment regimens, and their intersection with clinical research has emphasized the necessity for robust coordination. This is accentuated by the expansion of hospital infrastructures, departmental specializations, and the multi-institutional trajectory of a patient's cancer journey. Such dynamics accentuate the pivotal role of leadership and governance in orchestrating seamless care and research endeavours. In this milieu, governance transcends traditional boundaries, emphasizing relationships with regulatory bodies, collaborative partners, and intra-organizational units to support interdisciplinarity and cross-organizational cooperation.

In charting the course for EUCCCs, it is imperative to delineate governance criteria, irrespective of the centre's specialization or operational model. The governance paradigm is trifurcated into leadership architecture, operational processes, and the communicative nexus underpinning EUCCC leadership.

Reference : Sullivan, R., et al. (2011). Delivering affordable cancer care in high-income countries. The Lancet Oncology, 12(10), 933-980.

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1.1 Organisation of EUCCC Governance

Governance is inherently manifested through both formal and informal structures, which significantly influence the effects and outcomes of leadership. It's imperative for the governance criteria of EUCCCs to address their organisational structures, irrespective of healthcare systems or hospital models, a primary coordinating body is essential. Given the prevalent European models necessitating cross-organisational coordination, this body often assumes a matrix structure, underpinned by a clear mandate. Supplementary coordinating entities, such as a EUCCC research council and tumour management groups, further enhance this structure, each requiring well-defined objectives, roles, and regulations. The criteria presented are designed to be versatile, accommodating the diverse healthcare systems and hospital models across Europe.

Reference: Lawler, M., et al. (2014). A catalyst for change: the European cancer patient's bill of rights. The Lancet Oncology, 15(3), 258-260.

1.1.1 EUCCCs have a governance body to coordinate processes internally and externally	
Clarification of the criterion: The governing body includes representatives from all organisational entities with a major contribution to the comprehensiveness of the EUCCC.	
Standards:	**Evidence:**
1.1.1.1 The EUCCC has a governing body[1] responsible for the centre's strategy, including care, research, and education. (CORE)	Document (s) describing mandate, responsibility, and roles in the governing body.
1.1.1.2 The institutions forming the EUCCC are distinctly outlined, and their roles within the governing body are specified.	
1.1.1.3 If the EUCCC is composed of multiple legal entities, there are formal agreements in place that define the collaboration terms among these entities.	Formal agreements describing collaboration among legal entities.
1.1.1.4 The EUCCC's governing body includes senior representatives directly responsible for cancer diagnosis, care, research, and education.	
1.1.1.5 The EUCCC governance model emphasises clinical coordination, ensuring quality care across tumour groups, organisational boundaries, and the entire patient pathway.	
1.1.1.6 The EUCCC governance structure ensures that all patients, regardless of tumour group or whether they have a common or rare cancer diagnosis, have access to the necessary diagnostic and treatment options as specified by their patient pathways. These services are provided either directly by the EUCCC	Documentation of available diagnostic and treatment services within the EUCCC

[1] i.e. Cancer Centre Board (CCB) or Executive Committee

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	or through collaboration with other specialized units, coordinated by appropriate governance structures. (CORE)	Partnership agreements with external specialized units Patient referral and coordination protocols.
1.1.1.7	The EUCCC obtains key financial figures about the centre's operating costs and investments for care and research purposes.	
1.1.1.8	The EUCCC governance structure is securing it influence on key financial decisions influencing the centre's capability of delivering expected outcome	

1.1.2 EUCCCs have a governance model ensuring high-quality patient care	
Clarification of the criterion: In a EUCCC, the clinical quality framework emphasises tumour-specific care and diagnosis. It orchestrates resource and skill utilisation across patient journeys, safeguarding continuous and safe care. This governance integrates interdisciplinary growth, fostering knowledge transfer. This comprehensive governance structure builds upon a clear description of responsibilities for quality and safety both in cancer care in general and in each pathway specifically.	
Standards:	**Evidence:**
1.1.2.1 The EUCCC has multidisciplinary teams (MDT/tumour boards) for every tumour type[2] treated by the EUCCC or by collaborating institutions (CORE)	
1.1.2.2 There is a written and mutually accepted patient pathway for each tumour entity treated in the EUCCC including cooperating care networks describing interactions and responsibilities in interfaces between different legal entities involved in the pathways.	
1.1.2.3 The EUCCC has a clinical quality system that focuses on measuring quality indicators specific to cancer and are underpinned by a PDCA practice to ensure quality assurance and improvement.	
1.1.2.4 The EUCCC has a dashboard providing standardised metrics in order for governance and leadership to follow up quality of care and patient outcomes.	

[2] Proposal: % ICD coverage

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1.1.3 EUCCCs involve patient participation at all relevant levels	
Clarification of the criterion: EUCCCs acknowledge that patients are the ultimate beneficiaries of healthcare services and that their involvement can lead to better health outcomes. Patients have valuable insights and perspectives that can help inform healthcare policies, practices, and research. Involving patients in decision-making at all levels can also improve the quality of care, increase patient satisfaction, and promote transparency and accountability in healthcare systems.	
Standards:	**Evidence:**
1.1.3.1 The EUCCC integrates patient perspectives, through involvement of patient representatives and patient advisory council in assessing outcome and quality of care and relevant change and improvement initiatives. (CORE)	
1.1.3.2 The EUCCC offers educational program for patient representatives (and candidates[3]) to enhance their capacity to be involved in decision-making processes.	

1.1.4 EUCCCs governing bodies have adequate administrative and management support	
Clarification of the criterion: For effective coordination and progress governance within the EUCCC, the governing body rely on a proficient secretariat for preparatory and follow-up support.	
Standards:	**Evidence:**
1.1.4.1 The EUCCC governing body has administrative support related to managing their meetings and ongoing operations.	
1.1.4.2 The governing body of the EUCCC has sufficient resources[4] to deliver the regular provision of both cancer data-based reporting and analysis and *ad hoc* need of cancer related analysis. (CORE)	
1.1.4.3 The governing body of the EUCCC has access to project management support .	

[3] Definition: patients in the process of becoming a patient representative

[4] Competent personnel with capacity and responsibility

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1.1.5 EUCCC's governance includes formal agreements with external collaborators	
Clarification of the criterion: The EUCCC´s governance processes must manage external relationships, notably with CCCNs, primary care, and other research institutes, to ensure optimal patient outcomes.	
Standards:	**Evidence:**
1.1.5.1 The EUCCC is active in developing care networks (both tumour specific and pan-cancer based) in its local area.	
1.1.5.2 The EUCCC has formal agreements and a coordinating committee with other hospitals and external clinical units collaborating with the EUCCC on cancer patient pathways. (CORE)	
1.1.5.3 The governing body of the EUCCC (CCB/ coordinating committee) is setting out the goals for cooperation, the division of responsibilities and tasks and coordination mechanisms with its local care networks.	
1.1.5.4 The governing body of the EUCCC (CCB/ coordinating committee) has structured reporting on the coordinated activities with its associated/collaborating local care networks.	
1.1.5.5 The governance of the EUCCC ensures strategic links with primary and community care providers, including data sharing and communication for better patient care.	
1.1.5.6 The EUCCC has formal agreements with research institutions or universities for cancer research or education, where those entities are not contractually part of the EUCCC.	

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1.2 The Processes of EUCCC governance

Governance extends beyond mere structure, encompassing the leadership and management processes executed within the EUCCC framework. These processes must adeptly define the EUCCC's objectives and strategy, ensuring cohesive handling of both immediate and long-term challenges as well as creating support and consensus regarding the ambitions and initiatives of the centre.

1.2.1 EUCCCs have a unified cancer strategy covering care, education and research	
Clarification of the criterion: For effective integration within the EUCCC, a unified Cancer Strategy is essential, encompassing all EUCCC activities. This strategy is collaboratively developed by all departments, professions, and patient representatives. It requires endorsement from all affiliated legal entities and it is revisited and updated at least every five years, complemented by an ongoing development plan.	
Standards:	**Evidence:**
1.2.1.1 The EUCCC has developed and approved a comprehensive cancer strategy covering all aspects of oncology. (CORE)	
1.2.1.2 The EUCCC develops its cancer strategy with involvement from relevant stakeholders, including patients, and gains approval from all involved institutions.	
1.2.1.3 The cancer strategy is implemented through an action plan revised every year.	
1.2.1.4 The EUCCC´s cancer strategy has evaluation indicators designed to assess its implementation and expected outcomes.	

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1.2.2 EUCCCs governance facilitates coordination operationally and strategically	
Clarification of the criterion: EUCCC governance integrates patient pathways, synergises tumour group knowledge, and bridges research, education, and care, all while operationalising the cancer strategy through cancer centre board-led projects.	
Standards:	**Evidence**
1.2.2.1 The EUCCC has internal rules of procedure to guide the management of cross-organisational matters. (CORE)	
1.2.2.2 The governing body of the EUCCC has a defined model for organising and executing action plans to implement the cancer strategy and improvement recommended/guided by EUCCC certification.	
1.2.2.3 The EUCCCs has governance processes for the patient pathways of all tumours treated.	
1.2.2.4 The line managers of all units in the EUCCC have a defined responsibility for the integration of care, research, and education/training.	

1.2.3 EUCCCs leadership stays informed about care and research activities	
Clarification of the criterion: Effective EUCCC governance relies on real-time data access, reflecting care and research quality and activity. Dashboards, either at the EUCCC or pathway level, are display carefully selected indicators to ensure accurate representation.	
Standards:	**Evidence:**
1.2.3.1 The EUCCC actively uses a data monitoring system (dashboard) to follow up essential[5] metrics in care and research, available at both the centre and pathway/tumour group levels and accessible to all employees. (CORE)	
1.2.3.2 The EUCCC actively uses metrics collected by the data monitoring system to improve its management.	

[5] E.g. : patient outcomes, publications, and third-party funding

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1.2.4 EUCCCs collaborate regionally with other hospitals for equal access to care and research	
Clarification of the criterion: Active integration processes are essential to ensure that specialized diagnostics, treatment, and research align with broader regional offerings, promoting equitable cancer care[6].	
Standards:	**Evidence:**
1.2.4.1 The EUCCC has processes on collaboration and coordination in a geographical area of shared patient pathways and shared resources (in the fields of research, care, innovation, education, and training).	
1.2.4.2 The EUCCC has processes on collaboration on MDT/tumour boards in a geographical area with shared patient pathways regarding participation[7]. (CORE)	
1.2.4.3 The EUCCC has processes on collaboration in a geographical area with shared patient pathways regarding: • Inclusion of cancer trial activities of the EUCCC • Interoperable IT structures • Molecular tumour board • Cooperation with regional providers of survivorship care (incl. rehabilitation, psycho oncology, sexuality) • Cooperation with regional providers of palliative home care	
1.2.4.4 The EUCCC promotes that integrated care pathways include the role of each institution from the sub- /region in dealing with the diagnosis and treatment of cancer patients.	

[6] An example of coordinating structures is Comprehensive Cancer Care Networks as described by CanCon Joint Action (http://www.cancercontrol.eu/uploads/images/Guide/pdf/CanCon_Guide.pdf, p79) and its interfaces with CCCs (described by WP6 of CraNE JA, Task 6.1)

[7] participation of external physicians, also EUCCC physicians joining external tumour boards

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1.2.5 EUCCCs participate in european and/or international networks	
Clarification of the criterion: EUCCCs actively engage in national and European collaborative networks and programs, harnessing ongoing advancements in care and research. This engagement ensures the uptake of innovations and underscores a commitment to share progress with the broader European and global community.	
Standards:	**Evidence:**
1.2.5.1 The EUCCC participates in at least one cross-border network organising collaborative institutional activities between EUCCCs. (CORE)	
1.2.5.2 The EUCCC participates in at least one european and/or International collaborative research consortium.	

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2 Care

Objective: These standards aim at identifying requirements to develop and improve quality of diagnostics, treatment and follow up in a EUCCC. Behind these standards lies the perspectives of patient centeredness, equal access and cross-disciplinarity.

EUCCCs are able to provide its patients with access to diagnostics and treatment regardless on the type of cancer diagnosis or the needed type of treatment. EUCCCs also provide the patient with access to services along the whole patient pathway. If it is not directly organized by the EUCCC itself, the centre make arrangements for being provided by collaborative institutions. These dimensions are already covered by the topic governance. In addition, the organization of care at EUCCCs satisfy requirements that are expressed through the standards in these chapters. Care-related standards are also defined under the topic of Integrating Research and Care.

The standards under this part are characterized by some joint perspectives. The first perspective is patient centeredness. This implies that patient needs, priorities and experiences are explored and integrated in the individual decisions and patient pathways. Secondly, a penetrating perspective will be an ambition to continuous search for and implement better solutions and improvements on how to organize the care services and its diagnostic, treatment and follow-up activities both on single patient and on Cancer Centre and hospital level. One dimension of this is an ambition of learning from every patient. Third, the care standards for the EUCCCs are influenced by the desire to build equal access to advanced and experimental treatment not least to what is now labelled as precision cancer medicine. Fourth, the organizing of necessary cross-disciplinary cooperation are defined and practiced in the EUCCC.

This part is structured in three chapters. The first one is expressing basic requirements of quality management of the care processes, called, The quality of care and patient safety. The second chapter is about cancer care exceeding the basic requirements, called The state of the art diagnostics and treatment. And the last chapter focuses on the care given to cancer survivors and to end-of-life care, called The psycho-social support and rehabilitation

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2.1 Comprehensiveness of Care

The concept of comprehensiveness of care required by a EUCCC encompasses several facets. It is involving the question of managing access to all types of standard treatment - both early stage curative treatment and palliative treatment on one side and cases in need for highly specialized treatment on the other. Then comprehensiveness of care also raises the question on which and how many of the types of advanced treatment are supposed to be accomplished by the CCC itself. Then the question of comprehensiveness in care is a question of fulfilling the quality requirements set by the specific care standards in the next chapters of this care theme. The fulfilling of these are expected to be extensive but at the same time characterized by a process of continuous development towards the moving target toward excellence. The comprehensiveness of care also requires access to experimental treatment not just standard. How this is going to be operationalized regarding the EUCCC is treated under theme 2 and 3. The organizational considerations, addressing the issue on whether all types of diagnostics and treatment options and patient pathway alternatives are managed within the EUCCC or through collaborations with external institutions are addressed by criterion 1.1.1 specifically standard 1.1.1.6. The approach on this may vary based on the country's healthcare system and the history of cancer care, with further elaborations provided in the subsequent sections.

2.1.1 EUCCCs deliver complete set general and advanced Diagnostics and Treatment for a minimum number of specified cancer diagnoses	
Clarification of the criterion: Access both to complete and advanced diagnostic and treatment services for is crucial for delivering comprehensive cancer care. To be comprehensive a EUCCC should provide this completeness and the advanced services through its own organization. This is a requirement justified by the need to establish a satisfactory cross-disciplinary environment and pan-cancer community connected to a broad set of diagnostic and treatment modalities. The requirements connected to this dimension of comprehensiveness is divided into one standard related to the five most prevalent cancer diagnoses and one related to all other cancer diagnoses including rare cancers, paediatric cancers, and hematologic cancers.	
Standards:	**Evidence:**
2.1.1.1 The EUCCC provides complete and advanced diagnostic services and cutting-edge treatments for at least three of the five major cancers: 1. Breast cancer and gynaecological cancers such as ovarian and uterine cancer 2. Lung and thoracic cancers 3. Gastrointestinal cancers (including colorectal and gastric cancers, pancreas and liver) 4. Genitourinary cancers (including prostate and bladder cancers) 5. Skin cancers (melanoma and other advanced or aggressive skin cancers)	**Documentation of Diagnostic Services:** Detailed descriptions of available diagnostic technologies and services. **Documentation of Treatment Services:** Detailed descriptions of available treatment modalities, including surgical, radiological, and medical oncology services. **Partnership Agreements:** Formal agreements with external specialized units, if applicable, detailing collaboration for diagnostics and treatments.

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2.1.1.2	The EUCCC provides complete and advanced diagnostic and treatment options for at least two less prevalent cancers diagnoses, which may include rare cancers, paediatric cancers, or hematologic cancers.	**Documentation of Diagnostic Services:** Detailed descriptions of available diagnostic technologies and services. **Documentation of Treatment Services:** Detailed descriptions of available treatment modalities, including surgical, radiological, and medical oncology services. **Partnership Agreements:** Formal agreements with external specialized units, if applicable, detailing collaboration for diagnostics and treatments.

2.2 Quality of Care and Patient Safety

This section highlights the measures taken by EUCCCs to ensure patient empowerment, collection and monitoring of patient experiences, active involvement by caregivers, risk management, delivery of patient-centric and continuity in care, and coordination of post-treatment follow-up.

2.2.1 EUCCCs facilitate and ensure patient empowerment

Clarification of the criterion: Shared decision-making is the backbone of patient-centred, high-quality care. EUCCCs must provide patients accurate, reliable, and all-encompassing information about their condition, treatment alternatives, and potential risks and benefits. This information are presented clearly and concisely, empowering patients to make informed decisions about their care.

Standards:		**Evidence:**
2.2.1.1	The EUCCC has a physical and/or virtual information and support centre that is available for staff, patients, family members and care givers. (CORE)	
2.2.1.2	The EUCCC documents relevant information[8] communicated to the patient in the patient's record. (CORE)	
2.2.1.3	The EUCCC ensures that all individuals, including those with disabilities and special needs, have universal and equal access to the care they need.	

[8] Most relevant for the patient: patient rights, diagnosis, treatment options, shared decision making, treatment plan, prognosis, supportive care, rehabilitation, psycho-oncology, survivorship care..

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2.2.1.4 The EUCCC has implemented a policy that ensures that patients are treated with sensitivity and respect, and that their preferences are considered in all aspects of their care.	
2.2.1.5 The EUCCC has a procedure for practicing shared decision making and all relevant personnel are trained in the practice of this	
2.2.1.6 The EUCCC provides patients (and their caregivers) information material that is readable, up-to-date, appropriate, and available in languages commonly spoken by the population served and covers rights and access to: - Diagnostic and treatment options - Second opinions - Information about relevant patient pathways - Follow-up after treatment - Availability of clinical trials - Supportive care - Palliative care - Psycho- and social counselling - Patients' associations, self-help, and support groups	
2.2.1.7 The EUCCC has procedures that specify how (and by whom) patients are informed and included in shared decision-making (when relevant) covering: - Diagnostic procedure and results - Treatment options (including side-effects and late effects) - Follow-up - Survivorship (a plan detailing all relevant contact points for support services and peer groups)	
2.2.1.8 The EUCCC provides to its patients: - General information[9] about the hospital - Detailed information about the admission procedure - Contact people for all matters related to their care (e.g., navigator/coordinator) - Contact information to clinical staff in case of emergency - Clinical trial activity - Patients' Associations and support Groups	
2.2.1.9 The EUCCC ensures that patients are thoroughly informed and understand the continuity of care they are referred to another healthcare provider.	
2.2.1.10 The EUCCC has policies on informed consent for diagnostics, treatment, and research that meet national laws and regulations.	
2.2.1.11 The EUCCC guarantees that personal data protection is respected for patients according to the General Data Protection EU Regulation (GDPR) 2016/679.	

[9] Including quality of care, if publicly available for laymen

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2.2.1.12	The EUCCC guarantees 24/7 access to all emergent medical care, It has a 24-hour on-call service outside working hours (including weekends and public holidays), if necessary, through co-operation agreements.	

2.2.2	**EUCCCs are continuously exploring possibilities for improving its quality of care and outcome of treatment based on experience and knowledge gained from professionals and patients**	
Clarification of criterion: new knowledge, new technologies and experiences will provide the EUCCCs with room for improving their performance and their outcome of care. These possibilities are supposed to be exploited by the EUCCC. In these processes patients bring a unique perspective on how care is delivered and received, with an opportunity for the organization to learn and mature. The EUCCCs collect feedback and monitor the quality of care received at different stages, emphasizing understanding patient perspectives, and improving healthcare services aiming at learning from every patient. The EUCCC will thus make sure that they apply the principle of learning from every patient		
2.2.2.1	The EUCCC has routines to collect patients' experiences during outpatient and inpatient care and have routines to integrate the knowledge from this in its quality improvement program	
2.2.2.2	The EUCCC has a procedure for patient involvement as a part of its quality improvement program.	
2.2.2.3	The EUCCC is systematically collecting, presenting, and giving attention to main indicators[10] of quality of care and outcome of care	
2.2.2.4	The EUCCC ensures that improvement actions are prioritised, developed, and implemented regularly in agreement with all concerned departments and disciplines, at a minimum on an annual basis	
2.2.2.5	The EUCCC arranges or facilitates learning events for its personnel in quality improvement at least twice per year.	

[10] Definition: list of indicators

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2.2.3 EUCCCs facilitate active involvement by caregivers	
Clarification of criterion: Caregivers surrounding the patients in their private everyday life play a pivotal role in supporting the patients. Through encouraging and enabling active involvement of caregivers, the EUCCCs will facilitate that the patient and its caregiver(s) experience inclusivity and support. This again will lead to stronger adherence to recommendations on treatment and lifestyle (when relevant).	
2.2.3.1 The EUCCC has dedicated meeting areas for visits from caregivers.	
2.2.3.2 The EUCCC ensures flexible and dynamic adjustments on visiting time.	
2.2.3.3 The EUCCC can facilitate overnight stays/ adjustments on visiting time and can facilitate overnight stays for caregivers when needed.	
2.2.3.4 The EUCCC ensure that caregivers are invited to participate in certain personal activities (e.g., meals, washing) when feasible and in line with patients expressed wishes.	

2.2.4 EUCCCs ensure patient safety and risk management in Care	
Clarification of the criterion: Cancer care processes present potential threats to patient safety. EUCCCs have a leading role in coordinating cancer care for their patients. Therefore, EUCCC conducts risk analyses to identify patient safety hazards and implement measures to mitigate these risks along the care continuum including admission, discharge, treatment and post-treatment follow-up. (referencing: WHO Global Patient Safety Action Plan 2021-2030)	
Standards:	**Evidence:**
2.2.4.1 The EUCCC ensures safety, accuracy, and high-quality care by adequately staffing essential disciplines.	
2.2.4.2 The EUCCC has defined routines and procedures for: - Prescription, preparation, and administration of drugs - Mandatory training of staff adminstrating drugs - Documentation in a quality assured digital system	
2.2.4.3 The EUCCC has established quality and risk management routines that include procedures to handle and report all diagnostic and treatment-related side-effects.	

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2.2.4.4	The EUCCC has a comprehensive system for reporting, registering, and assessing complications and adverse events, including 30-day mortality and unexpected re-admissions to surgery within 90 days.	
2.2.4.5	The EUCCC provides facilities and procedures for the evaluation of acute toxicity, especially in relation to oncology treatment.	
2.2.4.6	The EUCCC has systematic procedures and action plan for measures after an adverse event and monitoring the efficiency of the implemented measure(s).	
2.2.4.7	The EUCCC conducts learning circles and conferences following unexpected outcomes such as mortality and morbidity.	
2.2.4.8	The EUCCC has procedures and routines for systematically assessing risk when implementing new technologies or interventions.	
2.2.4.9	The EUCCC ensures a maintenance programme for medical equipment, including calibrations, safety checks and clinical audits aligned with authorised authorities' recommendations and carried out as scheduled.	
2.2.4.10	The EUCCC has processes to ensure that new and specialised technical equipment is handled only by personnel trained and competent on this equipment	
2.2.4.11	The EUCCC ensures that only authorized personnel (specific training modules accomplished) administer anti-cancer drugs.	

2.2.5 EUCCCs deliver patient-centric and continuity in care based on managed patient pathways	
Clarification of the criterion: EUCCCs provide patient-centred and continuous care by prioritizing individual patient preferences, needs, and values. Key elements include the co-creation of care through active interactions between patients , patient organisations and healthcare professionals, integration with cancer research for evidence-based practices, and the use of patient-reported outcome measures to tailor treatment plans. EUCCCs ensure personalised care that improves physical, social, and emotional well-being.	
Standards:	**Evidence:**
2.2.5.1 The EUCCC performs regular reviews and updates on the documented patient pathway based on new evidence-based knowledge and assessment of practice experiences. (CORE)	
2.2.5.2 The EUCCC has implemented patient pathways for each tumour entity treated at the centre. These pathways describe the functions of involved disciplines, the role of MDTs, and include palliative care and survivorship care.	

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2.2.5.3	The EUCCC makes sure that the patient pathway management approach is also including other diagnostic and treatment units that the EUCCC share pathways with its local networks.	
2.2.5.4	In the EUCCC the documented cancer patient pathways are actively applied tools in quality improvement processes	
2.2.5.5	The EUCCC ensures that patients with rare cancers are referred to a designated reference centre or a European Reference Network (ERN).	
2.2.5.6	The EUCCC identifies and provides each patient with a with a pathway coordinator or case manager facilitating the patient´s pathway from admission until end of treatment, including the implementation of MDT recommendations.	
2.2.5.7	The EUCCC has clear procedures of the responsibility of pathway coordinator that includes referral and feedback amongst nursing, palliative care, and supportive disciplines.	
2.2.5.8	The EUCCC has defined standards for maximum waiting times[11] and record *actual* waiting times for each step in the whole trajectory from time of referral start treatment.	
2.2.5.9	The EUCCC applies data from monitoring[12] waiting time in its quality and improvement system	
2.2.5.10	The EUCCC has a discharge procedure that provides patient and its General Practitioner information on further treatment, follow-up, re-admission, and home care.	
2.2.5.11	The EUCCC has a pathway for general practitioners to follow when there is a need of consultation regarding questions affecting about further treatment of follow-up	
2.2.5.12	The EUCCC provides medical consultation prior to cancer treatment.	
2.2.5.13	The EUCCC has a policy and measures securing patients´ access to adequate time and communication channels to address their need.	
2.2.5.14	An EUCCC has established easily accessible procedure for patient's complaints	

[11] The accepted waiting times should be aligned with national regulations and professional recommendations for each individual tumour type and expected prognosis

[12] Either by real-time (if automated systems) or by a sufficient random sampling volume.

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2.3 Diagnostics

The presence of comprehensive services in pathology, radiology and nuclear medicine plays a crucial role in several steps of the pathway of cancer patients including primary diagnostics, evaluation of treatment (sometimes closely integrated with treatment) and follow-up examinations of recurrence in addition to their role in clinical research. This section covers requirements to EUCCCs' provision of these services.

2.3.1 EUCCCs deliver advanced diagnostics through pathology and molecular diagnostics	
Clarification of the criterion: The ability to deliver advanced diagnostics is an important aspect of a CCC, with its leading role on the diagnosis of medical conditions and the development of appropriate treatment plans. The EUCCC has the necessary infrastructure, equipment, and personnel to carry out a wide range of diagnostic tests and procedures, including but not limited to imaging studies, laboratory tests, and including advanced invasive procedures.	
Standards:	**Evidence:**
2.3.1.1 The EUCCC ensures state-of-the-art diagnosis aligned with national and international guidelines, reviewed periodically.	
2.3.1.2 The EUCCC has established policies and written procedures for scheduling diagnostic examinations, which include prioritising urgent cases.	
2.3.1.3 The EUCCC ensures that results from diagnostic procedures are available within recommended maximum turnaround time in line with national guidelines/regulations.	30 minutes for fresh frozen sections in inter-operative reports 5 working days for immunohistochemistry and 72 hours for radiology.
2.3.1.4 The EUCCC upholds high standards of diagnostic procedures and lab work under Good Clinical Practice and Good Laboratory Practice, performing regular quality assurance tests among different laboratories.	
2.3.1.5 The EUCCC ensures that its diagnostic laboratories have proper procedures to cover specimen collection, pre-analytic and analytical phases, and specimen storage.	
2.3.1.6 The EUCCC diagnostic laboratories maintain an accreditation from a recognized quality management system that documents all relevant steps in sample processing.	
2.3.1.7 The EUCCC ensures that its patients and physicians have access to the necessary infrastructures, including sufficient Board-certified pathologists and human geneticist (for germline analysis), to provide full scope of molecular diagnostics in alignment with	

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	recommended guidelines, including molecular tumour board (MTB).	
2.3.1.8	The EUCCC has established procedures for the preservation of fresh and frozen surgical specimens in diagnostic biobanks.	
2.3.1.9	The EUCCC has standardized pathologist reports that are aligned with best practice and guidelines to cover information on: - Histological type and grade (according to validated international classification) - Resection margins - Lymph nodes status - Any diagnose-specific predictive information	
2.3.1.10	The EUCCC has a molecular diagnostics programme for tumour-(sub)typing where recommended (and/or appraised) by national guidelines and regulations.	
2.3.1.11	The pathology laboratory/institute at the EUCCC has specialists and equipment for molecular pathology for those tumour sub-types for which molecular pathology is needed and in line with national guidelines.	
2.3.1.12	The EUCCC has an internal or a formal link and access to a MTB[13] to support therapeutic decisions.	

2.3.2 The deliver support in radiology and nuclear medicine	
Clarification of the criterion: Radiology and nuclear medicine plays a core role in the several steps of the cancer patient pathway – from screening, diagnostic support, treatment support and follow up. The EUCCC has the infrastructure, equipment, and personnel to carry out relevant procedures, optimize the performance of the relevant procedures and coordinate satisfactory with the clinical communities it will be closely working together with.	
Standards:	**Evidence:**
2.3.2.1 The EUCCC has up-to-date Standard Operating Procedures which describe the imaging methods and are reviewed at least once a year, in accordance with national procedures.	
2.3.2.2 In the EUCCC the radiologist's written report is available to the attending doctors at the latest 72 hours after the examination.	

[13] Definition of the roles and activities to be delivered.

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2.3.2.3	The EUCCC has a record of waiting times for radiology and nuclear, measured from the time of notification by the physician to the performing of the radiological examination.	
2.3.2.4	In EUCCC all images (mammograms, ultrasound documentation, MRI) are stored in a digital format	
2.3.2.5	In EUCCC quality control of all equipment used for imaging is routinely performed, according to the relevant national protocols and/or European guidelines.	

2.4 Treatment

Today there is a broad spectre of treatment measures available for cancer usually divided into three main groups, surgery, radiation therapy and systemic therapy – but often as a combined strategy including two or more ingredients from these three groups. Efficacy and patient centeredness in selecting and accomplishing treatment strategies requires cross-disciplinarity and quality along and in each step of the treatment. This applies both to palliative and curative pathways. This section covers EUCCCs' multidisciplinary treatment approach, evidence-based treatment, and access to advanced and innovative therapies.

2.4.1 EUCCCs ensure a multidisciplinary treatment approach	
Clarification of the criterion: The complexity of cancer requires all aspects of the disease, possible treatments strategies and their effects on the patient to be considered when defining the optimal care trajectory. EUCCCs ensure that diverse expertise (multidisciplinary teams at each group of cancer pathway) meet and agree on the best treatment for each patient, including considering additional diagnostic procedures needed and clinical trials within or outside its cancer centre to ensure the best patient outcome.	
Standards:	**Evidence:**
2.4.1.1 The EUCCC has established procedures for identifying eligible[14] patients for MDT consultation as part of their patient pathway and before any treatment decisions. (CORE)	
2.4.1.2 The EUCCC ensures that recommendations made by MDT-meetings (when available) are followed, and if relevant, reason for why these are not followed are documented in the medical record and communicated to the patient and the MDT. (CORE)	
2.4.1.3 The EUCCC has a written procedure that defines the criteria for which patient cases that shall be discussed at each type of MDT meetings	

[14] Eligible patients as defined by national tumour specific guidelines

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2.4.1.4 The EUCCC has defined procedures to: - State the type of MDT meetings that are present at each cancer diagnosis. - State the composition of MDT-meetings (core and extended attendance) from all relevant diagnostic and therapeutic disciplines (including MTB, oncology nursing, palliative care, supportive care) - State the meeting frequency of MDTs, per patient pathway. - Identify relevant extended expertise (case by case) - Inform the MDT about patients that will be discussed. - Execute the MDT; including roles, required documentation (medical records, images) and facilities. - Assess patient's eligibility for clinical trials. - Document recommendations and conclusions (in medical records, within 24 hours) - Define the indications for referral and the types of intervention from supportive disciplines	
2.4.1.5 EUCCC has procedures for communicating MDT-meetings' recommendations and conclusions to patients for shared decision-making. Patients can consent or refuse treatment.	
2.4.1.6 The EUCCC organises an annual learning event for MDTs to review patient outcomes, other quality indicators, patient pathway performance, compliance with guidelines, and applies this information in quality improvement initiatives.	
2.4.1.7 The EUCCC has a multi-disciplinary service providing the patients of pre-habilitation, psychosocial care, nutritional counselling based on screening of needs before and during treatment	

2.4.2 EUCCCs carry out treatment based on evidence	
Clarification of the criterion: EUCCCs use the latest medical research and scientific evidence to develop treatment plans for their patients (however, limited by national decisions regarding reembursement). This approach ensures that patients receive the most effective and appropriate treatments for their specific medical conditions. By relying on evidence-based treatment, EUCCCs could provide better outcomes for their patients and contribute to the overall improvement of healthcare services across Europe.	
Standards:	**Evidence:**
2.4.2.1 The EUCCC follows formally agreed clinical guidelines [15] for treatment and follow-up and provides easy access to the guidelines in written or digital form. (CORE)	

[15] institutional/local/regional/national/international

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2.4.2.2	The EUCCC ensures that all new clinical staff are familiar with the relevant guidelines. (CORE)	
2.4.2.3	The EUCCC ensures annual review and updates of its guidelines based on new evidence, with defined responsible personnel for authorisation.	

2.4.3 EUCCCs ensures high operational standards in surgery for its patients		
Clarification of the criterion: Maintaining high operational standards is a priority for EUCCCs to ensure that the patients receive the best possible care and experience. Comprehensiveness of standards will need to involve standards both connecting to work processes, staffing, equipment, patient information and patient and outcome related quality routines.		
2.4.3.1	In EUCCC the staffing levels of key disciplines contributing to cancer surgery are planned to ensure safety, accuracy, and high-quality care (CORE)	
2.4.3.2	In EUCCCs minimum surgical requirements of quality of personnel and equipment are documented and followed up in each tumour type (CORE).	
2.4.3.3	The EUCCC has established a minimum surgical volume requirement for each cancer surgeon and tumour type and in line with regional or national guidelines to ensure quality standards are met.	
2.4.3.4	In EUCCC all treatment plans and recommendations of the MDT form the basis for surgery.	
2.4.3.5	In EUCCC any deviations from the surgical treatment plan are recorded in the patient record and communicated appropriately to the patient and MDT.	
2.4.3.6	In EUCCCs technical and organisational processes for fresh tissue, frozen sections and bio-banking are in place for surgical procedures in line with national guidelines	
2.4.3.7	In EUCCC 30-day mortality after surgery is recorded and evaluated.	
2.4.3.8	In EUCCC, if unexpected re-admissions to surgery within 90 days are allowed, they are recorded and evaluated for risk management and continuous improvement.	
2.4.3.9	The EUCCC facilitates access to a full range of reconstructive surgery, immediate or delayed, including aesthetic and functional restoration surgery for all body regions.	

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2.4.3.10	In EUCCC patient information about reconstructive surgery is proactively provided in written form and includes benefits and risks.	

2.4.4 EUCCCs ensure high operational standards in radiotherapy for its patients		
Clarification of the criterion: Maintaining high operational standards is a priority for EUCCCs to ensure that the patients receive the best possible care and experience. Comprehensiveness of standards will need to involve standards both connecting to work processes, staffing, equipment, patient information and patient and outcome related quality routines.		
2.4.4.1	In EUCCC the staffing levels of key disciplines contributing to cancer radiotherapy are planned to ensure safety, accuracy and high-quality care (CORE)	
2.4.4.2	The radiotherapy department of EUCCCs has a written contingency plan.	
2.4.4.3	In EUCCC each patient has a medical consultation prior to the commencement of radiotherapy.	
2.4.4.4	In EUCCC adequate information is provided to each patient about diagnosis and therapy planning, which includes explanation of treatment options, side effects and self-management during therapy.	
2.4.4.5	In EUCC the relevant radiation data (e.g. RT treatment technique, single dose, total dose, total treatment time) are recorded in line with the guidelines.	
2.4.4.6	In EUCCCs any deviation from the dose prescribed by the physician is justified and documented.	
2.4.4.7	The EUCCC documents all relevant radiotherapy data (e.g., technique, single dose, total dose, total treatment time) and assess whether practice is in line with guidelines	
2.4.4.8	In EUCCC the unit has processes for recording the complications of treatment in the patient record and at department level for quality purposes.	
2.4.4.9	In EUCC has access to sufficient linear accelerators to meet the demands of providing radiotherapy to all its patients (CORE).	
2.4.4.10	In EUCC there is a maintenance programme for medical equipment, including calibrations and safety checks.	

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2.4.4.11	In EUCC safety checks and calibrations are carried out as scheduled.	
2.4.4.12	In EUCC medical devices used for treatment are periodically certified by an authorised authority.	

2.4.5 EUCCCs ensure high operational standards in systemic therapies for its patients		
Clarification of the criterion: Maintaining high operational standards is a priority for EUCCCs to ensure that the patients receive the best possible care and experience. Comprehensiveness of standards will need to involve standards both connecting to work processes, staffing, equipment, patient information and patient and outcome related quality routines.		
2.4.5.1	In EUCCC the staffing levels of key disciplines contributing to cancer systemic therapies are planned to ensure safety, accuracy and high-quality care (CORE)	
2.4.5.2	In EUCC there is a quality assured digital system for the prescription, preparation, and administration of anti- cancer drugs (CORE).	
2.4.5.3	In EUCC anti-cancer drugs are prepared in a centralised pharmacy unit.	
2.4.5.4	In EUCC there are SOPs for the preparation of anti-cancer drugs in pharmacy.	
2.4.5.5	In EUCCX a validation procedure for the whole process, including prescription, preparation, and distribution, is implemented.	
2.4.5.6	In EUCCC there are sufficient chairs and beds to manage patient numbers for systemic therapies.	
2.4.5.7	In EUCC there are SOPs for the administration of anti-cancer drugs (CORE)	
2.4.5.8	In EUCC anti-cancer drugs are administered only in oncology or haemato-oncology wards (for inpatients).	
2.4.5.9	In EUCC there are dedicated day-care units for the administration of anti-cancer drugs.	
2.4.5.10	In EUCC anti-cancer drugs are administered by nurses who have completed a specific training programme for chemotherapy administration (Core)	
2.4.5.11	In EUCC each patient has a medical consultation prior to the commencement of systemic therapy (Core).	

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2.4.5.12	In EUCC adequate information is provided to each patient about diagnosis and therapy planning, which includes explanation of treatment options, side effects and self-management during therapy.	
2.4.5.13	In EUCC the time between the patient consultation and agreeing to the treatment plan (post MDT) and the commencement of treatment does not exceed 21 days (if there are no medical contra-indications or patient preferences opposing this).	
2.4.5.14	EUCCCs record the relevant data (dosage and total treatment time) in line with the guidelines.	
2.4.5.15	EUCCCs provide all relevant new medication to patients upon discharge to prevent possible delay in treatment	
2.4.5.16	EUCCCs implement a specific procedure for reporting unexpected side effects of anti-cancer drugs	

2.4.6 EUCCCs provide access to advanced and innovative therapies		
Clarification of the criterion: The EUCCCs strive to provide the most comprehensive and effective treatment options to their patients and offer access to advanced and innovative therapies. This means that EUCCCs must offer patients the opportunity to receive treatments that are cutting-edge and may not be widely available yet.		
Standards:		**Evidence:**
2.4.6.1	The EUCCC provides state-of-the-art cancer treatment based on national and international guidelines.	
2.4.6.2	The EUCCC provides access to sequential/simultaneous radio-chemotherapy.	
2.4.6.3	The EUCCC has a written procedure to ensure the safe delivery of radio-chemotherapy, which includes specialist training, monitoring, and recording blood count and side-effects.	
2.4.6.4	The EUCCC provides patients with an overview of all relevant clinical trials and ensures an early screening of which could be eligible for the patients	

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2.4.7 EUCCCs ensure palliative care	
Clarification of the criterion: EUCCC delivers-patient centred, comprehensive cancer care along the continuum from diagnosis to ultimately survivorship or end of life care. Palliative care is considered an integral component in the care pathway, and provision of EUCCC services, from diagnosis to treatment to ultimate survivorship.	
Standards:	**Evidence:**
2.4.7.1 The EUCCC offers individual plans palliative care for each patient, which is discussed with the patient and caregivers.	
2.4.7.2 The EUCCC provides a defined composition of the palliative care team, led by a specialised physician in palliative medicine.	
2.4.7.3 The EUCCC has written procedures for the palliative team on how to identify and meet the patients' needs.	
2.4.7.4 The EUCCC has established protocols for promptly addressing pain and neurological symptoms resulting from spinal cord compression. A treatment plan is drawn up within 24 hours of the suspected diagnosis.	
2.4.7.5 The EUCCC provides palliative radiotherapy, and the therapeutic goal (local control or solely symptom alleviation) is documented.	
2.4.7.6 The EUCCC has defined responsibilities for the palliative care team to provide education and guidance of palliative care (e.g., symptom control) for patients, caregivers, and health professionals.	
2.4.7.7 The EUCCC palliative care team has established generic pathways describing the interaction with primary care, where basic palliative care is provided	
2.4.7.8 The EUCCC provides information on available hospice facilities/NGO support also for the relatives	

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2.5 Cancer survivorship care

Lots of cancer patients need access to relevant support to cope properly with medical or psycho-social side-effects and consequences caused by the cancer disease or the related treatment. Identifying these patients and their needs must be an integrated part of the patient pathways. This section expresses the criteria for EUCCCs to provide proper measures for cancer survivorship including psycho-social support and rehabilitation. The section outlines the specific standards and evidence required for EUCCCs to meet the criteria and provide comprehensive care along the continuum from diagnosis to survivorship.

2.5.1 EUCCCs work systematically with cancer patients who need follow-up related to consequences of cancer or cancer treatment	
Clarification of the criterion: As cancer patients going through a patient pathway based on treatment with curative intentions, they require attention to their physical, cognitive, emotional, and social challenges and needs. In addition, there is a need for attention on challenges connected to issues of co-morbidity and imposed illness in other organs than the one involved by the cancer. EUCCCs, with their patient-centered care, can offer a comprehensive and holistic range of support to help patients achieve their best possible outcomes.	
Standards:	**Evidence:**
2.5.1.1 The EUCCC has SOPs for screening to identify patients with needs of specific follow-up of needs connected to medical or psycho-social consequences of cancer disease or cancer treatment (CORE)	
2.5.1.2 The EUCCC has established procedures for referring patients to adequate professional follow up (like internal medicine, psychology, nutrition or social counselling) in specialist health care or primary care.	
2.5.1.3 The EUCCC provides those patients in need of survivorship follow-up measures with an individual plan for this.	
2.5.1.4 The EUCCC gives advice and support to patients and caregivers on how to detect early signs and symptoms of recurrence (CORE).	
2.5.1.5 The EUCCC gives advice and support to patients and caregivers on activities that may reduce risk of recurrence (among others diet, exercise) in line with latest recommendations.	
2.5.1.6 The EUCCC gives information and support to patients about the potential late effects of their cancer.	
2.5.1.7 The EUCCC gives information and support to patients about self-management.	

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2.5.1.8	The EUCCC has established clear procedures for referring patients to cancer rehabilitation services both within and outside the centre.	
2.5.1.9	The EUCCC ensures that there is access to rehabilitation services with multidisciplinary interventions for cancer patients and survivors based on screening of needs and coordinating individual plans for vocational rehabilitation and return to work if feasible.	

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3 Research

Objective: Determine the evaluation criteria for basic, translational, and clinical research infrastructure, processes, and outcomes to enhance cancer understanding and drive clinical practice advancements.

Research is a cornerstone of a Comprehensive Cancer Centre (EUCCC). Active participation in cancer research not only fosters quality improvements in care through novel insights but also facilitates collaboration and knowledge integration with other cancer centres. While the integration of research and care is pivotal for a EUCCC, its influence extends to innovation, prevention, and the enhancement of educational programs. The intricate interplay between research and other core EUCCC components hinges on effective coordination and governance, aspects addressed both within this section and under research leadership. This section further delineates research into three core criteria: research leadership, the breadth of research endeavours, and the practical execution of research that includes the support for young researchers.

Reference: Mok, T.S., et al. (2020). Integration of research and clinical care: the future of personalised medicine? The Lancet Oncology, 21(2), e80-e91.

3.1 The Comprehensiveness of Research

The concept of research comprehensiveness encompasses multiple facets. While the EUCCC criteria address these core dimensions, achieving excellence in every aspect isn't mandatory. An organizational consideration is whether all dimensions are managed within the EUCCC or through collaborations with external institutions. The approach may vary based on the country's healthcare system, with further elaborations provided in the subsequent sections.

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3.1.1 EUCCCs conduct bench-to-bedside research and opposite	
Clarification of the criterion: For a comprehensive understanding of cancer development, progression, and the creation of effective diagnostics and therapies, EUCCCs integrate the pillars of basic, translational, and clinical research. This integration accelerates the implementation of findings into clinical routine practice but also the opposite way by facilitating the journey of questions from the clinic to the agenda of translational research. To uphold their status, EUCCCs actively engage in all three research domains, with an emphasis on leading roles in translational and clinical research projects.	
Standards:	**Evidence:**
3.1.1.1 At least one organizational entity that makes up an EUCCC has in-house activity in translational research or is integrated in a network conducting translational research. (CORE)	
3.1.1.2 All units providing cancer care in the EUCCC is integrated in a network allowing clinical research activities. (CORE)	
3.1.1.3 The centre is part of a network that processes facilitating mutual interactions between translational research and clinical practice (transforming findings from translational research to clinical practise and bringing questions raised in clinical practise to the table of translational research).	
3.1.1.4 The EUCCC has either activity or have a formally organised collaboration with an institution conducting: • Basic research • Epidemiological research • Health care research	

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3.1.2 EUCCCs engage in comprehensive cancer research	
Clarification of the criterion: Comprehensive cancer research informs every facet of patient care. While diagnostics and treatment remain central, there's an increasing emphasis on understanding long-term side effects, enhancing quality of life post-treatment, patient reported experiences and addressing the broader spectrum from prevention to palliative care.	
Standards:	**Evidence:**
3.1.2.1 The EUCCC conducts research related to cancer diagnostics (pathology and radiology). (CORE)	
3.1.2.2 The EUCCC conducts research related to cancer treatment (both regarding medical treatment, radiotherapy, and surgery)(CORE)	
3.1.2.3 The EUCCC demonstrates high-quality research in at least 2 of the following areas: • Survivorship • Palliative and end-of-life care • Outcomes (QoL, adverse events) • Health Care Service • Patient-centred needs	
3.1.2.4 The EUCCC is actively involved in research that focusing on the risks and underlying causes of cancer development., prevention and early detection.	

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3.1.3 EUCCCs conduct research on major tumour groups	
Clarification of the criterion: Over ***half of all cancer*** cases are attributed to the five predominant tumour groups: lung, breast, prostate, colorectal, and melanoma. EUCCCs conduct research on these prevalent cancers.	
Standards:	**Evidence:**
3.1.3.1 The EUCCC carries out clinical research on three of these five common cancers: 1. Breast cancer and gynecological cancers such as ovarian and uterine cancer 2. Lung and thoracic cancers 3. Gastrointestinal cancers (including colorectal and gastric cancers, pancreas and liver) 4. Genitourinary cancers (including prostate and bladder cancers) 5. Skin cancers (melanoma and other advanced or aggressive skin cancers)	
3.1.3.2 The EUCCC carries out clinical research on pan cancer topics	
3.1.3.3 The EUCCC carries out translational research on at least two of the tumour groups mentioned in 3.1.3.1. possibly as a part of a network including other research or cancer centres	

3.1.4 EUCCCs conducts research on additional cancers	
Clarification of the criterion: Research on rare cancers is important for EUCCCs, given the methodological and organisational complexities they present, especially in the context of evolving precision medicine approaches.	
Standards:	**Evidence:**
3.1.4.1 The EUCCC is involved in research on at least two additional cancers, which may include Rare cancers, Pediatric cancers, Hematologic cancers (CORE).	
3.1.4.2 The EUCCC has either institutional MDT/tumour boards for rare entities or participates in multi-institutional MDT/tumour boards on a regular basis where all patients are discussed as candidates for clinical trials.	
3.1.4.3 The EUCCC is involved in a European Reference Network (ERN) in at least two themes.	

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3.1.5 EUCCCs commit research on patient-centred and personalized care	
Clarification of the criterion: A shift from an organ-based tumour group approach to non-tumour specific research is crucial, emphasizing both patient-specific biomedical and socio-psychological characteristics and their specific reactions to cancer diagnosis and treatment interventions. This requires both a multi-disciplinary approach and application of a broad spectrum of scientific methodologies.	
Standards:	**Evidence:**
3.1.5.1 The EUCCC carries out research integrating patient-centred care with oncological research throughout the patient's trajectory.	
3.1.5.2 The EUCCC has programmatic structures/mechanisms in place to promote multimethod research and connect to a research eco-system giving access to a broad spectrum of expertise in relevant research methodologies[16].	

3.2 Research Practice

To achieve comprehensive and exemplary cancer research, and to ensure seamless integration between research and care, specific criteria and standards targeting research practices are essential. These criteria encompasses areas like ethical standards, accessibility to clinical data, research infrastructure availability, external collaboration, and career development. The collective impact of these criteria will shape the research contributions at the EUCCC level.

3.2.1 EUCCCs foster research integrity and ethics	
Clarification of the criterion: Established protocols are essential to uphold research integrity and ethical standards. This encompasses research design approvals, training in proper research practices, and mechanisms to address potential research misconduct. The criteria cover research ethics, data practices, data management, and research publication protocols.	
Standards:	**Evidence:**
3.2.1.1 The EUCCC provides training in research integrity. (CORE)	
3.2.1.2 The EUCCC ensures standardised procedures to handle suspected research misconduct (falsification, fabrication, and plagiarism).	
3.2.1.3 The EUCCC ensures ethical evaluation (approval) of research projects by an ethical committee system.	

[16] Definition and examples: *including epidemiological studies, clinical trials, and healthcare research*

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3.2.1.4	The EUCCC provides guidelines for safe collection, storage, retention and deletion of informed consent and the connected research data. (CORE)	
3.2.1.5	The EUCCC ensures that adequate infrastructures for data management are accessible in the centre.	
3.2.1.6	The EUCCC ensures that legal and methodological advice in data sharing and transfer is offered by the centre.	
3.2.1.7	The EUCCC provides and acts according to established procedures for data breach.	

3.2.2 EUCCCS encourage the development of research talent and careers

Clarification of the criterion: The research at EUCCCs will depend on attractive research environments that foster future research leaders and stimulate interaction between basic and applied research. The standards herein relate to training and career development for research staff.

Standards:		**Evidence:**
3.2.2.1	The EUCCC offers mentoring programs to researchers (including evaluation). (CORE)	
3.2.2.2	The EUCCC partake in PhD and postdoc programs.	
3.2.2.3	The EUCCC provides structures for exchange programs in research.	
3.2.2.4	The EUCCC offers support services for grant proposals.	
3.2.2.5	The EUCCC performs regular evaluation on successful grants proposals.	

3.2.3 EUCCCs integrate research and care

Clarification of the criterion: This criterion is covered by a separate topic. In the current context, the standards are restricted to those underlining the required arrangements at the research side of EUCCCs that have to be present to ensure the necessary integration with care.

Standards:		**Evidence:**
3.2.3.1	The EUCCC secures provides measures to support investigator-initiated studies and research.	
3.2.3.2	The EUCCC host regular scientific meetings/seminars for all staff.	

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3.2.3.3	The EUCCC provides competitive research funding programs to offer split positions for MD between research and clinic.	
3.2.3.4	Patient inclusion in clinical trials is available in the electronic health record (EHR).	
3.2.3.5	The EUCCC has arrangements that provides possibilities to combine clinical practice with engagement in research.	

3.2.4 EUCCCs have permanent and strategic collaboration with academia on research		
Clarification of the criterion: The hospitals constituting the core of a EUCCC have to cooperate with universities on joint programs of research, on dissemination of new basic scientific knowledge based, and on collaboration on research projects.		
Standards:		**Evidence:**
3.2.4.1	The EUCCC has an agreement of research collaboration with one or more academic institutions regarding several academic disciplines.	
3.2.4.2	The EUCCC provides the opportunity for split hospital and university affiliation for MDs and also for other relevant groups of employees.	

3.2.5 EUCCCs provide core research infrastructures		
Clarification of the criterion: To achieve the goal of learning from every patient, it's essential to have access to real-world clinical data, tissue, and liquid samples from all patients visiting the cancer centre. This necessitates the appropriate infrastructure. Moreover, distinct infrastructure requirements exist for basic, translational, and clinical research.		
Standards:		**Evidence:**
3.2.5.1	The EUCCC has access to technological research core facilitates (CORE).	List of core facilities
3.2.5.2	The EUCCC has a system for registering broad consent from patients (in accordance with national regulations) being easily accessible for eligible researchers.	
3.2.5.3	The EUCCC provides administrative/legal support to perform (design, coordinate, run and monitor) research and specifically clinical trials. (CORE)	

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3.2.5.4	The EUCCC has access to the required capabilities and resources to run early-phase/ first-in-man clinical trials.	
3.2.5.5	The EUCCC ensures periodical external site visit/review of the clinical trial unit.	

3.2.6 EUCCCs collaborate nationally and internationally in research	
Clarification of the criterion: Cancer research is an activity dependent on a multi-centre and cross-border activity. The arrangements facilitating this will therefore be crucial for CCCs and they are active in developing their role in external networks of cancer research.	
Standards:	**Evidence:**
3.2.6.1 The EUCCC participates in national/multi-centre studies.	
3.2.6.2 The EUCCC acts as PI/sponsor for national trials.	
3.2.6.3 The EUCCC participates in international research projects in translational and clinical medicine (CORE).	List of projects.
3.2.6.4 The EUCCC partakes in leadership roles in national (multi-institutional)/ European/international research projects.	

3.3 Research leadership.

Advancements in cancer research hinge on the coordination of intricate processes that require cross-disciplinary and multi-organizational collaboration, as well as adept management of stakeholders and regulatory frameworks. In a EUCCC context, effective leadership is paramount to offer direction, ensure integration, and foster continuous learning and enhancement. This section outlines the criteria pertinent to these leadership aspects.

3.3.1 EUCCCs structure supports cancer research development	
Clarification of the criterion: Comprehensive Cancer research necessitates input from varied organizational units, levels, professional groups and other stakeholders, like patients. For effective coordination and alignment with the research strategy within EUCCC, specific organizational structures and governance processes are essential. The design of these arrangements will be tailored to the local healthcare and research systems that make up the EUCCC and its associated external networks.	
Standards:	**Evidence:**

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3.3.1.1	The EUCCC has a research council with the mission to coordinate and facilitate cooperation across organisational borders and in implementing the research strategy of the EUCCC.	
3.3.1.2	The EUCCC provides an organigram that defines research departments and leaders of research groups.	
3.3.1.3	The EUCCC reports data on key financial figures regarding its research on an annual basis.	
3.3.1.4	The EUCCC provides access to shared ICT platforms for research activities. (CORE)	Agreement to share technology platforms / procedure sharing technology platforms.

3.3.2 EUCCC has a research strategy	
Clarification of the criterion: The EUCCC's research direction is articulated through a cancer research strategy, highlighting main goals, challenges, and planned initiatives for upcoming years.	
Standards:	**Evidence:**
3.3.2.1 The EUCCC has a research strategy, updated regularly (at least every three years), defining the main objectives and the means (resources) to reach these objectives.	
3.3.2.2 The EUCCC ensures a development plan that includes research, regularly updated, and actively integrated into the governance processes of the EUCCC.	
3.3.2.3 The EUCCC ensures a research strategy collaboratively formulated, is integrating perspectives and insights from all relevant stakeholders including clinical and laboratory research professionals and academic researchers and patient representatives.	

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3.3.3 EUCCCs evaluate their research	
Clarification of the criterion: Research undergoes consistent monitoring and evaluation for enhancement, encompassing both internal tracking and external periodic or situational assessments.	
Standards:	**Evidence:**
3.3.3.1 The EUCCC publishes an annual report on the activities and the performances of research programs/groups.	
3.3.3.2 The EUCCC has an external Scientific Advisory Board (SAB)[17] meeting periodically (at least every three years) to evaluate research activities of the centre.	Written report by SAB including performance and development points.
3.3.3.3 The EUCCC offers internal evaluation and guidance for research grant applications before submission.	
3.3.3.4 The EUCCC provide a procedure for the evaluation of clinical trials (e.g., number of patients, zero accrual trials, etc.).	
3.3.3.5 The EUCCC participates in regular, external evaluation of Research groups. (CORE)	

3.3.4 EUCCCs involve patient representatives in research	
Clarification of the criterion: Incorporating the patient perspective enriches the research process, enhancing its relevance and applicability. From strategy formulation to results dissemination, patient involvement not only ensures research aligns with patient needs but also amplifies its societal impact. This criterion underscores the significant value added by patient representation throughout the research journey.	
Standards:	**Evidence:**
3.3.4.1 The EUCCC involves participation in the decision on prioritisation of research programs.	
3.3.4.2 The EUCCC has a mandatory educational program for patient representatives providing them with necessary information and	

[17] Scientific Advisory Board: Definition and functional description (mention that it can/should be separate than an authority/funding body)

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	insights on cancer research and relevant topics preparing them for involvement in decisions relating to research.	
3.3.4.3	The EUCCC involves patients at a general level and for specific research projects, in the ethical aspects of research.	
3.3.4.4	The EUCCC organizes participation of patients in planning and realising research programs specifically in research projects on patient centred care (like connected to supportive disciplines i.e. rehabilitation, pain management, psychosocial care, etc.).	

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4 Integration Research and Care

Patients treated at Comprehensive Cancer Centres (EUCCCs) experience enhanced survival rates, attributed to the seamless integration of top-tier cancer care and innovative research. This synergy is vital, with multidisciplinary teams bridging clinical needs and research advancements. Recent innovations, from personalized medicine to artificial intelligence, underscore the evolving landscape of cancer care. EUCCCs, equipped with robust Information and Communication Technology (ICT), lead these changes, ensuring consistent and advanced care. This section outlines the criteria for effective research-care integration across structural, management, and outcome dimensions.

Objective: This section establishes criteria and standards for personalized medicine, encompassing molecular diagnostics, genomics/proteomics, artificial intelligence, molecular tumour boards, and tailored treatment pathways, emphasising the multidisciplinary collaboration of professionals.

4.1 Structural prerequisites for integrating research and care.

Structural challenges can impede the integration of research and care in cancer centres. However, with the right infrastructure, these centres can drive impactful research projects. EUCCCs are tasked with bridging top-tier research and care. This section outlines criteria addressing essential structural elements, such as electronic information systems, research support near clinical settings, and research network infrastructure, to ensure seamless integration.

4.1.1 EUCCCs promote broad patient consent for research	
Clarification of criterion: For robust research outcomes, large cohorts with detailed annotations and adequate follow-up are essential. An institutional approach that promotes broad patient consent facilitates prospective data gathering, enabling the use of general clinical data for research.	
Standards:	**Evidence:**
4.1.1.1 The EUCCC has defined procedures to invite all new cancer patients to give a broad consent to collect prospective data for research purposes (according to national regulations) (CORE)	Procedure for broad consent for new cancer patients in the centre and informed consent
4.1.1.2 The EUCCC ensures that the patient consent is obtained and stored according to the local requirements on ethics, privacy, and data protection.	Procedure for storage of patient consent

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4.1.2 EUCCCs have structural ICT facilities making clinical data and samples available for research	
Clarification of criterion: To foster clinical and translational research, it's essential to develop ICT solutions that provide access to anonymized patient clinical and biological data for research purposes. This approach must comply with strict institutional, national, and European regulations on data collection and usage. Proper guidance on these regulations is crucial to empower researchers with the necessary resources to conduct patient material research	
Standards:	**Evidence:**
4.1.2.1 The EUCCC provides access to a centralised database connected to its biobank which is also linked to primary sources of clinical data. (CORE)	Protocol for the biobank
4.1.2.2 The EUCCC provides access to ICT tools to build the necessary databases connected to the accomplishment of clinical trials. (CORE)	

4.1.3 EUCCCs encompass or provide access to clinical trial units for all relevant professions	
Clarification of criterion: There are strict regulations of ethics and protection of patients' rights in on institutional, national, and European level. Managing routines connected to this depend on professional and institutionalized support. In addition, the supportive structures also secure easy access to assistance for coordination and administrative functions. These support functions are offered through the presence of a clinical trial management unit providing clinicians with essential support to efficient execute sound clinical trials and safeguard patients' rights.	
Standards:	**Evidence:**
4.1.3.1 The EUCCC provides an institutional clinical research management unit dedicated to trials. (CORE)	Organogram research and protocol /procedure clinical research management unit.
4.1.3.2 The unit supports/coordinates the aspects of administration, funding, feasibility assessment and ethical approvals.	Protocol /procedure clinical research management unit
4.1.3.3 The services offered by a clinical trial unit are equally access able for all relevant professional groups and organizational units.	

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4.1.4 EUCCCs have access to early-phase clinical trial units	
Clarification of criterion: Proof-of-concept studies (e.g. phase I/II) are resource demanding. Early-phase clinical trials are rarely sufficiently backed by industry or other funding sources, though have a high potential gain. EUCCCs have a leading role in early-phase clinical trials and in facilitation of proof-of-concept studies.	
Standards:	**Evidence:**
4.1.4.1 The EUCCC has formal agreements to promote and facilitate access to early-phase clinical trials.	Agreements early clinical trials with other centres and a procedure for promotion of clinical trials
4.1.4.2 The EUCCC provides procedure(s) to identify eligible patients for early phase trials.	Procedure selection / clinical trial inclusion.
4.1.4.3 The EUCCC´s procedures on recruiting patient to early phase trials are regularly updated and patients are actively identified.	

4.1.5 EUCCCs provide easy access to ongoing clinical research information	
Clarification of criterion: Effective patient enrolment and engagement, along with clear communication within the cooperating network of EUCCC, are vital for successful clinical trials and ensuring equal access for patients. This depends on communication structures with a well-developed ability to spread information and communicate customised to the target groups. Again, this is a prerequisite to providing equal access to clinical trials for patients while ensuring sufficient recruitment to trials coordinated by EUCCCs.	
Standards:	**Evidence:**
4.1.5.1 The EUCCC has a policy and measures for promoting clinical trials, including internal information and communication to public and laymen on trial availability and results.	Procedure for clinical trial promotion: e.g. brochures, websites, public events etc.
4.1.5.2 The EUCCC has a procedure and policies to promote the participation of patients in clinical trials.	Procedure on promoting inclusion patients in clinical trials.
4.1.5.3 The EUCCC promotes participation in clinical trials from collaborating entities in its local area.	

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4.2 Managing dynamics of integrating research and care

Successful integration of research and care hinges on effective management and coordination. This section emphasizes the importance of fostering dynamic interactions across the research-care continuum and leveraging structures that enhance this integration.

4.2.1 EUCCCs emphasize research competence in recruitment and education	
Clarification of criterion: Recruitment of clinical staff[18] with research competence is crucial for high-quality care in EUCCCs. Continuous education programs also enhance research skills relevant to cancer care positions.	
Standards:	**Evidence:**
4.2.1.1 Research competence is promoted in the recruitment of clinical personnel.	SOP for recruitment of personnel, KPI: Table indicating clinical staff involved in research projects (yearly updated).
4.2.1.2 The EUCCC has an explicit measurable ambition for research competence requirements for its staff (CORE)	Programs/plans for increasing research competence of clinical staff, KPI: list of training/education programmes to increase research competencies, including number of participants.
4.2.1.3 Relevant research topics are integrated in continuous education programs for relevant professional groups	

4.2.2 EUCCCs integrate research in cancer patient pathways
Clarification of criterion: EUCCCs structure their clinical operations according to cancer patient pathways, necessitating a seamless integration of research and care that aligns with each stage of the patient journey. Key junctures for this integration include outpatient clinic visits, Multidisciplinary Team (MDT) case discussions, and institutional and regional pathway network meetings. This synergy between research and care are established throughout the entire patient pathway, encompassing early detection, diagnosis, primary treatment, supportive care, follow-up/survivorship, and palliative care.

[18] Clinical personnel includes all professions that are involved in the diagnosis, treatment and follow-up of patients (e.g.: doctors, nurses, psychologists, physicists, nutritional therapists, social workers).

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Standards:		Evidence:
4.2.2.1	The EUCCC provides patient pathways delineating specific junctures where clinical trial inclusion is assessed. (CORE)	Patient pathways/written procedure presented with clearly stated checkpoints for clinical trial inclusion including minutes of the MDT meeting indicating patient inclusion in clinical trials.
4.2.2.2	The EUCCC has procedures securing that the Multidisciplinary Team (MDT) meetings serve as the primary forum for evaluating a patient's eligibility for clinical trials.	
4.2.2.3	The EUCCC has protocols on documenting of patient's eligibility for clinical trials, in the meeting minutes or EHR[19] adhering to local protocols. (CORE)	This procedure must be clearly outlined for each patient pathway
4.2.2.4	The EUCCC provides screening for molecular alterations to identify patients for targeted treatment trials to all relevant patients.	Patient pathways/written procedure presented with clearly stated checkpoints (stating which patients and at which time) for molecular analyses. Written procedure describing composition and process in the molecular tumour board (or similar).
4.2.2.5	The EUCCC has access to a molecular tumour board (MTB) with competent staff is in place for interpreting results, which are then documented in medical records. (CORE)	
4.2.2.6	The EUCCC ensures regular revision of clinical tumour-specific patient pathways in order to incorporate results from research and development.	
4.2.2.7	The EUCCC has procedures ensuring documentation on clinical trial inclusion and broad consents for collection of data/biological material in the EHR.	Evidence: Examples of standard phrases in the EHR

[19] topics on inclusions (recommendations, eligibility/ineligibility)

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4.2.3 EUCCCs integrate translational research into clinical practice	
Clarification of criterion: Parallel involvement in translational and clinical research, alongside clinical practice, enhances the EUCCC's ability to foster synergies between research and care. Key factors include physical proximity, dual affiliations for employees, protected research time, and the inclusion of clinicians in research groups, extending to diagnostics.	
Standards:	**Evidence:**
4.2.3.1 The EUCCC promotes that all research groups have affiliated clinicians[20]. (CORE)	All research groups show lists of members including role.
4.2.3.2 The EUCCC promotes that all cross-disciplinary professional tumour groups have members of each and mixed affiliation between clinic or research departments. .	List of tumour groups and research environment with which they are affiliated.
4.2.3.3 The EUCCC facilitates regular meeting points to promote discussion and integration of clinical and research experiences.	Programs from past events.
4.2.3.4 The EUCCC´s meeting on this allow presentations/contributions of activities and needs from both research and clinic to increase collaboration and research. (CORE).	

4.2.4 EUCCCs integrate advanced knowledge into general practice	
Clarification of criterion: EUCCCs play a pivotal role in pioneering ground-breaking clinical research and facilitating the implementation of evidence-based technological and therapeutic advances. Key areas of focus include precision medicine, targeted therapies, theragnostic, molecular diagnostics, genomics/proteomics, and artificial intelligence, all aimed at enhancing patient care and contributing to their networks.	
Standards:	**Evidence:**
4.2.4.1 The EUCCC has written strategies to study and implement personalised cancer medicine based on: • Molecular diagnostics (including targeted therapy), • Imaging techniques (including theragnostic)	Written strategies and examples of studies, equipment and process instructions are presented; KPI: Concrete examples of studies, equipment and process instructions are presented.

[20] Definition: *clinician* includes all personnel employed in routine clinical diagnostics, treatment and care

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4.2.5 EUCCCs connect with excellence networks in research and care	
Clarification of criterion: A EUCCCs play a crucial role in maintaining a strong and up-to-date network and knowledge base to connect patients with the right clinical trials, whether they are national, regional, or international. This is particularly important for rare diagnoses and specialized areas of clinical practice where not every EUCCC may have the necessary research activity and expertise. By linking to expert networks (i.e. Networks of Expertise, NoE), EUCCCs can facilitate investigator-driven trials in regions or countries with few incidents and make European networks of EUCCCs attractive for industry-initiated trials in cases where each EUCCC may have too few cases.	
Standards:	**Evidence:**
4.2.5.1 The EUCCC offers eligible patients access to international clinical trials at one owns EUCCC or through organising visits to other EUCCCs (CORE).	List of projects.
4.2.5.2 The EUCCC participates in both academic and industrial clinical trials along the whole patient pathway (CORE).	List of trials with specification of where in the patient pathway patients will be included.
4.2.5.3 The EUCCC collaborates with neighbouring hospitals in disseminating results from research and implementing it into clinical practice.	.

4.3 Outcome of integrating research and care

EUCCCs are tasked with delivering cutting-edge information on research and care advancements to patients, families, patients´ social environments and professionals. Successful research-care integration results in the effective translation of research-based knowledge into guidelines, education, quality enhancements, and broad dissemination to both caregivers and patients**.**

4.3.1 EUCCCs implement research-based knowledge in clinical guidelines	
Clarification of criterion: EUCCCs play a vital role in contributing to the development and updating of regional, national, or international clinical practice guidelines. By actively participating in expert panels and disseminating evidence-based advances, EUCCCs help ensure that guidelines reflect the latest research and best practices in cancer care.	
Standards:	**Evidence:**
4.3.1.1 The EUCCC has routines securing that its clinical practice is governed by clinical guidelines updated in line with recent research-based evidence (CORE)	A strategy plan (e.g. Cancer strategy) describing how research is integrated into care (both ways).

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4.3.1.2	The EUCCC contributes in national and/or international expert panels and authorities to develop new guidelines for clinical practice.	

4.3.2 EUCCCs include research knowledge in education programs.	
Clarification of criterion: Educational programs affiliated with EUCCCs incorporate the latest research findings to maintain current and relevant syllabuses.	
Standards:	**Evidence:**
4.3.2.1 The EUCCC has syllabuses of educational programs with focus in new research advances (developments) (CORE).	Written procedure on how the educational program covers research and regularly incorporate new knowledge from research.
4.3.2.2 The EUCCC has regular educational events updating data from relevant topics in accordance with updates brought up in major scientific meetings.	

4.3.3 EUCCCs transform research into innovations and improvements	
Clarification of criterion: EUCCCs facilitate platforms such as projects, colloquia, and seminars to foster multidisciplinary collaborations and build networks among researchers, clinicians, and entrepreneurs.	
Standards:	**Evidence:**
4.3.3.1 The EUCCC organises regularly meetings for dissemination and implementation of new research involving multidisciplinary attendants. (CORE).	List of events, with frequency and distribution/dissemination channels (professionals), list of professionals participating.
4.3.3.2 The EUCCC sets up formal collaborations with key enterprises and entrepreneurs interested in promoting clinical improvements	List of events, with frequency and distribution/dissemination channels, list of participants, including agreements with enterprises/entrepreneurs.

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4.3.4 EUCCCs disseminate new research to professionals and patients.	
Clarification of criterion: EUCCCs are responsible for effectively disseminating new knowledge and ongoing research activities to relevant professional communities, as well as to patients and their caregivers. This dissemination is crucial for enhancing patient awareness and providing professionals involved in cancer care with the latest advances in cancer understanding, prevention, diagnostics, and treatment options.	
Standards:	**Evidence:**
4.3.4.1 The EUCCC regularly arranges public events for patients and caregivers (CORE).	List of events, with frequency and distribution/dissemination channels (professionals), list of professionals participating (disciplines (caregivers), patients (proportion), authorities.
4.3.4.2 The EUCCC regularly involves patients who have participated in clinical research, in lectures and training of health care professionals such as physicians and specialist nurses, as well as to the general public.	Documentation of events including patients.
4.3.4.3 The EUCCC publishes clinical research results in open-source journals and has regular dissemination of research and clinical newsletters and channels targeting laymen.	Proportion of publications in open-source journals Newsletters or similar publications from last year.

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5 Innovation

Objective: To define a cohesive set of standards that catalyze innovation within Comprehensive Cancer Centres, emphasizing the integration of pioneering technologies and enhanced patient care. This framework prioritizes fostering a conducive ecosystem for technology transfer and spin-offs, amplifying the translational impact of research and elevating patient outcomes.

Comprehensive Cancer Centres (EUCCCs) stand at the forefront of global cancer care, championing innovative solutions and advanced treatments. Leveraging state-of-the-art technologies, from robotic surgery to artificial intelligence, EUCCCs set the gold standard in patient care. Their collaborative ethos extends to partnerships with both governmental and non-governmental entities, ensuring a holistic approach to innovation. This commitment is further underscored by incentives like awards that fuel the spirit of innovation.

Within the EUCCC framework, innovation is structured into three core areas : **Management and Facilitation of Innovation** (Outlining how EUCCCs strategize and oversee innovation), **Areas of Innovation** (Highlighting the diverse innovation domains, from medical advancements to organizational shifts), **Supportive Infrastructure for Innovation** (Emphasizing the foundational elements that nurture innovation, from education to technology transfer), which provides a roadmap to evaluate and amplify the innovative process of EUCCCs in their quest to address the multifaceted challenges of cancer.

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5.1 Culture and commitment to innovation

Comprehensive Cancer Centres (EUCCCs) champion a culture of research and innovation, dedicated to elevating treatments and patient care. Their commitment spans diverse research fields, leveraging cutting-edge technologies. Strategic frameworks guide and integrate innovation within EUCCCs, harmonizing it with other institutional activities.

5.1.1 Integration of Innovation in Cancer Strategy and Development Plans	
Clarification of the criterion: EUCCCs play a pivotal role in shaping the future of cancer care, with innovation at the forefront of their strategic and developmental plans. By championing innovation, EUCCCs contribute to the integration of ground-breaking activities in both research and care. It is essential for EUCCCs to maintain current knowledge of regulatory requirements and available resources that support innovation, ensuring that their strategic activities are in sync with national and European contexts.	
Standards:	**Evidence:**
5.1.1.1 The EUCCC has innovation as a topic integrated and visible in its cancer strategy.	A formal, written strategic plan that explicitly mentions innovation objectives and initiatives in cancer care and research.
5.1.1.2 The EUCCC has follow up action plan specifically addressing innovation related to cancer connected both to care and research including innovation both technology, medicine and services. (CORE)	
5.1.1.3 The EUCCC has access to an organizations unit with the purpose to coordinate and facilitate innovation, providing regulatory requirements and bridging internal potentials and initiatives with external resources.	

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5.1.2 Monitoring and improving innovation performance	
Clarification of the criterion: Expanding capabilities and capacities to innovate depend on systematically learning from own experiences and from exchange with other innovating communities and academic knowledge on innovation. Both quantitative and qualitative indicators of innovation serve as tools to evaluate strategic activities, emphasizing the importance of innovation and enhancing the cultural awareness of innovation as a strategic element within the EUCCC. In addition, involving patient representatives as key partners in the innovation processes is crucial.	
Standards:	**Evidence:**
5.1.2.1 The EUCCC has established a set of performance indicators on innovation.	E.g. list of patents filed, registered industrial collaborations.
5.1.2.2 The EUCCC provides evidence of active development and implementation of innovative practices in care and research.	The number of new or unique programs, treatments, or research initiatives that the EUCCC has launched in a given time period.
5.1.2.3 The EUCCC organises at least annually an event evaluating innovation practice and outcome of innovation.	A list of agendas and meeting minutes exemplifying the topic discussion.

5.1.3 Participation in Innovation Networks	
Clarification of the criterion: EUCCCs foster a collaborative environment that engages commercial, technical, and academic partners in dynamic processes essential for successful innovation. They also support and encourage innovative entrepreneurship among their staff and cooperating entities.	
Standards:	**Evidence:**
5.1.3.1 The EUCCC participates actively in networks or clusters with institutions external to the CCC itself that foster innovation.	The EUCCC must be able to list its participations in various collaborative networks, specifying its role and level of involvement, and if applicable, the accreditation or recognition awarded to the network.
5.1.3.2 The EUCCC is involved in collaborative projects or partnerships aimed at promoting innovation.	Document its participation in various collaborative projects and partnerships, specifying its role and level of involvement, and, if applicable, the valorisation or

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	recognition resulting from these collaborations.

5.2 Areas of Innovation

In EUCCCs, innovation targets enhancing the patient care journey, tackling healthcare hurdles, and advancing diagnostic and therapeutic methods. Evaluations of such innovations consistently incorporate health economic assessments and cost-benefit analyses.

5.2.1 EUCCCs foster diverse innovations in oncology	
Clarification of the criterion: EUCCCs lead in technological advances, actively engaging in activities that develop the next generation of diagnostic and treatment innovations for patients. Their innovation initiatives are structured as matrix programs, encompassing various diagnoses and levels of care. The innovative activities are targeted at both commercial and not commercial products.	
Standards:	**Evidence:**
5.2.1.1 The EUCCCs foster innovation on issues relevant across various cancer diagnoses and levels of care, utilizing advanced technologies (such as AI, big data, genomics, new imaging or interventional techniques, human science, and epidemiology).	Evidence of these innovations is readily available and demonstrates the centre's commitment to cutting-edge cancer care and research.
5.2.1.2 The EUCCCs are active in supporting development and implementation of innovations addressing services and organizational areas.	

5.2.2 EUCCCs nurture both commercial and non-commercial innovations	
Clarification of the criterion: EUCCCs play a pivotal role in fostering cultural and organizational capacities through active innovation and entrepreneurship. These initiatives not only have the potential to generate revenue in commercial fields but also lead to significant resource savings and improvements in patient care within non-commercial domains.	
Standards:	**Evidence:**
5.2.2.1 The EUCCC is engaged in early-phase trials with Principal Investigators (PIs) from within their own network.	
5.2.2.2 The EUCCC initiates and is engaged into investigator-initiated trials (IITs)	

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5.3 Supportive Infrastructure

EUCCCs, equipped with advanced technology and care frameworks, champion innovation throughout their operations. Essential infrastructures are in place to stimulate educational and networking initiatives, empowering staff to pioneer innovation in their respective domains.

5.3.1 EUCCCs train researchers in innovation processes	
Clarification of the criterion: Successful innovations rely on skilful practice and understanding of contextual constraints. EUCCCs promote these skills by elucidating the process from ideation to intellectual property, proof-of-concept, and commercialization. This empowers employees, particularly researchers, to identify potential for innovation in their activities and improve research strategies.	
Standards:	**Evidence:**
5.3.1.1 The EUCCC partakes in educational programs that offer training on the innovation process (e.g. intellectual property rights, proof-of-concept development, and commercialization strategies.)	This is evidenced by the availability and content of these programs.

5.3.2 EUCCCs have intellectual property schemes and a Technology Transfer Office (TTO)	
Clarification of the criterion: Research staff receive comprehensive guidance on intellectual property rights and the processes for reporting and developing inventions into mature products, facilitated by a Technology Transfer Office (TTO). A standing agreement with a TTO unit, whether internal or external to the EUCCC, ensures access to essential support. TTOs provide a holistic view of developmental stages and commercial potential, connecting resources and expertise accordingly.	
Standards	**Evidence**
5.3.2.1 The EUCCC provides access to a TTO unit, either internal or external, including records of interactions or transactions. (CORE)	
5.3.2.2 The EUCCC has rules for ownership of intellectual property and patents, either through the EUCCC or the TTO.	

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5.3.3 EUCCCs support innovative spin-offs from R&D.	
Clarification of the criterion: Supportive units play a crucial role in streamlining the commercialization process, aiding in areas such as commercialization strategies, venture capital acquisition, and the establishment of spin-offs and start-ups. However, such support such also be available for innovations that might deliver improvements in quality of care without necessarily having commercial potentials.	
Standards:	**Evidence:**
5.3.3.1 The EUCCC facilitates entrepreneurship by offering commercialization support and access to venture capital	
5.3.3.2 The EUCCC maintains a record of facilitated spin-offs and start-up companies, showcasing their proactive stance in nurturing entrepreneurship and innovation.	
5.3.3.3 The EUCCC supports transformation of research-based knowledge to implementation of improved services, practice and governance of cancer care	

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6 Prevention

Prevention spans three distinct tiers: primary, which mitigates cancer risk by curtailing carcinogen exposure; secondary, which prioritizes early detection to thwart carcinogenesis; and tertiary, which targets interventions specific to cancer patient care. Central to this triad, EUCCCs champion tertiary prevention as an integrated part of its follow-up procedures and survivorship program. However, the increased engagement of EUCCC in primary and secondary prevention will follow as an inevitable consequence of the development of more personalized prevention measures the connection to and collaboration with research, education and even integrated in care activities and the role of the CCCs in screening programs.

Objective: Establish criteria underscoring EUCCCs' pivotal role in the triad of cancer prevention: primary, secondary, and tertiary. This encompasses pinpointing and attenuating risk elements, bolstering early detection, delivering holistic patient care, and fostering prevention-oriented research. The objective converges on fostering collaboration among EUCCC stakeholders, steering towards a unified, prevention-focused healthcare paradigm.

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6.1 Scope of prevention

Cancer prevention is a collaborative effort, requiring national policies and programs. The EUCCCs, with their specialised expertise and resources, are uniquely positioned to lead, contribute to, and promote activities in cancer prevention across primary, secondary, and tertiary levels. Their role are synergistic, working in tandem with community-based initiatives and health facilities to holistically address the health of their patients, staff, and the broader community.

6.1.1 EUCCCs collaborate with primary prevention policies and programs	
Clarification of criterion: EUCCCs play a crucial role in enhancing the full range of cancer control programs for both patients and staff. This includes implementing primary prevention policies and reinforcing public health recommendations to minimize carcinogenic exposures and encourage positive behaviour changes and acceptance of immunization.	
Standards:	**Evidence:**
6.1.1.1 The EUCCC provides comprehensive information on cancer risk control and health promotion that are aligned with national and regional prevention campaigns, focusing on lifestyle and environmental factors.	
6.1.1.2 The EUCCC is recognized as smoke-free facilities and facilitates cessation services for both patients and staff.	

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6.1.2 EUCCCs enhance secondary prevention through screening	
Clarification of criterion: Leveraging their advanced expertise and technical platforms, EUCCCs can offer risk stratification services and screening for high-risk groups. These activities complement national policies and local infrastructure, and EUCCCs also endorse recommended population-based screening programs.	
Standards:	**Evidence:**
6.1.2.1 The EUCCC has established specialised structures, such as oncogenetic clinics that are integrated with biomolecular laboratories.	
6.1.2.2 The EUCCC has access to specialised structures, such as oncogenetic clinics that are staffed with oncogeneticists, following specific guidelines, and offering counselling and psychosocial support to patients and their families.	
6.1.2.3 The EUCCC contributes to national or local population-based screening programs, serving as a screening unit, a referral centre, or both. (CORE)	
6.1.2.4 The EUCCC has access to screening and early detection services (including through network collaborations) for high-risk subgroups across various tumour types such as pancreas, ovaries, lungs, colorectal track, prostate, and breast, adhering to established national guidelines.	
6.1.2.5 Staff within the EUCCC are regularly updated and informed about the available screening and early diagnostic programs and services.	

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6.1.3 EUCCCs integrate tertiary prevention into the survivorship care of their patients	
Clarification of criterion: A primary responsibility of a EUCCC is to ensure its patients receive high-quality care and treatment throughout their journey, from diagnosis to end-of life care. Actions to prevent of the consequences of treatments and risks of relapse is a pre-requisite of activities to be provided by or coordinated by a EUCCC.	
Standards:	**Evidence:**
6.1.3.1 The EUCCC integrates tertiary prevention into patient care pathways.	Clinical pathways or protocols detailing the tertiary prevention measures integrated into patient care, along with patient statistics showcasing the number of patients enrolled in and benefiting from such services.
6.1.3.2 The EUCCC provides early and late post-cancer follow-up for risk factor evaluation, management and prevention.	

6.2 Research on Prevention

Understanding its aetiology to outcome is vital for effective prevention and management in the cancer continuum. EUCCCs play a pivotal role, offering platforms for interdisciplinary research that delves into cancer causatives and risk factors. Leveraging infrastructures that aggregate clinical and biological data, EUCCCs can elucidate the interplay between internal and external determinants of cancer risk, providing avenues for impactful preventive strategies.

6.2.1 EUCCCs contribute to research on prevention	
Clarification of criterion: To strengthen the link with prevention, a deeper understanding of the risk factors for cancer development is crucial. This understanding can aid in the identification of high-risk populations and the development of effective screening programs. EUCCCs possess infrastructures that enable clinical and translational research, fostering the discovery and validation of factors that influence the risk and effects of cancer.	
Standards:	**Evidence:**
6.2.1.1 The EUCCC performs research on areas like: • Methods for early detection and screening for cancer • Identification of high-risk groups • Targets for immunisation (primary prevention) • Causes for relapse and connections to tertiary prevention	

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6.2.1.2	The EUCCC has set up collaborative structures with stakeholders on research in primary prevention (including Cancer Registries).	
6.2.1.3	The EUCCC facilitates data sharing with stakeholders in primary prevention (including Cancer Registries) for research purposes and in line with local, regional, and national regulations.	

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7 Education and Training

Objective: Develop comprehensive Standards for Education and Training in Comprehensive Cancer Centers (EUCCCs) that encompass inter-specialty collaboration in multidisciplinary teams and integrated practice unit training. These standards will ensure the continuous professional development of healthcare providers, promote knowledge dissemination, and enhance the delivery of high-quality, patient-centered care in cancer settings.

Education and training stand as pillars for Comprehensive Cancer Centres (EUCCCs). Rapid advancements in cancer biology and therapeutic strategies underscore the importance of keeping health professionals updated, ensuring patients benefit from the latest in cancer care. As cancer management adopts a multidisciplinary lens, collaboration among various oncology disciplines becomes paramount for optimal patient outcomes. This dynamic calls for an encompassing, interdisciplinary curriculum. A central mission of EUCCCs is continuous educational opportunities for professionals and knowledge dissemination to patients, their families, patients 'social environment and the broader community. Establishing such programs demands significant resources. EUCCCs often collaborate with educational entities and patient groups to craft comprehensive educational curricula. This document delineates the educational framework for EUCCCs, spotlighting core criteria and activity areas for ongoing education and training for staff, patients, and other stakeholders.

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7.1 Integration of Education and Training into care

Training and education play a crucial role in the strategic vision of EUCCCs, providing tools to improve prevention and treatment outcomes for cancer patients. A comprehensive policy for education and training is key to ensuring that the latest advancements in cancer care are integrated throughout the patient pathway.

7.1.1 EUCCCs provide comprehensive cancer-related education and training (CORE)	
Clarification of criterion: The comprehensive policy and programs for cancer-related education and training align with the strategic goals of the EUCCCs. These programs offer a variety of learning opportunities to staff, covering advancements within their fields of expertise and areas related to their daily responsibilities and operations.	
Standards:	**Evidence:**
7.1.1.1 The EUCCCs offers its employees access to comprehensive list of formal education programs (CORE)	List of educational programs of the formal education programmes offered, including objectives and target group.
7.1.1.3 The list of educational programs serves as an annual checklist to ensure that the program offers the education and training needed for the EUCCC to reach its strategic goals.	
7.1.1.4 The EUCCCs promotes a range of educational programs meeting professional needs and covers: • Undergraduate and post-graduate education • Continuous Professional Development (CPD) programs • Postdoctoral research training in cancer • Public outreach and awareness programs	

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7.1.2 EUCCCs support multi-disciplinary integration of research and clinical practice	
Clarification of the criterion: EUCCCs offer educational programs that intertwine research principles and evidence-based medicine. This approach equips healthcare professionals with the tools to actively participate in clinical research and seamlessly incorporate the latest discoveries into their everyday clinical practice.	
Standards:	**Evidence:**
7.1.2.1 The EUCCC fosters interdisciplinary and multidisciplinary collaboration by providing educational programs to unite healthcare professionals in a cohesive working relationship. (CORE)	
7.1.2.2 The EUCCC offers cancer research training programs that emphasise research methodologies, data analysis, and critical appraisal of scientific literature to facilitate integration research and care.	
7.1.2.3 The EUCCC offers training program bolstering healthcare professionals' capacity to seamlessly integrate research findings into clinical practice.	

7.1.3 EUCCCs establishe a network for comprehensive cancer-related training	
Clarification of the criterion: EUCCCs collaborate formally with training centres, universities, research institutions, and community partners, including patient representatives. The objective is to develop and provide educational programs tailored to the unique needs of healthcare professionals involved in cancer care at both undergraduate and postgraduate levels. These partnerships ensure a holistic and interdisciplinary approach to education and training.	
Standards:	**Evidence:**
7.1.3.1 The EUCCC collaborates with training centres, universities, research institutions, and community partners, including patient representatives, to create and offer cancer-related training and education programs. (CORE)	
7.1.3.2 The EUCCC ensures stakeholder involvement in revision of the educational program.	

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7.1.4 EUCCCs educate patients and caregivers[21] for active participation in care	
Clarification of the criterion: EUCCCs provide educational programs and resources to equip patients and their families with the necessary knowledge and skills for informed decision-making, self-care, and active participation in shared decision-making with healthcare professionals.	
Standards:	**Evidence:**
7.1.4.1 The EUCCC develops and offer a range of educational programs and resources for patients and their families, including topics on: • Cancer prevention • Treatment options • Supportive care • Self-care • Informed decision-making	Catalogue of educational materials available: • Written materials • Videos • Interactive workshops • Online resources
7.1.4.2 The EUCCC offer personalised counselling and support services to assist patients and their families in understanding and managing the complexities of cancer care.	
7.1.4.3 The EUCCC provides access to support groups, survivorship programs, and community resources that can offer additional support and information. (CORE)	

7.2 Organisation of Training and Education

Education and training initiatives within EUCCCs foster future scientists and healthcare providers, promote employee development, enhance patient and public knowledge, and facilitate community outreach. Strategic partnerships with educational institutions, other specialised organisations, and leading experts in the field are key to ensuring a comprehensive, high-quality, and contemporary portfolio of educational and training programs.

7.2.1 EUCCCs offer diverse educational formats	
Clarification of the criterion: The EUCCC prioritizes diverse educational formats to accommodate the different learning styles and preferences of healthcare professionals in cancer care. These educational opportunities are accessible, engaging, and tailored to the specific roles and responsibilities of various professionals. Furthermore, EUCCCs regularly assess the effectiveness and impact of their training and education programs, seeking continuous improvement and gathering feedback to enhance their quality and relevance.	
Standards:	**Evidence:**

[21] A person who provides private everyday care to an ill person

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7.2.1.1	The EUCCC offers a comprehensive range of educational activities to meet the diverse learning needs of healthcare professionals and cover all stages of the cancer patient pathway. (CORE)	Examples of: • Workshops, seminars • Online courses • Conferences • Topics
7.2.1.2	The EUCCC evaluates the specific educational needs and competencies required for different professional roles in cancer care and design training programs accordingly.	Examples of channels to report needs.
7.2.1.3	The EUCCC regularly based on peer experts and feedback from participants evaluates their training and education programs to inform improvements.	Written policy and routines to collect data on: • Participations • Participant feedback • Gain in knowledge. • Outcomes

7.2.2 EUCCCs involve patients in education program development

Clarification of the criterion: EUCCCs actively involve patients in shaping education and training programs, ensuring these initiatives are tailored to meet patients' specific needs and provide a patient-centred approach to care.

Standards:		**Evidence:**
7.2.2.1	The EUCCC collaborates with patient associations or advocacy groups to co-create education and training programs, ensuring they are aligned with patients' needs and perspectives. (CORE)	
7.2.2.2	The EUCCC integrates patient-centred principles in their education and training programs, highlighting the significance of shared decision-making and empowering patients in their healthcare journey.	
7.2.2.3	The EUCCC offers training opportunities for healthcare professionals, aiming to improve their communication skills with patients, involve them in treatment planning, and cater to their unique needs and preferences. (CORE)	

7.2.3 EUCCCs foster international learning experiences for relevant staff

Clarification of the criterion: EUCCCs foster international collaboration in education, cancer care and research by participating in undergraduate and postgraduate student exchange, clinical and research staff mobility and international activities to create opportunities for best practice and knowledge exchange.

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Standards:		Evidence:
7.2.3.1	The EUCCC participates in student exchange programs, fellowships, and staff mobility to support international education and training.	
7.2.3.2	The EUCCC engages in a variety of international activities, such as conferences, workshops, research, and meetings, to facilitate knowledge sharing, idea exchange, and collaborative efforts.	

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PART II: Additional information related to Context - Activity - Performance

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Introduction

In addition to the information given through the self-assessment process applying the standards for EUCCCs, providing other and supplementary sets of information is required connected to the certification process.

These types of information and data belong to three categories and here each of them are specified in one chapter.

1) Relevant information and data on the context of a EUCCC
2) Administrative data on the activities and resources of a EUCCC
3) Key data on performance development of a EUCCC

The first category will give provide the necessary contextual understanding of the governmental framing of the cancer centre. The second category is aiming at delivering an image of the volume of activities of the cancer centre. While the reason behind the last of these points connects to one of the main purposes of this certification: contributing to continuous development and improvement of the cancer centre´s capabilities and performance. To assess this as a part of a certification, it is not enough to get a picture of how the situation is at a specific reference year, but it is also important to have data on the performance development on some key indicators over recent years. The requirement for the data on performance development is that they shall cover at least the last five years.

The primary purposes of collecting these additional information are two-fold. First, it is the need of information useful to interpret the self-assessment-based data, to prepare and conduct the on-site audit process not least, the audit interviews, and for the preparation of the improvement plan. The second purpose of the additional information is to leverage its potential for secondary use, providing the EU Net CCC with a tool to monitor the development of the EUCCC eco-system of EU. It will thus supply the EU network of CCCs with a knowledge base that will have huge potential impact on the efforts towards continuous quality development of this network as a community and provide the network with valuable insights supporting its efforts across several of its activities in joint activity areas.

When linked with the EUCCC certification and recertification of centres every fifth year, the emerging data from these additional information will build a database of significant information for the EU Network. The decision on which information to collect under this umbrella will have to balance between adaption and development resulting from experience and acknowledgement of new needs and the convenience of stability to make comparisons over time.

The objective of this database is to describe each EUCCC and its development over time. This information could then be accumulated to make some rough trend descriptions of the status and development the community of EUCCCs. An ambitions of aggregating data across EUCCC requires a joint and precise operationalisation of indicators and a standardization of how they are treated. This is a process that the EUnetCCC may decide to aim at but will certainly not be the situation at the initial phase. The database of EUnetCCC additional information can therefore not be applied directly to compere or rate the EUCCCs based on a common scale.

The data that is expressed through this part of the preparation for audit and certification are both quantitative and qualitative. The methods of analysing the two types of data are different and there will be a need in the analysis to develop to some extent a standardized approach for reading the comprehensive picture of the EUCCC across the contributions from different types of quantitative and

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qualitative data. The need for development of standardized coding of data is present in relation to both types of data.

The application and analysis of the joint additional information and data can either be based on an approach where these data are stored in the joint data repository or the information and data could be stored at each centre or delivered from each EUCCC upon request connected to specified purposes or projects. If the latter is the case, some standardized common requirement should be expressed regarding the storage of these data.

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1 Contextual information

1.1 Information regarding national cancer policy affecting the EUCCC

Policy areas: Are there specific areas given national political attention regarding cancer care and research with impact on the EUCCC? If yes, which?
Policy measures: By which measures are the national cancer policies being implemented at the EUCCC? (A national cancer strategy, national cancer control plan, specific cancer policy initiatives and more)
The role of the EUCCC in national cancer policy Is the EUCCC involved in the development and decision of national cancer policies?
Specify:
Supportive documents:

1.2 Information regarding the overall organizational framing of the EUCCC

What type of EUCCC is your centre (just one alternative): • A cancer care hospital limited to treating cancer • A centre specialized in oncology, but not limited to it • An integrated part of a general hospital / university hospital • An integrated part of a general hospital / university hospital but supplemented with formally agreement with other hospital(s) /institute(s) on specified areas where the first have deficiencies • A collaborative consortium of several legally separate hospital and/or research units • Other constructions
Specify:
Supportive documents:

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1.3 Information on ownership of the institution(s) constituting the EUCCC

Ownership structure ▪ Who is the owner(s) of the institution(s) constituting the EUCCC ▪ How is the ownership organized in levels and in decision processes
Relationship ownership and funding How is the relation between external funding/budgeting and ownership specifically
External governance mechanisms What are the governing mechanisms of the ownership towards the institution(s) comprising the centre? (Board-meetings, assignments, policy statements, monitoring mechanisms and so on)
Specify:
Supportive documents:

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1.4 Information regarding the catchment area of the EUCCC

Rules specifying a catchment areas for the EUCCC (Each question to be answered. Specify and add documents below if needed) ▪ Are specific catchment areas defined? ▪ Are there any specific rules for the referral of the patients in general to specific hospitals? For cancer patients specifically? ▪ Does a system for referral and catchment area also include the definition of a secondary level (regional) for referral in cancer care? ▪ Does patients outside the catchment area also have access to the EUCCC? If yes, on which premises?
Proportions of cancer patients from primary catchment area ▪ What is the percentage of new cancer patients that comes from the primary catchment area of the centre (if such an area is defined)
Characteristics of catchment area Is the main catchment area ▪ Urban or rural ▪ Covering short or long distances ▪ Covering the same area as a defined governmental administrative district ▪ Having considerable parts of its population not being citizens of the country or the regional district
The type of regulations on referral to the EUCCC? ▪ Which kind of regulations influence the flow of patients to the hospital? If yes, what kind of rules/regulations? ▪ By whom are this kind of regulations given?
Specify:
Supportive documents:

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1.5 Information regarding principles and processes for financing and reimbursement

The sources of financing the EUCCC ▪ What is the main financial source of the EUCCC (governmental budgets (on local, regional or national level), insurance institutions (publicly or privately owned)) ▪ What is the requirement for out of pocket payment for cancer patients at the EUCCC? ▪ The relative size of funding based on private donations?
Budgeting mechanisms ▪ Which external funding bodies decide the budget framework of the centre /hospital ▪ Specifically, how is the framework for investment decisions structured? ▪ How is the budgeting process regarding coordinating and aligning budgetary decisions between interdependent units in the EUCCC
Funding sources for cancer research ▪ Professional associations ▪ Ministries of health ▪ Ministries of research ▪ National or regional research councils ▪ Cancer Unions ▪ Private donations (competitive and not competitive grants) ▪ Other external research funding sources ▪ European commission ▪ Others
Specify:
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1.6 Information regarding the structure of shared patient pathways involving other health or social institutions

Structuring of joint pathways with other hospitals Describe the formal collaboration and coordination with other hospitals that are not a part of the EUCCC but are sharing patients pathways for groups of patients with to some extent overlapping catchment areas
Categories of cooperation in networks of shared patient pathways ▪ Shared standard operating procedures (SOPs) ▪ Consultation second opinion ▪ Tumour board ▪ Staff with shared affiliation ▪ Collaboration on vocational education and training ▪ Joint clinical trial activities ▪ Joint clinical ICT systems ▪ Joint cancer registries
Structuring of collaboration with health care outside the hospitals Describe the: ▪ Formal collaboration with institutions representing cancer prevention and screening ▪ Formal collaboration with home care organizations ▪ Formal collaboration and coordination with general practitioners ▪ Formal collaboration and coordination with nursing homes ▪ Formal collaboration and coordination with palliative care institutions and hospices
Specify:
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1.7 Certification and accreditation on activity areas related to cancer

National quality certification Is the EUCCC have quality certification(s) and/or accreditation(s) with National Accreditation bodies? If yes: ▪ On which parts of its activities? ▪ What is the purpose? ▪ Is it statutory or voluntary? ▪ How is the audit process conducted? ▪ Who is the accreditation/ certifying bodies?
International quality certification Is the EUCCC have quality certification(s) and/or accreditation(s) with International Accreditation bodies? If yes: ▪ On which parts of its activities? ▪ What is the purpose? ▪ How is the audit process conducted? ▪ Who is the accreditation/ certifying bodies?
Specify:
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1.8 Audits conducted on areas not covered by certification/accreditation

Internal quality related audits Do the EUCCC perform internal audits on clinical procedures? If yeas: ▪ How are relevant audits organized? ▪ Specifically: Are the audits managed by the coordinating body of the CCC or by the hospital(s) that the EUCCC is embedded into? ▪ Are they based on documented routines? ▪ Which areas do they cover? ▪ Are there any quality audits specifically regarding research?
Internal quality related audits Are the EUCCC subject to audits by some supervisory authorities? ▪ Which authorities might this be? ▪ Which areas might be covered by such audits? ▪ Do such audits have a legal bases? ▪ Are they conducted at some kind of regularity or connected to specific cases? ▪ How might such audits be organized?
Specify:
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1.9 The contextual structure of research

Collaborating structure for cancer related research Describe the relation between the EUCCC and relevant related research institutions not being a part of the CCC - through these points: ▪ Which institutions do the EUCCC have partnerships with on this topic? ▪ What is the main role and contribution of the EUCCC into this partnership and vice versa? ▪ How is this partnership organized? ▪ What is the main national principles of research organization? ▪ Other relevant information regarding external collaboration related to prevention?
Specify:
Supportive documents:

1.10 The contextual structure of prevention

Collaborating structure for cancer prevention Describe the relation between the EUCCC and relevant institutions with a role related to cancer prevention (but not being a part of the CCC) through these points: ▪ Which institutions do the EUCCC have partnerships with? ▪ What is the main contribution of the EUCCC into this partnership and vice versa? ▪ How is this partnership organized? ▪ What is the main national principles of organization of cancer prevention? ▪ Other relevant information regarding external collaboration related to prevention?
Specify:
Supportive documents:

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1.10 The contextual structure of education and training

Collaborative relations regarding cancer related education and training Describe the relation between the EUCCC and relevant institutions with a role in cancer related education and training (but not being a part of the CCC) through these points: ▪ Which institutions do the EUCCC have partnerships with? ▪ What is the main contribution of the EUCCC into this partnership and vice versa? ▪ How is this partnership organized? ▪ What is the main national principles of organization of cancer related education and training? ▪ Other relevant information regarding external collaboration related to prevention?
Specify:
Supportive documents:

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1.11 The contextual structure of innovation

Collaborative relations regarding cancer related innovation Describe the relation between the EUCCC and relevant institutions with a role related to innovation with relevance to cancer (but not being a part of the CCC) through these points: ▪ Which institutions do the EUCCC have partnerships with? ▪ What is the main contribution of the EUCCC into this partnership and vice versa? ▪ How is this partnership organized? ▪ What is the main national principles of organization of innovation? ▪ Other relevant information regarding external collaboration related to prevention?
Specify:
Supportive documents:

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2 Administrative information – activity of the centre

2.1 Cancer related activity

Key figures on patient numbers (total numbers and on specific diagnoses) ▪ Number of cancer patients: all cancer patients seen or treated in the year Specifically: Number of cancer patients in treatment ▪ Number of new cancer patients (cancer patients newly treated in the year) ▪ Number of new cancer patients divided into localized, advanced and metastatic disease ▪ Age profile of new cancer patients ▪ Number of patients discussed in MDT meetings/year ▪ Proportion of cancer patients discussed in MDT meetings
Specify:
Supportive documents:

2.2 Capacity of cancer treatment

Estimated numbers of strategic facilities available for cancer patients (rough estimates) ▪ Number of beds available for cancer patients ▪ Number of chairs for systemic therapies ▪ Number of operation theatres (in terms of infrastructures) ▪ Number of outpatients consultations ▪ Share of outpatient consultations performed through telemedicine solutions
Specify:
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2.3 Available technical resources and infrastructures for cancer patients

Specialized treatment technology available ▪ Number of radiation therapy units (linear accelerators, Cobalt-60 units, Caesium-137 therapy units, low to orthovoltage x-ray units, high dose and low dose rate brachytherapy units and conventional brachytherapy units) ▪ Number of operations theatres equipped for robotic surgical ▪ Presence of a cell therapy unit in the EUCCC
Diagnostic technology ▪ Number of CT scans (available machines for cancer patients) ▪ Number of MRIs (available machines for cancer patients) ▪ Number of PET scans (available machines for cancer patients) ▪ Equipment for molecular analysis (specify type of gene-panel)
Specify:
Supportive documents:

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2.4 Relevant ICT applications

Data application for primary use Does the EUCCC have integrated clinical data applications that in an automated way create consolidated patient information through automated processes Does the EUCCC have an in-house ICT support unit that is a partner for clinicians in managing and adapting the relevant ICT applications for primary use?
Facilities for secondary use of data ▪ Is a data-warehouse solution available and applied for cancer data ▪ Does the EUCCC have a ICT system that facilitates RWD based analysis for quality or research purposes ▪ Is there a data application supporting establishment and management of local cancer registries ▪ Is AI technology applied for diagnostic purposes regarding pathology or radiology Does the EUCCC have an in-house ICT support unit that is a partner for clinicians, managers and researchers in managing and adapting the relevant ICT applications for secondary use?
Specify:
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2.5 Key indicators for cancer research activity

<table>
<tr><td colspan="2">Clinical and care related research activity

Number of cancer patients included in clinical trials and number of active studies:

• Interventional trials
  ○ Phase I
  ○ Phase II
  ○ Phase III
• Prevention studies
• Cohort studies
• Observational studies
• Health services studies</td></tr>
<tr><td>Number of patients</td><td>Number of studies</td></tr>
<tr><td colspan="2">Human resources engaged in research

▪ Number of FTE dedicated to cancer research (roughly estimates)
▪ List of cancer related research group in the hospital or predominantly in the hospital</td></tr>
<tr><td colspan="2">Research programs

List of 10 major research programs/projects connected to the EUCCC with specification of the role of the centre</td></tr>
<tr><td colspan="2">External partnership

Partnerships with companies, public agencies or NGOs related to research and innovation about cancer</td></tr>
<tr><td colspan="2">Publications

Number of publications related to cancer with an author from the EUCCC</td></tr>
<tr><td colspan="2">Dissertations

Number of dissertations related to cancer</td></tr>
<tr><td colspan="2">Specify:</td></tr>
<tr><td colspan="2">Supportive documents:</td></tr>
</table>

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2.6 Key budgetary figures for cancer related activities

Financial spending for the reference year – rough estimates in euro: • Annual budget for the total activities in the EUCCC • Annual budget for cancer related research – specified into internal and external sources • Annual budgets for vocational education and training (direct costs only) • Annual budget for investment in technical equipment applied in cancer treatment and research
Specify:
Supportive documents:

2.7 Available human resources

Estimates on FTE MD specialized on cancer (residents not included) ▪ Medical oncologists ▪ Surgical oncologists ▪ Oncological radiotherapists ▪ Haematologists ▪ Paediatric MD specialised on cancer ▪ Pathologists ▪ Radiologists
Nurses specialized on cancer related areas ▪ Cancer nurses ▪ Other cancer related specialities
Specialists in specific relevant areas ▪ General practitioner with an oncology expertise ▪ Nutrition specialists on cancer ▪ Rehabilitation specialists ▪ Onco-psychiatric specialists ▪ Onco-sexologists ▪ Others (specify)
Supportive documents:

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2.8 Vocational education and training for relevant professions on relevant topics

Vocational education and training - MDs Number of doctors of medicine in training in oncology Number of doctors of medicine in training in sub-specialities (like palliative care, onco-psychiatric care and others) Number of University Professors and lecturers in medicine at the EUCCC on oncology
Vocational education and training - nurses Number of nurses in education and training specializing in cancer care Number of nurses in education and training programs sepcilzing in other areas with relevance for cancer care Number of University Professors and lecturers in nursing at the EUCCC related to cancer
Vocational education and training – other professions Number of employees in such groups in programs specialized in cancer related topics? (Specify which professions and which topics) Number of University Professors and lecturers in other professions at the EUCCC related to cancer
PhD students Number of PhD students on cancer topics
Specify:
Supportive documents:

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3 Information on performance developments

3.1 Key processes quality indicators of care

Patient pathways ▪ Share of patients satisfying the requirement set for maximum waiting time until start treatment (if such requirement exist on EUCCC or national level) – for all cancers and for the major cancers diagnoses specifically ▪ Share of patients following a standardized documented treatment program ▪ Share of patients offered a pre-habilitation program ▪ Share of patients offered a personalized survivorship plan ▪ Development in key indicators from patient reported experience measures (if PREM data exist)
Patient safety ▪ Number of not planned patient readmissions ▪ Number of deviation reported to public authorities ▪ Number of treatments that have led to complications that has affected patient´s safety
Specify:
Supportive documents:

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3.2 Key research and innovation quality indicators

Patents Number of patents over the last 5 years
Publications Number of publications where the EUCCC has the lead author Number of publications with IF>10
Clinical studies Number of clinical studies with Principal Investigator from the EUCCC Number of clinical studies with international participation
Specify:
Supportive documents:

3.3 Outcomes of cancer treatment

Survival rates for patients receiving their main treatment at the EUCCC 1-year Overall Survival/Net survival 5-years Overall Survival/Net survival
Mortality rates
Patient reported outcome (PROMS) Developments in key indicators from PROMS
Back to work Share of patients (in relevant age-groups) that has completed curative treatment and is back in full time work

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PART III: Certification process

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Table of illustration

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This document is the result of the work executed in the Work Package 7 of the Joint Action CraNE. It encompasses an overview of a suggested certification process for the future EU CCC Certification Program. This deliverable also presents suggested roles, both within the Applicant Centre and the Certification Organisation. These are described as either decisive, leading, managing, operational or administrative roles.

It is to be noted that all the information detailed in this document are (1) functional and directly related to the processes identified in the Work Package 7 of CraNE and (2) subjected to the final alignment with the legal framework and the operationalization of the Joint Action's scheme.

I. Overview of the certification process

The complete certification process is organized into 5 main parts, and punctuated by 4 checkpoints, which the Applicant Centre will mandatorily need to go through and validate, prior to accessing the following steps of the process. The overview organisation of the certification process is represented in *Figure I-1,* also in appendix.

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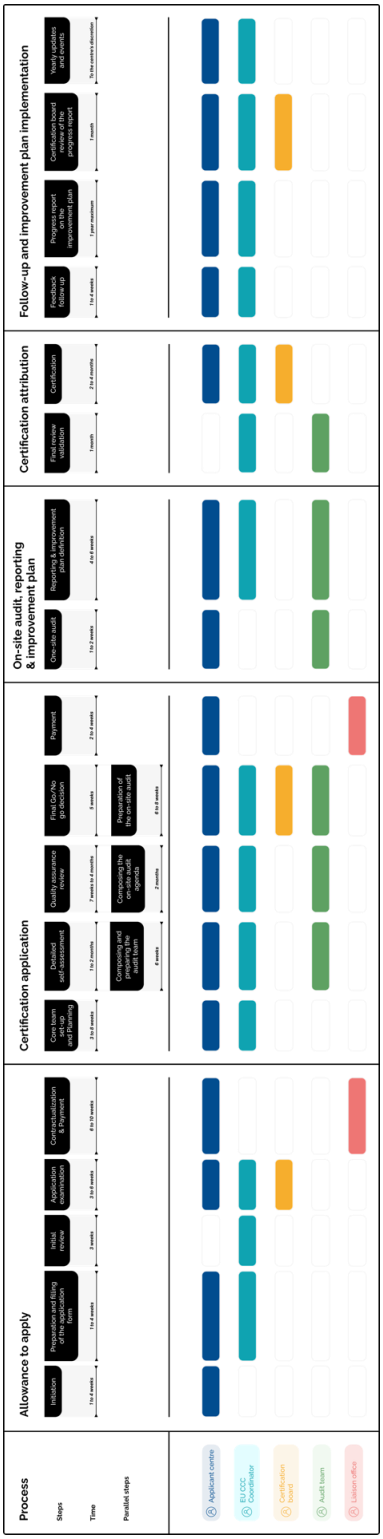

Figure I-1 - Overview organisation of the complete Certification Application Process

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3.1 Allowance to apply

This first part of the Certification Process is key to ensure the centre's readiness to undergo the complete Certification Process.

On the one hand, we need to provide the Applicant Centre with all the information it needs to complete the certification process: this is a real project launch, so the centre needs to make sure it has the availability and resources it needs to complete it successfully.

On the other hand, the aim is to assess the centre's ability and readiness to undergo the full Certification Process, and therefore its chances of obtaining certification. The EU CCC Certification Program Coordinator and Certification Board carries an initial review and examination of the Centre's application before allowing them to move on with the rest of the process.

The Certification Board's resulting decision from the application examination is the first checkpoint the centre should go through.

The criteria for the evaluation of the application form during the initial review will be refined in the Joint Action EU Net CCC.

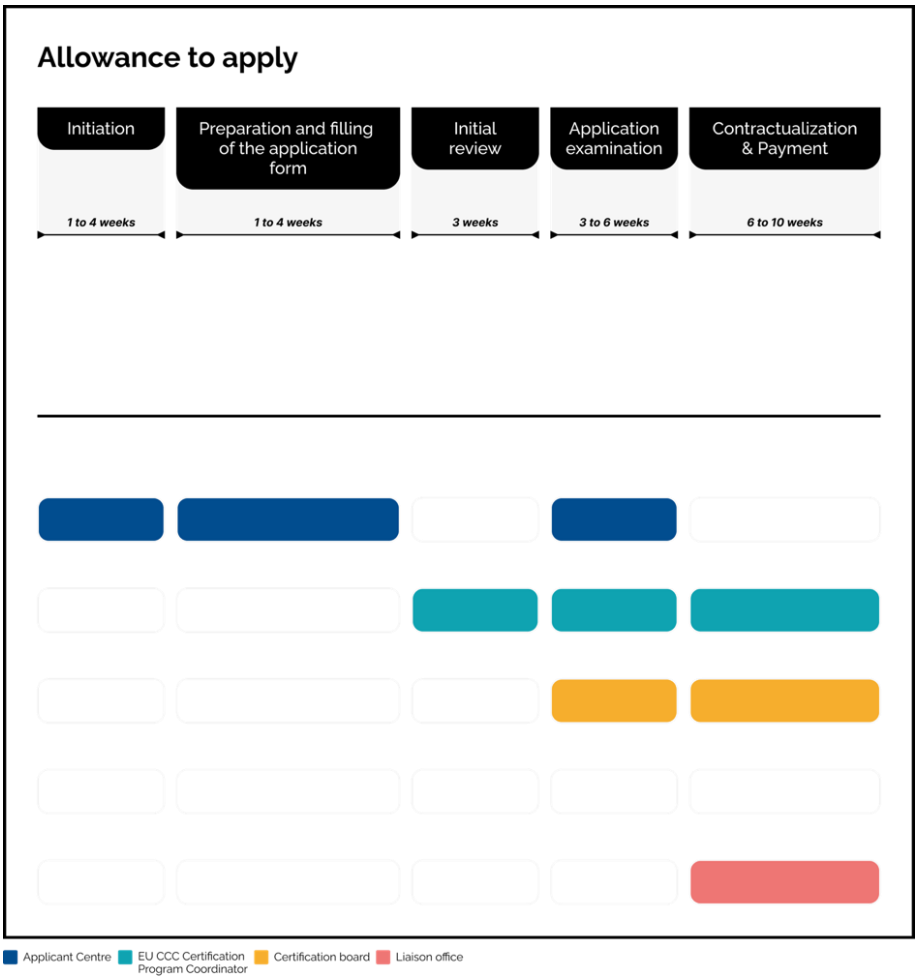

Figure I-2 - Allowance to apply

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3.2 Certification application

This second part of the Certification Process is the longest one, especially for the Applicant Centre.

In the first part, the Applicant Centre will need to focus on its group planning and completion of the self-assessment. Then, the centre will go through and benefit from a quality assurance review with the EU CCC Certification Program Coordinator and Chairperson of the Audit team, before submitting their finalized self-assessment for the Certification Board.

The EU CCC Certification Program Coordinator's quality assurance review and the associated advice will be mandatory and represent the second checkpoint the centre should go through.

The criteria of assessment for the quality assurance review will be refined in the Joint Action EU Net CCC.

The Certification Board's approval or rejection of the self-assessment, expressed as a "go" or a "no-go" decision, will be mandatory and is the third checkpoint the centre should go through.

The scoring model for the evaluation of the Applicant Centre's self-assessment during the application examination will be refined in the Joint Action EU Net CCC.

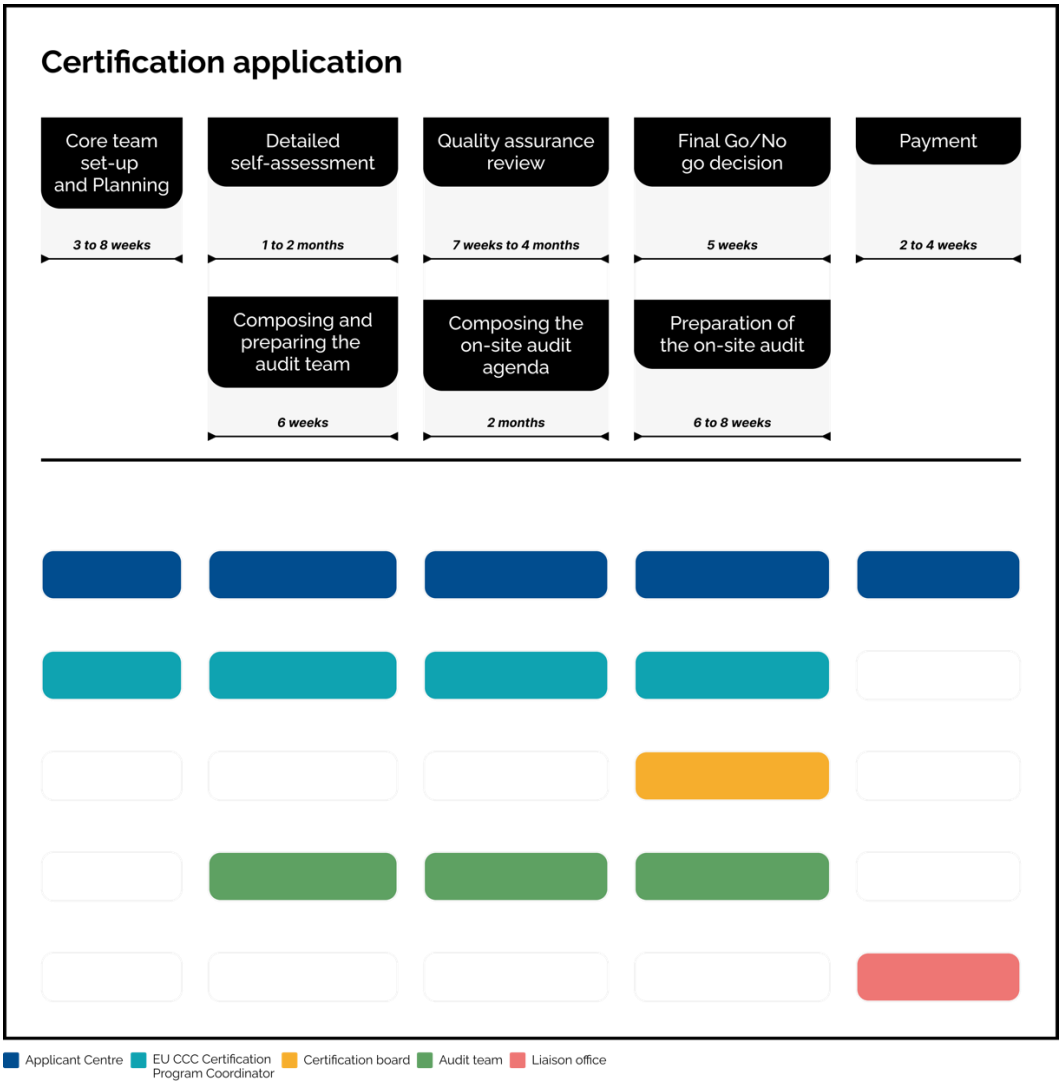

Figure I-3 - Certification Application

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3.3 On-site audit, reporting and improvement plan

This third part of the Certification process first focuses on the interactions between the Applicant Centre and the Audit Team during the execution of the on-site audit Then, the EU CCC Certification Program Coordinator will interact with the Audit Team and the Applicant Centre separately to work and finalize the on-site audit report and resulting improvement plan.

3.4 Certification

This fourth part of the Certification is dedicated to the final decision-making process of the Certification Board. In this part, they will evaluate the Applicant Centre's final report and improvement plan, and therefore decide to approve or reject the Centre's application for the EU CCC Certification.

The Certification Board's approval or rejection of the centre's application through this final review validation is the fourth and last checkpoint the centre should go through.

The audit evaluation grid for the on-site audit, and Certification Board's final review validation criteria, will be refined in the Joint Action EU Net CCC.

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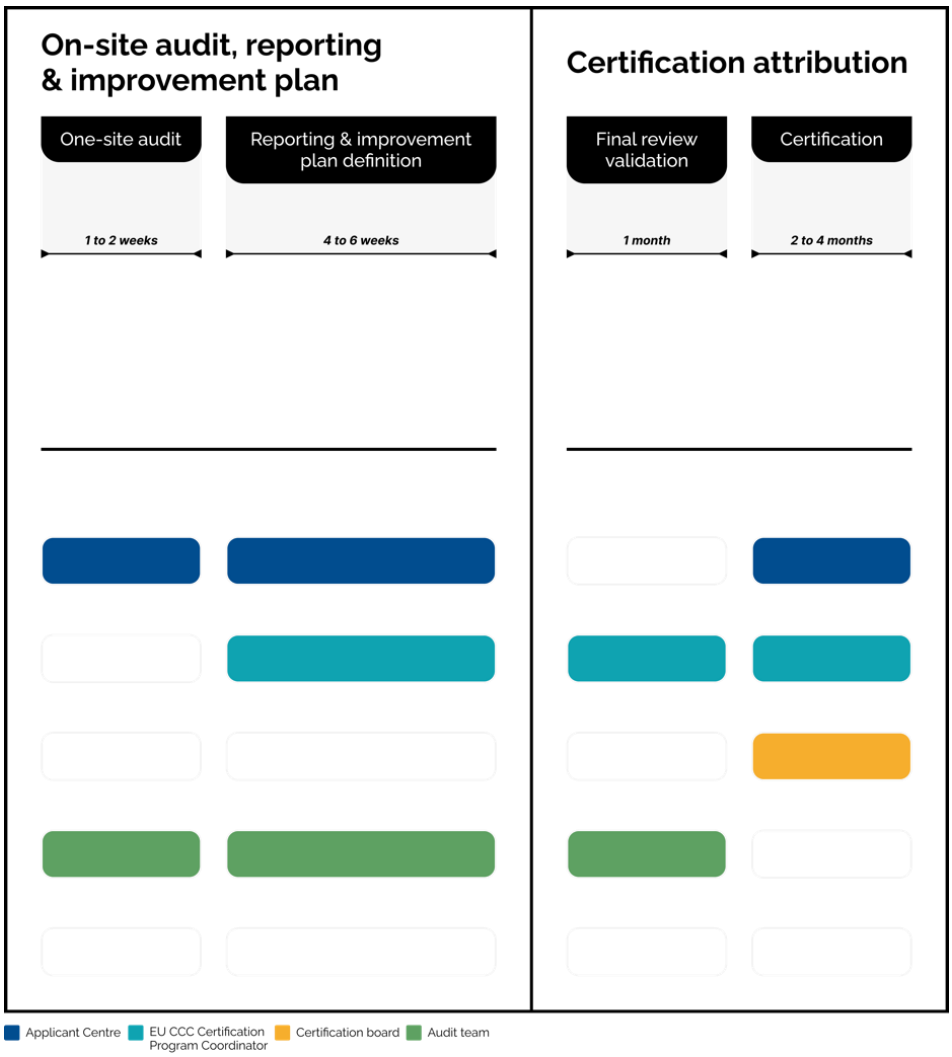

Figure I-4 - On-site audit, reporting, improvement plan and certification attribution

3.5 Follow-up and improvement plan implementation

In this fifth and last part of the Certification Process, the focus is put on the continuous quality improvement, both on the Certification Organisation's side, and the Centre's. In this regard, the now Certified Centre will be asked to provide feedback on their experience of Certification, before initiating the work of implementation of their improvement plan. The Certified Centre will need to go through a progress review 12 months after their certification obtention and will later be requested to submit an annual report, highlighting their potential improvements, innovations and research projects.

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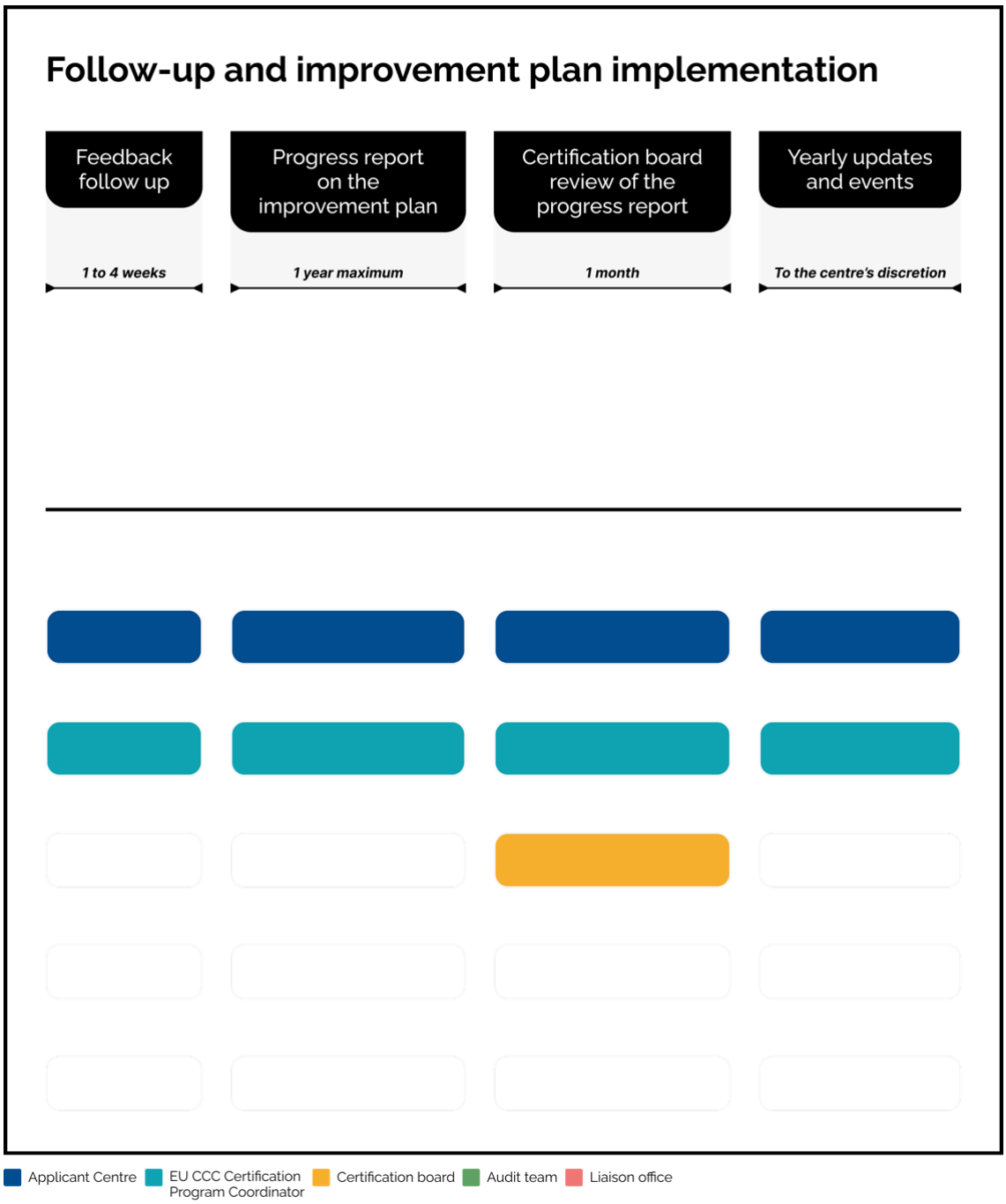

Figure I-5 - Follow-up and improvement plan implementation

II. Roles in the Certification Process

The suggested processes developed display several contributors, each with specific roles and responsibilities. It is to be noted that these descriptions are functional and directly related to the processes identified in the Work Package 7 of CraNE. These roles, as well as the processes, will be subjected to the final alignment with the legal framework and the operationalization of the Joint Action's scheme.

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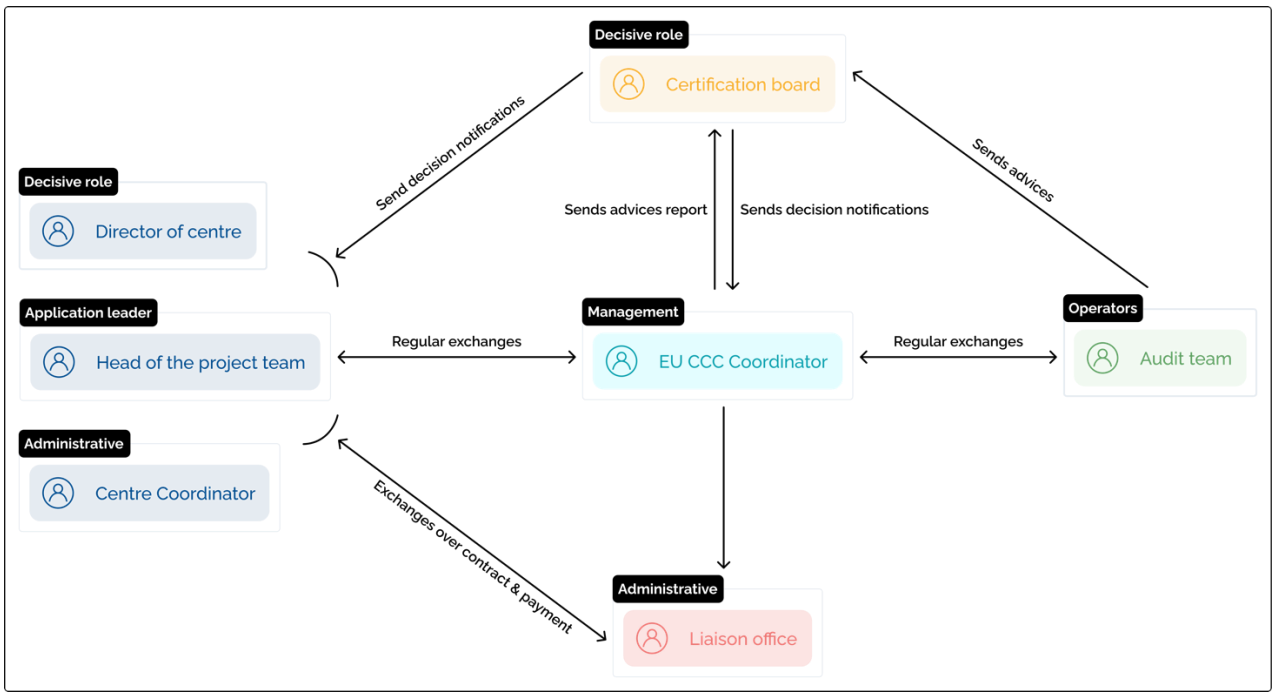

Figure II-1- Global mapping of the roles in the Certification Process

3.6 The Applicant Centre

The Applicant Centre can be a single legal entity or a combination of entities, applying for the 1st time or asking for the renewal of the certification. Within the Applicant Centre, four specific users were identified:

1. The Director(s) of the centre(s) or institute(s)
2. The Head of the Project team.
3. The members of the Project team.
4. The Centre Coordinator.

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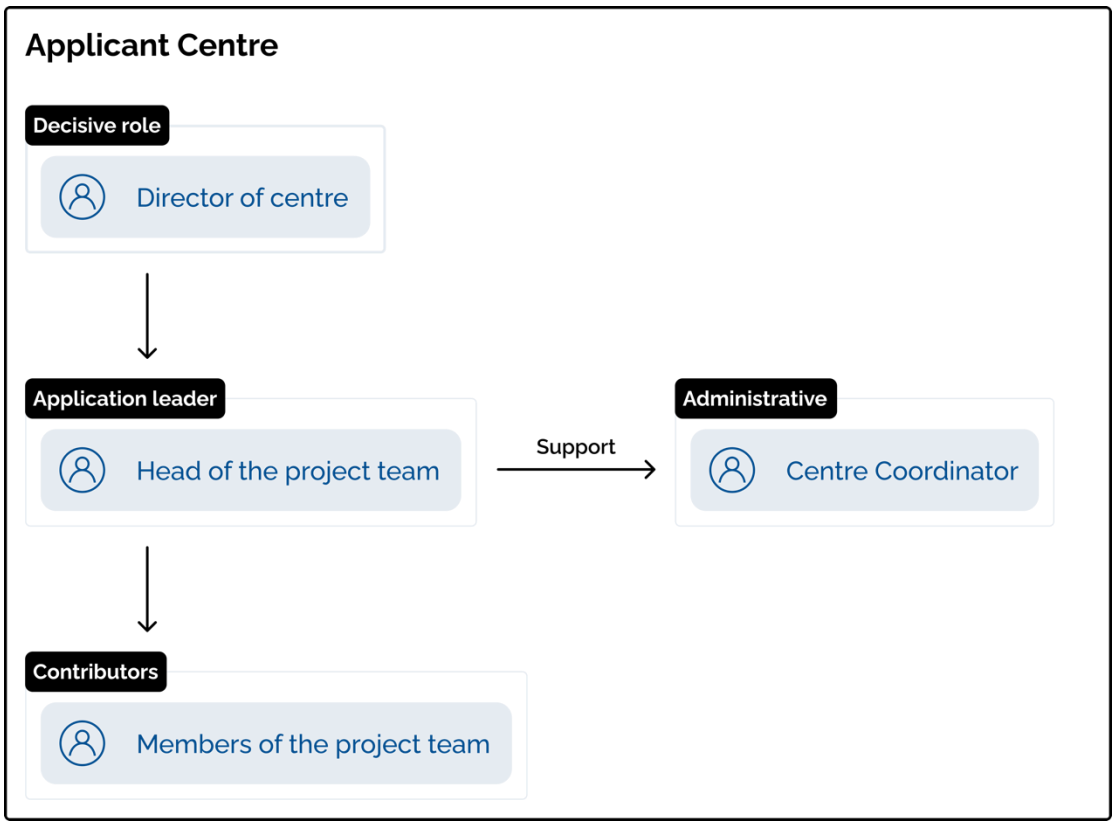

Figure II-2- Suggested user mapping of the Applicant Centre

3.6.1 The Director of the centre or institute – *Decisive role*

Within the EU Net CCC Organisation, the centres may decide to constitute a CCC with a single or a combined legal entity. In this regard, there can be one or several directors for the CCC. The role, whether it is a single legal entity or a combination, will hereby be mentioned as 'the Director of the centre'.

The role of the Director of the centre is thought as a decisive role. They will have responsibilities regarding the decisions taken by and for the centre's application and the nomination of the Head of the Project team. The Director of the centre will also receive all the decisions issued by the Certification Board.

3.6.2 Project team

The Project team gathers all the contributors to the certification application, especially for the completion of the self-assessment and the on-site audit. It is composed of a leader (i.e. the Head of the Project team), and contributors with different levels of responsibility and required involvement (i.e. the members of the Core team and members of the extended final Project team).

3.6.3 Head of the Project team – *Application leader*

The Head of the Project team should be designated by the Director of the centre/institute in the early stages of the processes. The Head of the Project team should be identified as the leader of the certification process in the centre and will:

- Be involved in the composition of the Project team.

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- Be responsible for the overview of meeting schedules, project planning and methodology to implement within the centre for the certification process.
- Be responsible for the overview of the on-site audit, its preparation and the relation and communication with the audit team.
- Be one of the main contacts for the Certification Board throughout the process.

3.6.4 Members of the Project team – *Contributing role*

As mentioned above, the members of the Project team can either be included in the Core team, or in the extended final Project team, depending on the expected level of involvement that is requested from them.

Therefore, the Project team is composed in two stages as follows:

Stage #1: Composition of the Core team which intervenes at the beginning of the certification process, once the centre passed the application examination and received the notification of approval to undergo the full certification process. This Core team should be composed 4-5 people, **leading the certification process and its coordination** with the Head of the Project team. They will be appointed by the Director of the centre and the Head of the Project team. They will be recognized as highly knowledgeable on the centre's activities, and key personnel to contact and refer to obtain essential information for filling out the application.

Stage #2: Completion of the Project team (i.e. final Project team) which intervenes after the quality assurance review and before the finalisation of the self-assessment. These remaining members of the Project team should **respond to the on-site audit's requirements** and involve people who will be able to and should **contribute to the completion of the self-assessment and to the on-site audit.**

3.6.5 Centre Coordinator – *Administrative role*

The Centre Coordinator with its administrative and supportive role, will be one the first ones involved in the certification process. The Centre Coordinator will be responsible for:

- The interactions with the EU CCC Certification Program Coordinator regarding email exchanges and planning.
- Supporting the Head of the Project team in the planning and progress monitoring of the certification process.
- Completing the administrative parts of the process.
- Gathering of supporting evidence.

3.7 The Certification Organisation

The following roles have been defined as part of what could be the Certification Organisation of EU Net CCC. The goal is to present the decisive, managing, operating and administrative roles within the organisation, and the way they should interact in the certification process. Regardless, all the roles will be reviewed and refined in the next Joint Action EU Net CCC.

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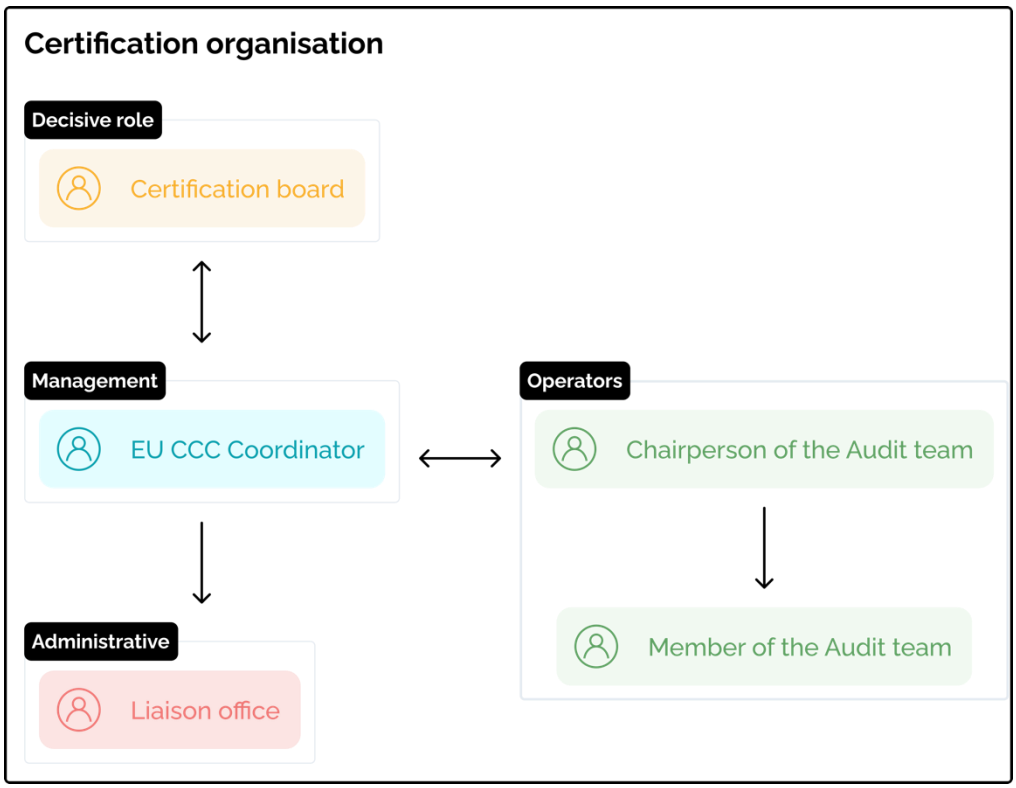

Figure II-3- Suggested user mapping of the Certification Organisation

3.7.1 The Certification Board – *Decisive role*

The Certification Board as a decisive role in the certification process and intervenes as an evaluator and is responsible for the final decisions in the four checkpoints of the process.

In addition, the Certification Board, through their chairperson, will communicate their decisions to the Director of the centre, the Head of the Project team, and the EU CCC Certification Program Coordinator.

3.7.2 The EU CCC Certification Program Coordinator – *Managing role*

The EU CCC Certification Program Coordinator exercises its role through the Joint Action. They are the main contact for the Applicant Centre and all the other contributors. They represent the main link in the exchanges and information transmission of all the acting contributors. All the information regarding the Applicant Centre's certification process will translate through them.

3.7.3 The Audit Team – Operational role

The audit team and their chairperson are certification operators. They will have several interactions with the EU CCC Certification Program Coordinator and the Applicant Centre throughout the certification process, in addition to the preparation and execution of the peer-reviewed on-site audit.

3.7.3.1 Chairperson of the audit team

The chairperson of the audit team has more responsibilities in the certification process. The chairperson of the audit team:

- Must validate or invalidate the on-site audit report.
- Is responsible for the management and organisation of the on-site audit, in relation with the coordinator and the Head of the Project team.

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- Will be required to follow a training program to exercise this role.

3.7.3.2 Members of the Audit team

The members of the Audit team will be solicited for the on-site audit and its preparation. They will:

- Have direct interactions with their Chairperson.
- Have access to documents and data provided by the centre before the on-site audit.
- Contribute to the drafting of the on-site audit report.
- Be required to follow a training program to exercise this role.

3.7.4 The Liaison Office – *Administrative role*

The Liaison Office should intervene in the payment and contractualization steps of the certification process. This role is purely administrative and has most of its interactions with the EU CCC Certification Program Coordinator and the Applicant Centre.

III. Detail of the certification process

3.8 Step 1: Initiation

~ Estimated execution time: to centre's discretion ~

In this step, the Applicant Centre discovers information about the EU CCC Certification and its certification process. **All the information material is publicly available in the EU Net CCC website.**

In this step the centre will also create their first account on the e-tool and complete their profile.

This step is mostly administrative and technical and does not involve any interactions, since it is to be executed to the centre's discretion.

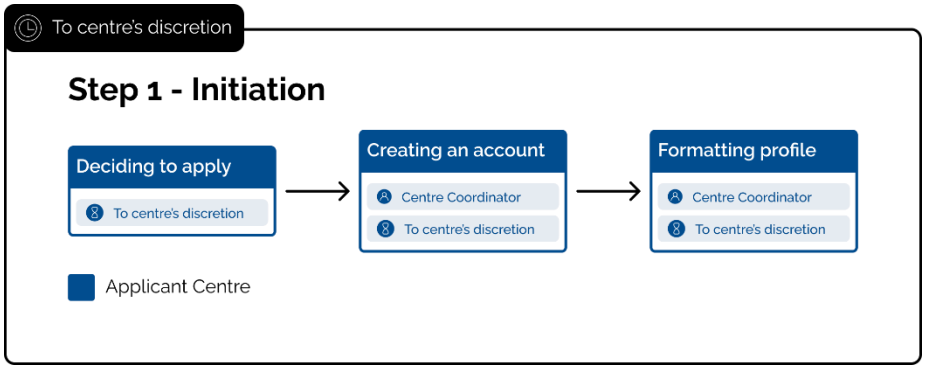

Figure III-1 - Step 1: Initiation

Deciding to apply	
Applicant Centre	To centre's discretion
The Applicant Centre may find general information on the application in the EU CCC Certification Program's website. *[Insert exact link once created]*	

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The below mentioned material information should be publicly available in the EU Net CCC website:

- Description of the certification process and what it means to be a certified CCC.
- Complete list of criteria and standards.
- Requested additional information.
- Glossary.
- Obligations for the centre (i.e. the general contract to be signed if certified).

Creating an account	
Centre Coordinator	To centre's discretion
The Centre Coordinator can access the EU CCC Certification Program e-tool by following path *[insert exact link once created]* The Centre Coordinator will receive a confirmation e-mail to activate their account and access their profile in the e-tool.	

Formatting profile	
Centre Coordinator	To centre's discretion
The Centre Coordinator now has access to the EU CCC Certification Program e-tool. The e-tool should allow the Applicant Centre to follow their advancement in the certification process, to complete their administrative and technical information, to upload documents, to consult useful templates based on the process step they are currently following and to find help when needed.	

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3.9 Step 2: Preparation and filling of the application form

~ Estimated execution time: 1 to 4 weeks ~

Here, the Applicant Centre will complete its application form and finalize it before submitting it to the EU CCC Certification Program Coordinator.

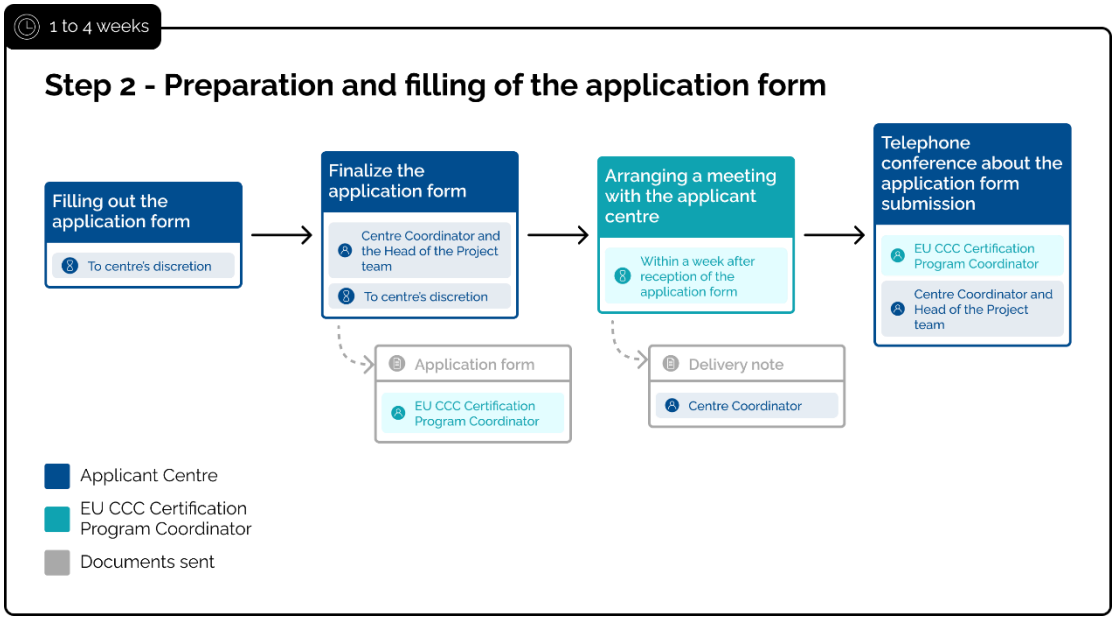

Figure III-2- Step 2: Preparation and filling of the application form

Filling out the application form	
Centre Coordinator and Head of the Project team	To centre's discretion
The Centre Coordinator starts completing the application form on the EU CCC Certification Program e-tool. *The questions, mandatory information and required documents to provide are yet to be determined.*	

Finalize the application form	
Centre Coordinator and Head of the Project team	To centre's discretion
Once the centre finalized the application form, the Centre Coordinator will validate it on the e-tool. Before validation, the Applicant Centre should verify that: • All questions have been answered. • All mandatory documents have been added to the application form.	

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The application form will be automatically submitted to the EU CCC Certification Program Coordinator.
Application form: *sent through the e-tool, from the* Centre Coordinator *to the EU CCC Certification Program Coordinator*

Arranging a meeting with the Applicant Centre	
EU CCC Certification Program Coordinator	Within a week after reception of the application form
Upon reception of the centre's application form, the EU CCC Certification Program Coordinator will send a delivery note to the Centre Coordinator. In addition, the EU CCC Certification Coordinator will arrange a telephone call with the Applicant Centre to ensure they have properly understood the goal of the application form and have properly completed it before submission.	
Delivery note: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the* Centre Coordinator.	
Email exchange and planning: *from the EU CCC Certification Program Coordinator to the* Centre Coordinator	

Telephone conference about the application form submission
EU CCC Certification Program Coordinator, Centre Coordinator and Head of the Project team of the Applicant Centre
The EU CCC Certification Program Coordinator, the Centre Coordinator and the Head of the Project team participate in a call to validate the submission of the application form. This telephone call is mandatory as it will ensure that the EU CCC Certification Program Coordinator does not review application forms that do not meet the requested format and minimum requirements of completion.

3.10 Step 3: Initial review

~ Estimated execution time: 3 weeks ~

The initial review of the application form is used to evaluate the readiness of the centre for full accomplishment of the certification process. It allows the EU CCC Certification Program Coordinator to identify the gaps the Applicant Centre faces to meet the initial requirements.

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The initial review can either be positive or negative. In both cases, the EU CCC Certification Program Coordinator will issue an advice and a report for the Certification Board.

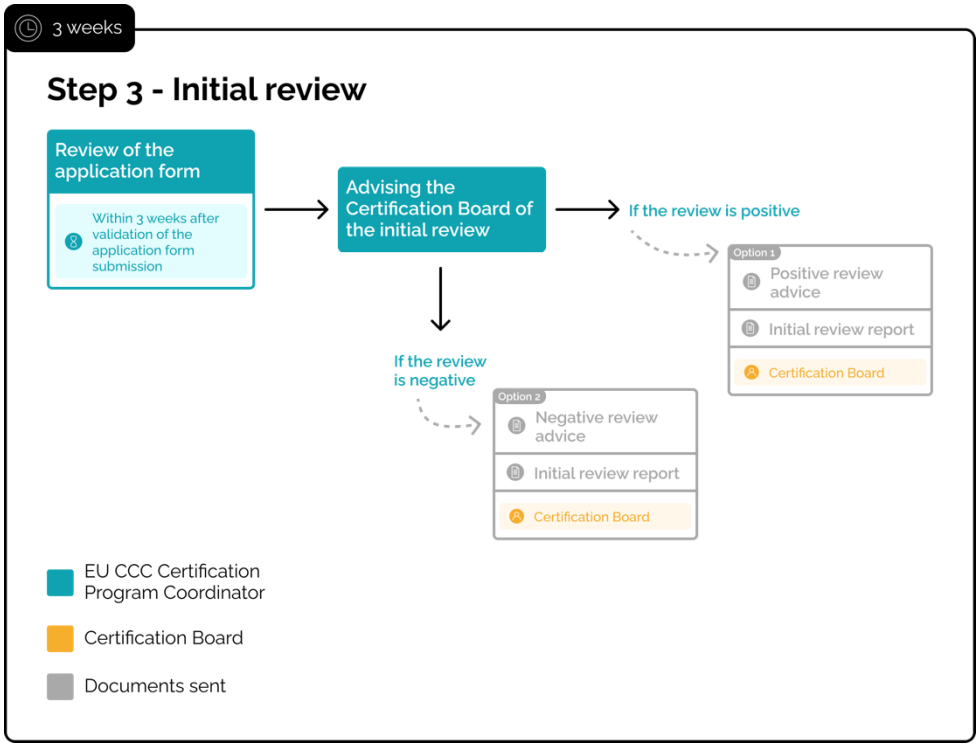

Figure III-3 - Step 3: Initial review

Review of the application form	
EU CCC Certification Program Coordinator	Within 3 weeks after validation of the application form submission

The EU CCC Certification Program Coordinator reviews the application form to evaluate the readiness of the centre for full accomplishment of the certification process. This step is meant to allow the coordinator to identify the gaps the centre faces to meet the initial requirements.

Option 1: The review is positive

If the initial review of the application form is positive, it means that the Applicant Centre's meets the initial requirements to undergo the full certification process.

Option 2: The review is negative

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If the initial review of the application form is negative, it means that the Applicant Centre's is yet to meet some of the requirements to undergo the full certification process.

Advising the Certification Board of the initial review
EU CCC Certification Program Coordinator
Depending on the outcome of the initial review, the EU CCC Certification Program Coordinator will notify and advise the Certification Board with an initial review report and either a positive review advice (*option 1*) or a negative review advice (*option 2*).
Initial review report: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
Option 1: • ***Positive review advice:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
Option 2: • ***Negative review advice:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

3.11 Step 4: Application examination

~ Estimated execution time: 3 to 6 weeks ~

Based on the elements the Certification board received from the EU CCC Certification Program Coordinator, they will either approve or reject the Applicant Centre's application.

Then, the EU CCC Certification Program Coordinator will write a notification for the Centre Coordinator and discuss the results over a telephone conference with them.

This call should also be used to discuss the improvements the Applicant Centre needs to make to be able to successfully complete the process.

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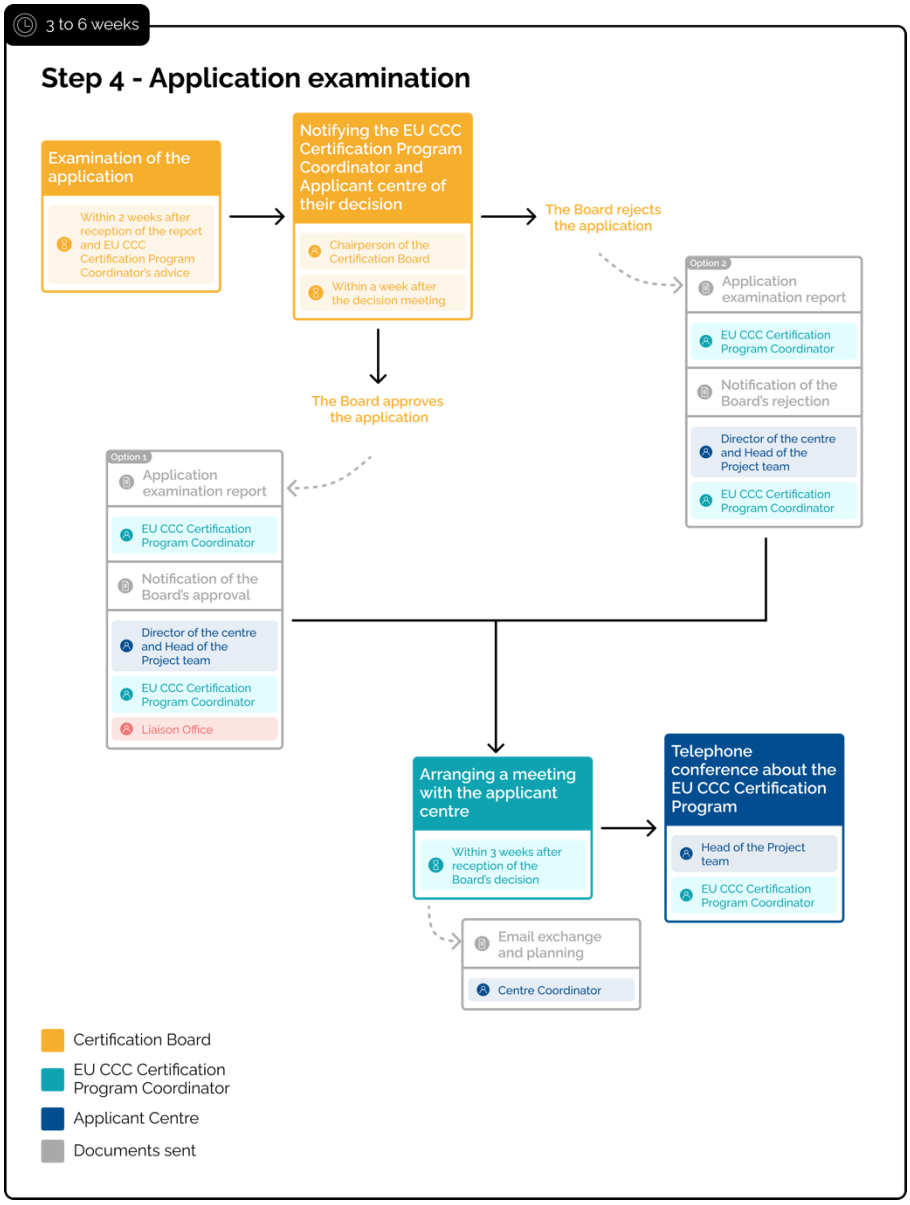

Figure III-4 - Step 4: Application examination

Examination of the application	
Certification Board	Within 2 weeks after reception of the report and EU CCC Certification Program Coordinator's advice
The Board examines the EU CCC Certification Program Coordinator's initial review report and its associated advice to decide on the readiness for full accomplishment of the certification process. Its decision can defer from the EU CCC Certification Program Coordinator's advice and is left to the interpretation of the Certification Board. *Option 1: Approval of the application*	

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The Board approves the application submitted by the Applicant Centre. This means that they believe the Applicant Centre is ready to undergo the full EU CCC Certification Program. *Option 2: Rejection of the application* The Board rejects the application submitted by the Applicant Centre. This means that they believe the Applicant Centre is not ready to undergo the full EU CCC Certification Program and needs to work on several improvement points before going through the full process.

Notifying the EU CCC Certification Program Coordinator and the Applicant Centre of their decision	
Chairperson of the Certification Board	Within a week after the decision meeting.
Depending on the outcome of the Board's examination of the application, the Chairperson of the Certification Board will notify and advise the EU CCC Certification Program Coordinator and the Applicant Centre with an application examination report and either a notification of the Board's approval of the application (*option 1*) or a notification of the Board's rejection of the application (*option 2*). The Certification Board will also send the notification of approval to the Liaison Office to anticipate the contractualization and payment steps.	
Application examination report: *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to the EU CCC Certification Program Coordinator.*	
Option 1: • ***Notification of the Board's approval of the application:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the EU CCC Certification Program Coordinator, (2) the Director of the centre and the Head of the Project team and (3) the Liaison Office.*	
Option 2: • ***Notification of the Board's rejection of the application:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the EU CCC Certification Program Coordinator and (2) the Director of the centre and the Head of the Project team.*	

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Arranging a meeting with the Applicant Centre	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the Board's decision
Regardless of the Certification Board's decision, the coordinator arranges an appointment with the Centre Coordinator.	
Email exchange and planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator*	

Telephone conference about the EU CCC Certification Program
EU CCC Certification Program Coordinator, Centre Coordinator and Head of the Project team of the Applicant Centre
Option 1: the Applicant Centre received a notification of approval The coordinator and the Applicant Centre participate in a telephone conference and discuss the following topics: • The Certification Program. • The planning and organisation of the Certification Process (next steps). • The improvements and development the centre will have to tackle. *Option 2: the Applicant Centre received a notification of rejection* The coordinator and the Applicant Centre participate in a telephone conference and discuss the following topics: • The Certification Program. • Explanation of the causes that led to the rejection of the application. • The improvements and development the centre needs to tackle to reach the requirement level for full accomplishment of the certification process. The EU CCC Certification Program Coordinator will also orient the Applicant Centre towards the WP6 of EU Net CCC and its development plan. This support should help the centre work on the requirements and the application form before attempting another submission.

3.12 Step 5: Contractualisation & Payment

~ Estimated execution time: one month ~

This step, mostly administrative, involve the Liaison Office and the Applicant Centre. These steps will be refined in the next Joint Action, as it was determined that the EU Net CCC Certification Program will require a payment, but the person or organisation responsible for payment has not yet been identified, nor have the basis for the contract and contractors.

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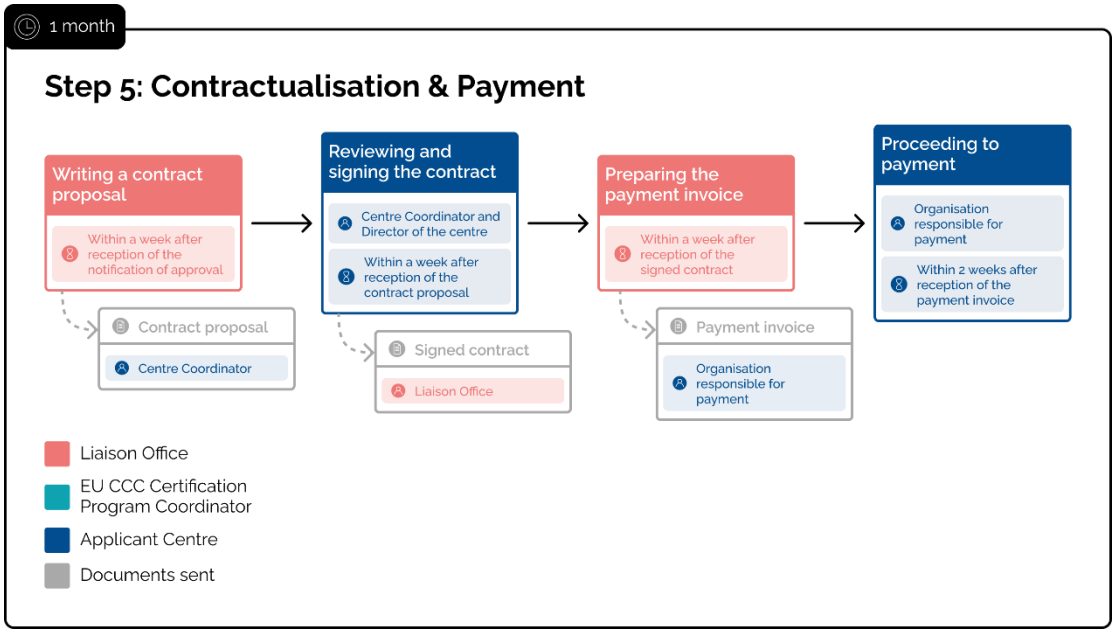

Figure III-5- Step 5: Contractualisation & Payment

Writing a contract proposal	
Liaison Office	Within a week after reception of the notification of approval
Following the Certification Board approval of the centre's application, the Liaison Office writes a contract proposal for the Applicant Centre. This contract is based on the general standard contract that is publicly accessible, amended with the specific information pertaining to the Applicant Centre. The terms of the contract contain the commitments the centre agrees to when entering the Certification Program and the following process. Once it is finalized, the Liaison Office can send the contract proposal to the Centre Coordinator.	
Contract proposal: *sent through the e-tool, from the Liaison Office to the Centre Coordinator.*	

Reviewing and signing the contract	
Centre Coordinator and Director of the centre	Within a week after reception of the contract proposal
Following the reception of the contract, the Applicant Centre proceeds to the review and signature of the contract. In the eventuality of questions, the Applicant Centre can contact the EU CCC Certification Program Coordinator or use the help system included in the Program's e-tool.	

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Once the centre finalized the review and signed the contract, they will send it back to the Liaison Office.
Signed contract: *sent through the e-tool, thanks to digital signature from the Centre Coordinator to the Liaison Office.*

Preparing the payment invoice	
Liaison Office	Within a week after reception of the signed contract
After reception of the signed contract from the Applicant Centre, the Liaison Office will prepare and send a payment invoice to *the organisation responsible for payment*	
Payment invoice: *sent through the e-tool or email, from the Liaison Office to the organisation responsible for payment.*	

Proceeding to payment	
Organisation responsible for payment	Within 2 weeks after reception of the payment invoice
Following the reception of the invoice, the organisation responsible for payment will proceed to pay the fees indicated in the invoice. This action will allow the centre to move on to the next steps of the processes.	

3.13 Step 6: Core team set-up and Planning

~ Estimated execution time: 3 to 8 weeks ~

In this step, the Centre Coordinator and Head of the Project team meet with the EU CCC Certification Program Coordinator to discuss the upcoming steps of the certification process, as well as the requirements. This conversation should allow the applicant centre to express any concern or problem.

At this stage, the Applicant Centre should also compose a core Project team, organize, plan and structure their work to ensure the proper execution of the Certification process.

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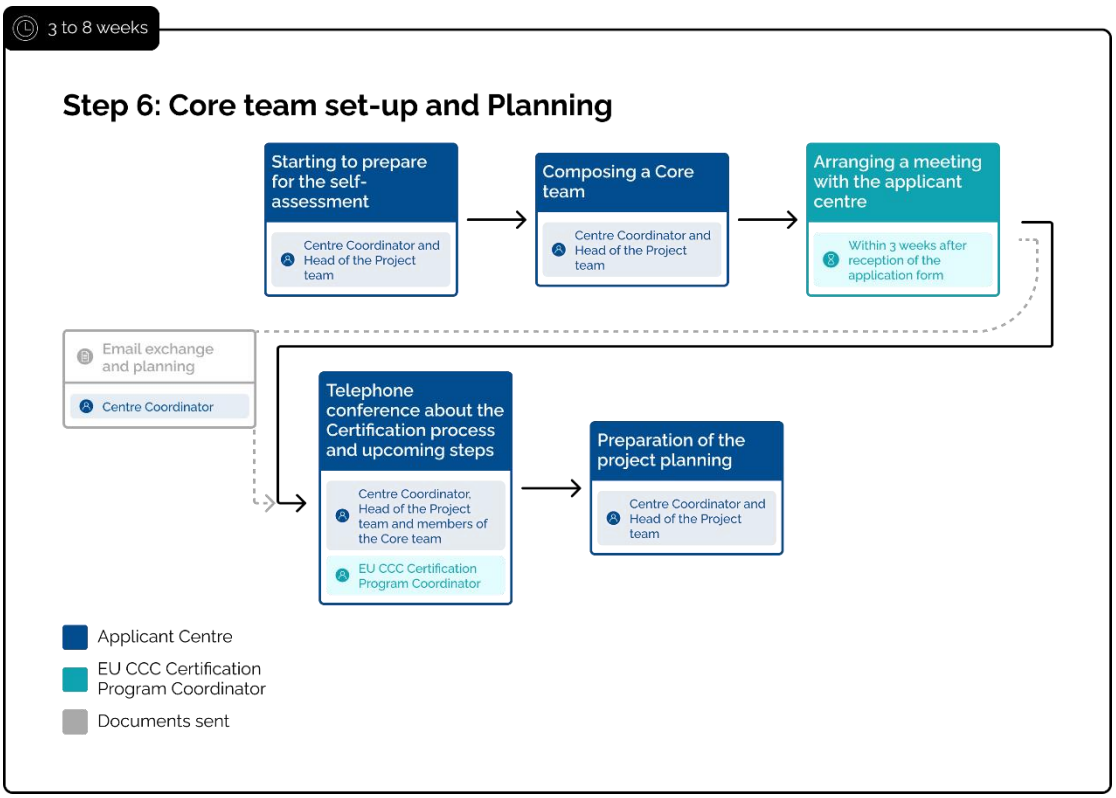

Figure III-6 - Step 6: Core team set-up and Planning

Starting to prepare for the self-assessment
Centre Coordinator and Head of the Project team
The Applicant Centre starts preparing for the upcoming steps. They should particularly be aware of the following resources: • List of Criteria and Standards • Glossary • Additional information notice • List of evidence

Composing a Core team
Centre Coordinator and Head of the Project team
The Centre Coordinator and Head of the Project team work on the composition of a Core team in their cancer centre/institute. The Core team should be composed of the people who will be leading the certification process and coordination alongside the Head of the Project team and Centre Coordinator.

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Arranging a meeting with the Applicant Centre	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the application form
Upon reception of the centre's application form, the EU CCC Certification Program Coordinator will send a delivery note to the Centre Coordinator. The EU CCC Certification Program Coordinator arranges a meeting with the Applicant Centre to discuss the certification process. Ahead of the meeting, the EU CCC Certification Program Coordinator should encourage the contributing members of the Applicant Centre's team to consult the following items: • Explanation of the project plan requirements. • Project plan template (available in e-tool). It is to be noted that the project plan is rather flexible and that the template can be used as an example but is not mandatory to follow.	
Email exchange and planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator*	

Telephone conference about the Certification process and upcoming steps
EU CCC Certification Program Coordinator, Centre Coordinator, Head of the Project team and members of the Core team of the Applicant Centre
The EU CCC Certification Program Coordinator, the Centre Coordinator, the Head of the Project team and the members of the Core team participate in a meeting to discuss the Certification process and the different steps awaiting the Applicant Centre. The meeting agenda should include the following topics: • The certification process, its requirements and steps, including the checkpoints. • Validation of the access to the e-tool for all the contributing members. • Validation of the access to the project plan template in the e-tool and the EU CCC Certification Program's expectations. • The list of requested documents the Applicant Centre will have to provide and their eligible formats for an easy upload in the e-tool. • The obligations and roles of both parties (i.e. EU CCC Certification Program Coordinator and Applicant Centre.

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Preparation of the project planning
Centre Coordinator and Head of the Project team
Following the meeting with the EU CCC Certification Program Coordinator, the Centre Coordinator and the Head of the Project team should oversee the project planning. Hence, they should notably: • Set meetings to follow the progress on the forms' completion. • Define a concrete schedule and deadlines. • Set up a timeline and methodology to ensure the centre's staff (i.e. Core team and other contributors) is involved in the Certification process. • Identify experts and other contributors. • Anything the centre identifies as necessary for its internal organisation.

3.14 Step 7: Detailed self-assessment

~ Estimated execution time: 2 to 3 months ~

The self-assessment period is dedicated to the Applicant Centre. During this step, they will fill out the required forms, provide any required documents and work on non-compliances and improvement points. Once the centre can submit a draft version of the self-assessment, they will submit it to the EU CCC Certification Program Coordinator through the e-tool.

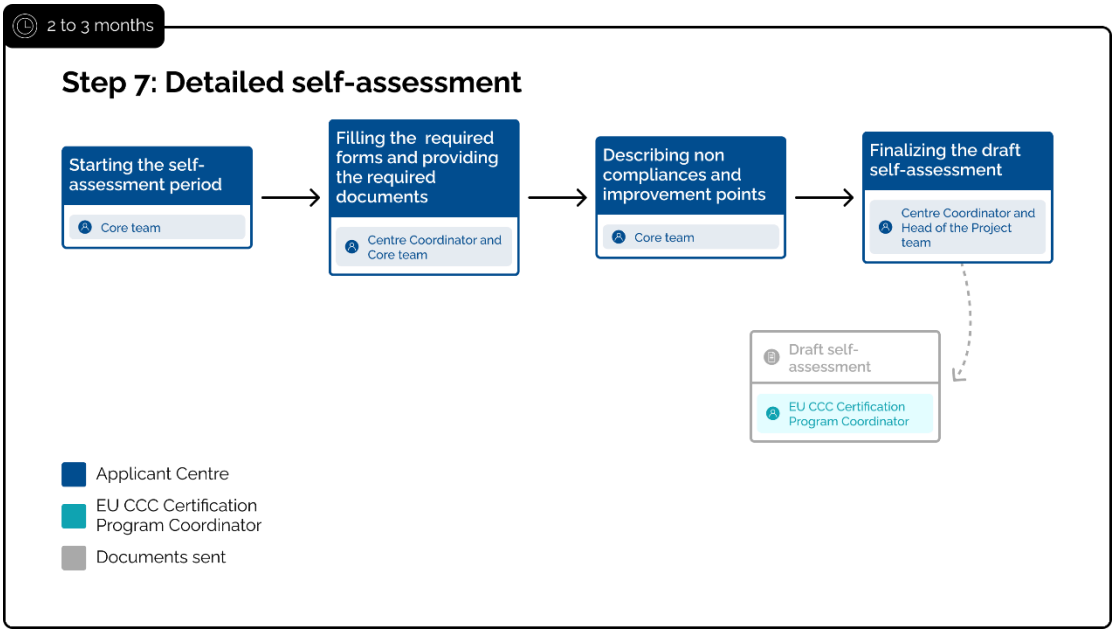

Figure III-7 - Step 7: Detailed self-assessment

Starting the self-assessment period
Core team
The Applicant Centre starts its self-assessment period and checks the information and requirement on the e-tool. All the forms can be completed in the e-tool. Documents,

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responding to the eligible formats, can also be uploaded directly in the e-tool and associated to their related criteria, standards or additional question.

At this stage, it is essential to ensure all the members of the Core team are fully involved in the process, to facilitate the completion of the self-assessment and ensure the reliability of all the answers and documents provided by the centre.

Filling the required forms and providing the required documents

Centre Coordinator and Core team

The Applicant Centre starts responding to the forms in the e-tool. They are required to make notes and comments to explain their scores and answers, in line with the recommended lines for evidence. If necessary, they can be asked to provide documents to justify their answers.

Finally, the Applicant Centre must attach all the required documents to their self-assessment. [*The list of evidence is yet to be defined. It will depend on the criteria, standards and additional information documents.]*

Describing non compliances and improvement points

Core team

The Applicant Centre must describe the potential non-compliances and improvement points in the e-tool.

By improvement points, we imply all the complementary information the centre may provide to justify their answer or score to one or several of the criteria, standard, or additional information.

For instance, if a centre answered 'partly' to one of the items but is currently implementing an internal plan or improvement strategy, this should be mentioned and justified using the related evidence in this part.

Similarly, if the data used in the additional information document is dated and the numbers have significantly evolved, this should be described and justified in this part.

These descriptions and additional justifications will be used to build the improvement plan and transferred to the Audit team prior to the on-site audit.

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Finalizing the draft self-assessment
Centre Coordinator and Head of the Project team
For the 1st submission of the draft self-assessment: The Applicant Centre reviews the self-assessment forms and documents before submission. They must ensure all the questions have been properly answered and all the required documents have been uploaded in the right categories. The e-tool should also give them indications of the questions that may require further elaboration, or areas of mis completion to facilitate their review. *For the 2nd submission (or more) of the draft self-assessment:* Before the re-submission of their draft self-assessment, the centre should work on areas of improvement indicated by the EU CCC Certification Program Coordinator. *Some of these elements should be highlighted in the e-tool, following the EU CCC Certification Program Coordinator's review.*
Draft self-assessment: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

3.15 Step 7.2: Composing and preparing the Audit team

~ Estimated execution time: 6 weeks~

→ Step 7.2 is part of the preparation of the on-site audit and should be executed around the self-assessment step.

In this step, the EU CCC Certification Program Coordinator will work on the composition of the Audit team and make sure there are no conflicts of interests between the chosen team and the Applicant Centre.

This step should be initiated about 4months before the on-site audit, based on the Applicant Centre's level of self-assessment.

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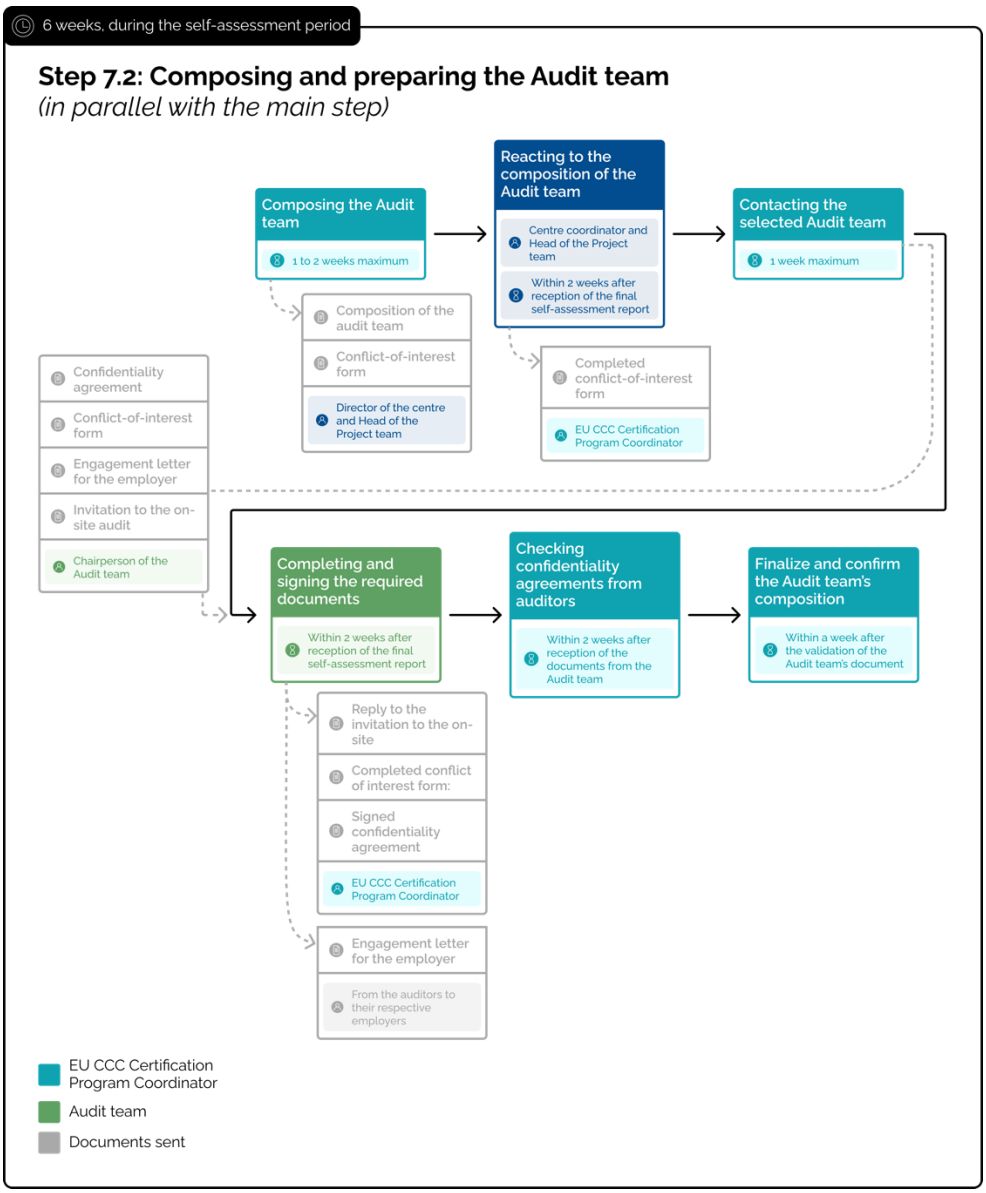

Figure III-8 - Step 7.2: Composing and preparing the Audit team

Composing the Audit team	
EU CCC Certification Program Coordinator	1 to 2 weeks maximum
The EU CCC Certification Program Coordinator composes the Audit team for the on-site audit of the Applicant Centre. The Audit team should be composed of peers. The composition of the team should therefore be arranged to cover all the areas of expertise and of analysis demanded for the on-site audit and the assessment of the centre on the required Criteria and Standards of the EU CCC Certification.	
Composition of the Audit team: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	

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Conflict-of-interest form: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*

Reacting to the composition of the Audit team	
Centre Coordinator and Head of the Project team	Within 2 weeks after reception of the Audit team composition
The Centre Coordinator and Head of the Project team can, if necessary, express any potential conflict of interest against one or more of the Audit team members. To do so, the Applicant Centre should complete the conflict-of-interest form associated to the list of the Audit team members that they received in the e-tool.	
Completed conflict of interest form: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator*	

Contacting the selected Audit team	
EU CCC Certification Program Coordinator	A week maximum
The EU CCC Certification Program Coordinator prepares the invitation for the Audit team, as well as all the documents they will need to fill before the on-site audit: • Confidentiality agreement. • Conflict-of-interest form. • Engagement letter for the employer.	
Confidentiality agreement: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Conflict-of-interest form: *sent through the e-tool from the EU CCC Certification Program Coordinator to the Audit team.*	
Engagement letter for the employer: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Invitation to the on-site audit: *from the EU CCC Certification Program Coordinator to the Audit team.*	

Completing and signing the required documents	
Audit team	Within 2 weeks after reception of the documents
The members of the Audit team received an invitation to take part in a certification process. If they accept the invitation, they should complete and sign all the documents sent by the EU CCC Certification Program Coordinator.	
Reply to the invitation to the on-site audit: *from the Audit team to the EU CCC Certification Program Coordinator.*	

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Completed conflict of interest form: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*
Signed confidentiality agreement: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*
Engagement letter for the employer: *from the Audit team to their respective employers.*

Checking confidentiality agreements from auditors	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the documents from the Audit team
The EU CCC Certification Program Coordinator checks that the documents received from the Audit team were carefully completed and signed. If some of the documents were mis-completed or mis-signed, the EU CCC Certification Program Coordinator should contact the Audit team members as soon as possible to validate this step.	

Finalize and confirm the Audit team's composition	
EU CCC Certification Program Coordinator	Within a week after the validation of the Audit team's document
The EU CCC Certification Program Coordinator verifies that there is not any conflict of interests between the Applicant Centre and the elected Audit team members to finalize the composition of the team and initiate the next preparation step.	

3.16 Step 8: Quality assurance review

~ Estimated execution time: 7 weeks to 4 months ~

This step has two main goals. The first one is to review and assess the centre's self-assessment to identify areas for quality improvement and discuss them before either moving to the next step or going back to the self-assessment step.

The second one is an optional pre-visit of the centre by the EU CCC Certification Program Coordinator and Chairperson of the Audit team, before the submission from the centre of the final self-assessment.

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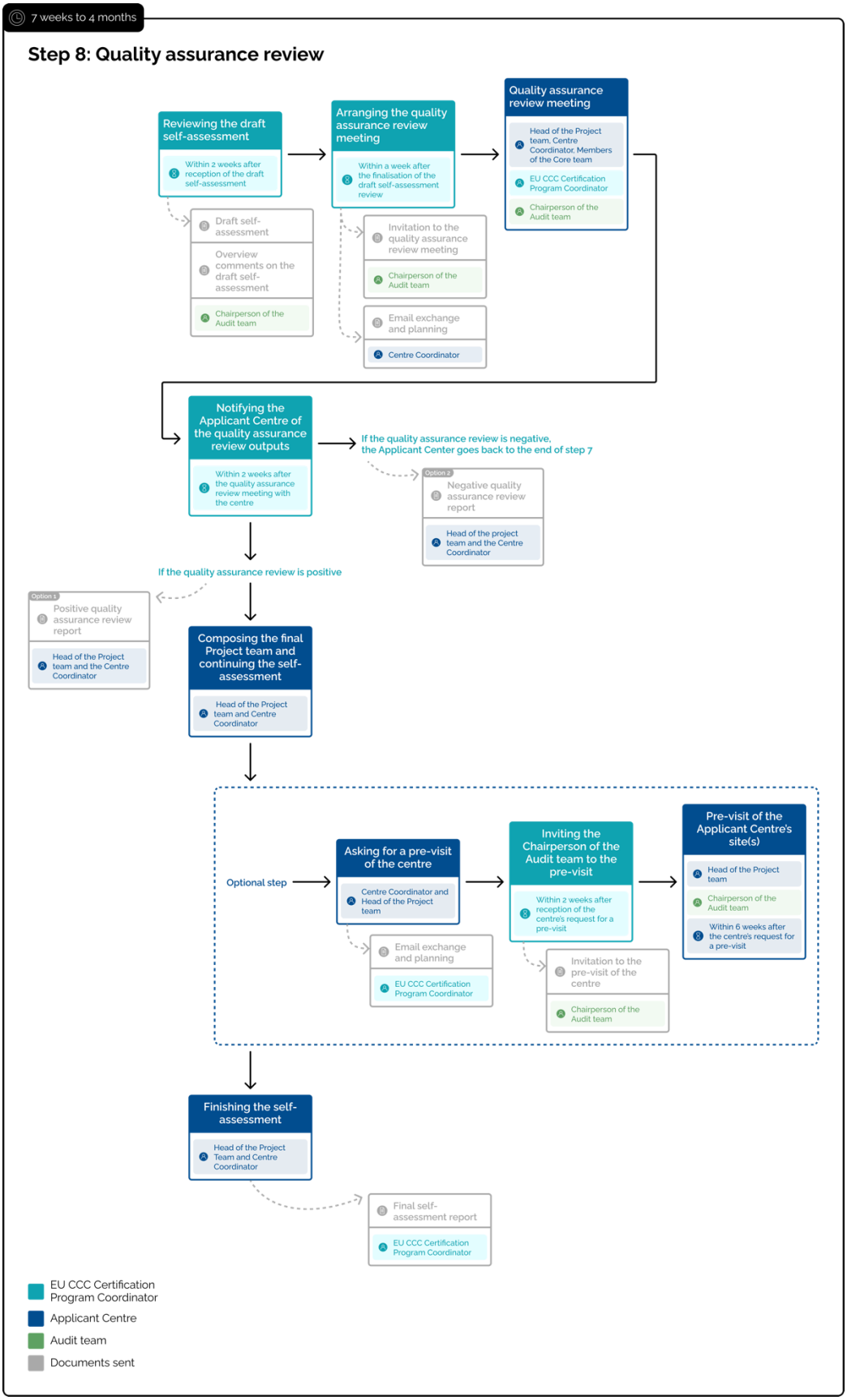

Figure III-9 - Step 8: Quality assurance review

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Reviewing the draft self-assessment	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the draft self-assessment
The EU CCC Certification Program Coordinator reviews the draft self-assessment and produces a list of overview comments. It is to be noted that this review should be technical, hence, made to identify any technical deficiencies in the self-assessment, or information that can be further elaborated before the final submission. This review is not meant to identify improvements points within the centre's organisation, or current capacities based on their answers in the forms. The draft self-assessment, as well as the EU CCC Certification Program Coordinator's comments will be transferred to the Chairperson of the Audit team	
Draft self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	
Overview comments on the draft self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

Arranging the quality assurance review meeting	
EU CCC Certification Program Coordinator	Within a week after the finalisation of the draft self-assessment review
Upon the finalisation of the draft self-assessment review, the EU CCC Certification Program Coordinator will contact the Centre Coordination and Head of the Project team and arrange a meeting to discuss quality/technical improvement points on the self-assessment. The Chairperson of the Audit team will also be invited to participate in this meeting with the centre, as they will be able to provide specific inputs regarding the needs for the preparation of the on-site audit.	
Email exchange and planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator.*	
Invitation to the quality assurance review meeting: *from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

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Quality assurance review meeting
EU CCC Certification Program Coordinator, Centre Coordinator, Head of the Project team, members of the Core team and Chairperson of the Audit team
The EU CCC Certification Program Coordinator, the Centre Coordinator, the Head of the Project team, the members of the Core team and the Chairperson of the Audit team participate in the quality assurance review meeting to discuss qualitative and technical improvement points for the centre's self-assessment. The meeting agenda should include the following topics: • Discussion over the EU CCC Certification Program Coordinator's comments from their review of the draft self-assessment. • Inputs from the Chairperson of the Audit team regarding its team needs for the preparation of the on-site audit. • Inputs from the centres on their capacity to provide further elements to elaborate their self-assessment before final submission.

Notifying the Applicant Centre of the quality assurance review outputs	
EU CCC Certification Program Coordinator	Within 2 weeks after the quality assurance review meeting with the centre
Upon their review of the draft self-assessment and the quality assurance review meeting, the EU CCC Certification Program Coordinator will finalize its report and send it to the Applicant Centre. *Option 1: The quality assurance review is positive* If the quality assurance review is positive, it means that the self-assessment requires few improvements. At this stage, the information provided, and completion of the forms is satisfactory and there is enough data to prepare for the on-site audit. *Option 2: The quality assurance review is negative* If the quality assurance review is negative, it means that the information provided, and completion of the forms is not satisfactory enough, and/or some information are missing to prepare for the on-site audit.	

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The Applicant Centre should work on the completion of the self-assessment before re-submitting it, within 2 months after the quality assurance review.
Option 1: • ***Positive quality assurance review report:*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and the Centre Coordinator.*
Option 2: • ***Negative quality assurance review report*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and the Centre Coordinator.*

Composing the final project team and continuing the self-assessment
Head of the Project team and Centre Coordinator
The Head of the Project team and Centre coordinator compose the final Project team. This team's composition should respond to the on-site audit's requirements and involve people who will be able to and should contribute to the completion of the self-assessment and to the on-site audit. Once the final Project team is composed, the Applicant Centre should focus on the finalisation of the self-assessment, based on their quality assurance review.

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Optional steps below. If the Applicant Centres does not require a pre-visit, they will directly move to the 'Finishing the self-assessment step'.

Asking for a pre-visit of the centre
Centre Coordinator and Head of the Project team
The Head of the Project team and the Centre Coordinator can ask for an appointment with the EU CCC Certification Program Coordinator to request a pre-visit of their centre before finalizing the self-assessment.
Email exchange and planning: *from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

Inviting the chairperson of the Audit team to the pre-visit	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the centre's request for a pre-visit
Upon reception of the Applicant Centre's request, the EU CCC Certification Program Coordinator sends an invitation to the Chairperson of the Audit team, to invite them to the pre-visit of the Applicant Centre's site(s).	
Invitation to the pre-visit of the centre: *from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

Pre-visit of the Applicant Centre's site(s)	
EU CCC Certification Program Coordinator, Head of the Project team, Chairperson of the Audit team	Within 6 weeks after the centre's request for a pre-visit
The EU CCC Certification Program Coordinator, the Chairperson of the Audit team and the Head of the Project team meet for a pre-visit of the centre. This pre-visit can be useful for in person support during the self-assessment period and in some cases to manage the centre's expectations regarding the certification obtention.	
At the end of the pre-visit, the Head of the Project should have a moment of debriefing with the EU CCC Certification Program Coordinator and the Chairperson of the Audit team. This debriefing should help the Head of the project gather all the necessary inputs before the finalisation of the Applicant Centre's self-assessment. The costs of the visit should be covered by the centre.	

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Finishing the self-assessment
Head of the Project team and Centre Coordinator
Upon the feedback received in the quality assurance review and the optional pre-visit, the Head of the Project team and Centre Coordinator will amend and finalize the self-assessment in the e-tool. Once they have checked all the information, forms and documents, they can validate the self-assessment and submit it directly on the e-tool.
Final self-assessment report: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

3.17 Step 8.2: Composing the on-site audit agenda

~ Estimated execution time: 2months ~

→ Step 8.2 is part of the preparation of the on-site audit and should be executed around the quality assurance review step.

Following the composition and validation of the Audit team, the EU CCC Certification Program Coordinator will work on a draft agenda for the on-site audit in collaboration with the Chairperson of the Audit team.

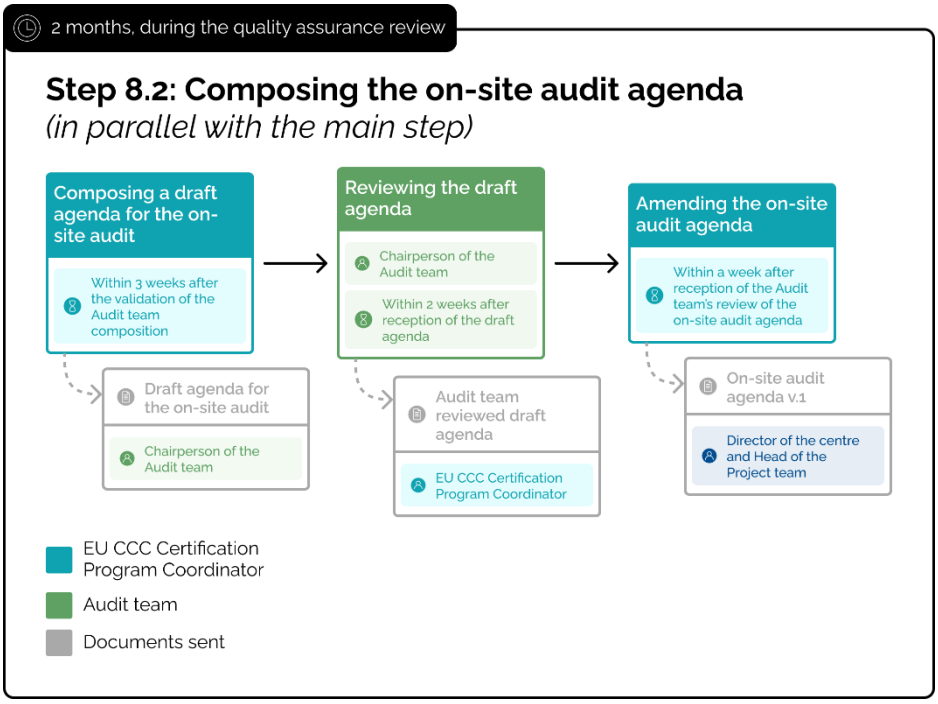

Figure III-10 – Step 8.2: Composing the on-site audit agenda

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Composing a draft agenda for the on-site audit	
EU CCC Certification Program Coordinator	Within 3 weeks after the validation of the Audit team composition
The EU CCC Certification Program Coordinator starts a draft agenda for the on-site audit. The agenda will be based on a template agenda, which they will be to access in the e-tool.	
Draft agenda for the on-site audit: *sent through the e-tool, from the EU CCC Certification Program to the Chairperson of the Audit team.*	

Reviewing the draft agenda	
Chairperson of the Audit team	Within 2 weeks after reception of the draft agenda
Upon reception of the draft agenda for the on-site audit, the Chairperson of the Audit team will review the agenda and amend it, if necessary, before sending back his comments and approval to the EU CCC Certification Program Coordinator.	
Audit team reviewed draft agenda: *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	

Amending the on-site audit agenda	
EU CCC Certification Program Coordinator	Within a week after reception of the Audit team's review of the on-site audit agenda.
Upon reception of the Chairperson of the Audit team's review of the draft agenda, the EU CCC Certification Program Coordinator will, if necessary, amend the agenda, before sending a first version to the Head of the Project team and the Centre Coordinator.	
On-site audit agenda v.1: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	

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3.18 Step 9: Final Go/No go decision

~ Estimated execution time: 6 to 8 weeks ~

Following the reception of the final self-assessment, the EU CCC Certification Program Coordinator will review and issue some advice for the Certification Board.

The Certification Board will discuss the self-assessment and notify the Head of the Project team of the Applicant Centre and the EU CCC Certification Program Coordinator with a go or a no-go decision, based on the rightful completion of the self-assessment and presence of appropriate evidence for the on-site audit.

The Applicant Centre will then be in contact with the EU CCC Certification Program Coordinator to discuss the next steps, including a second payment stage.

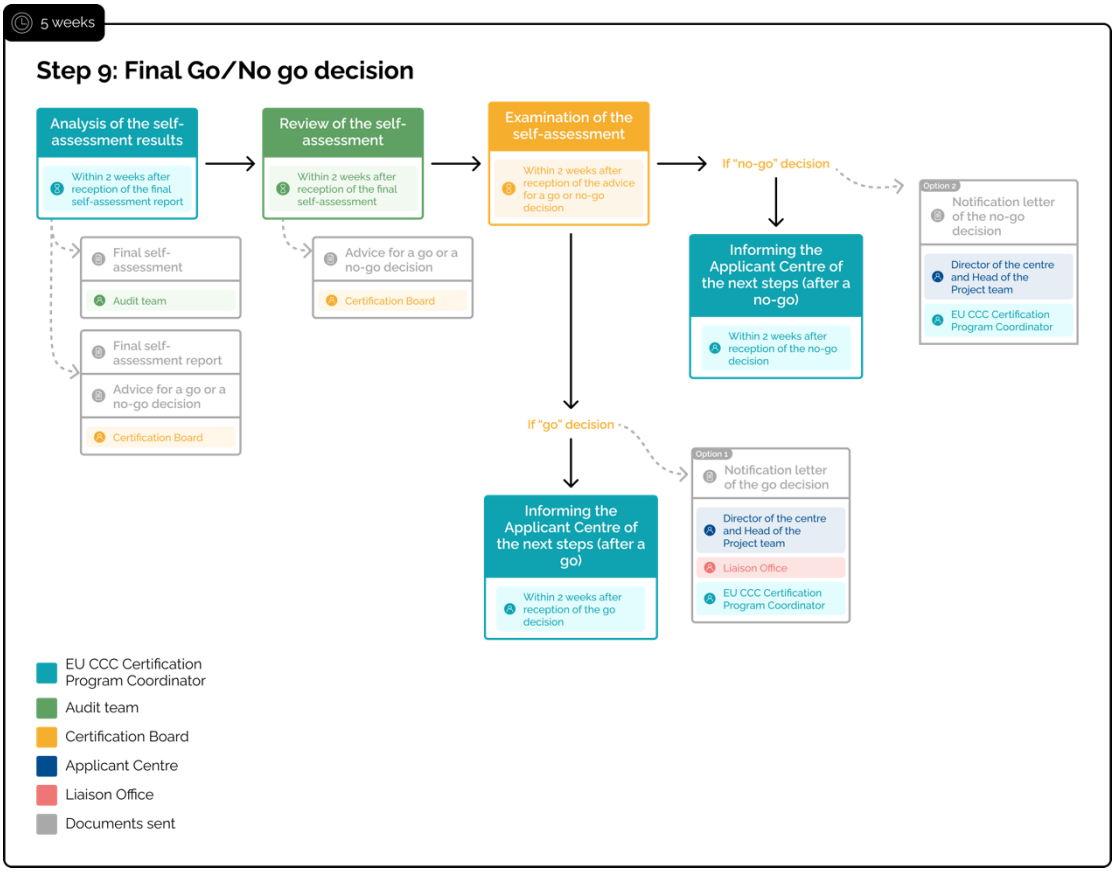

Figure III-11 – Step 9: Final Go/No go decision

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Analysis of the self-assessment results	
EU CCC Certification Program Coordinator	Within a month after reception of the final self-assessment report
The EU CCC Certification Program Coordinator analyses and examines the final self-assessment report before the on-site audit. This analysis should be carried on in the e-tool, as it will provide the EU CCC Certification Program Coordinator with a pre-analysis of the results. Then, they should review the notes, comments and elements that could not be automatically verified by the e-tool. Upon reception and after a preliminary verification, the EU CCC Certification Program Coordinator should transfer the final self-assessment report to the Audit team. Once they have finalized their review and analysis, the EU CCC Certification Program Coordinator will issue some advice for a go or a no-go decision and send it to the Certification Board.	
Final self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Final self-assessment report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Certification Board.*	
Advice for a go or a no-go decision: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*	

Review of the self-assessment	
Audit team	Within a month after reception of the final self-assessment
The Audit team reviews the self-assessment to submit some advice to the board before their go- or no-go decision. This review should be carried on in the e-tool, as it will provide the auditors with a pre-analysis of the results and particularly focus on the elements and documents they will need to prepare their on-site audit. Once they have finalized their review and analysis, the Chairperson of the Audit team will issue some advice for a go or a no-go decision and send it to the Certification Board.	

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Advice for a go or a no-go decision: *sent through official communication channels of the Certification Organisation, from the Audit team to the Certification Board.*

Examination of the self-assessment	
Certification Board	Within 2 weeks after reception of the advice for a go or no-go decision

Upon reception of the advice for a go or a no-go decision from the EU CCC Certification Program Coordinator and the Chairperson of the Audit team, the Certification Board will examine all the elements and take the final decision.

By the end of the examination, the Certification Board will have recommended either for a 'go' or a 'no-go' decision, regarding the centre's application at this stage of the process, and their readiness for the on-site audit.

Option 1: The Certification Board recommends a go decision

If the Board's final decision is a go, it means that all the items in the self-assessment were scored and completed, and that the information and documents provided are sufficient for the Audit team to prepare for the on-site audit.

Option 2: The Certification Board recommends a no-go decision

If the Board's final decision is a no-go, it means that the information and documents provided are not sufficient for the Audit team to prepare for the on-site audit.

The final decision is left to the interpretation of the Certification Board, hence, may differ from the EU CCC Certification Program Coordinator's and Chairperson of the Audit team's advice.

The Chairperson of the Certification Board will directly notify the following contributors of their decision:

- The Head of the Project team
- The EU CCC Certification Program Coordinator
- The Audit team
- The Liaison Office (if it is a go decision)

Option 1:

- ***Notification letter of the go decision*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to*

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(1) the Director of the centre and Head of the Project team, (2) the EU CCC Certification Program Coordinator and (3) the Liaison Office.
Option 2: • ***Notification letter of the no-go decision*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the Director of the centre and Head of the Project team and (2) the EU CCC Certification Program Coordinator.*

Informing the Applicant Centre of the next steps	
EU CCC Certification Program Coordinator	Within a week after reception of the Certification Board's decision for a go or no-go
Upon reception of the Certification Board's decision, the EU CCC Certification Program Coordinator will contact the Head of the Project team and Centre Coordinator to inform them of the steps awaiting them. *Option 1: If the Applicant Centre received a go decision* The EU CCC Certification Program Coordinator will inform the Head of the Project team of the elements they will need to upload in the e-tool as well as any other pre-requisites for the on-site audit, and the associated deadlines. *Option 2: If the Applicant Centre received a no-go decision* The EU CCC Certification Program Coordinator will inform the Head of the Project team of the reasons that led to the no-go decision following their self-assessment report. Thus, they should discuss the elements the centre needs to review, the documents they should add, and the modification they should do prior to a 2nd submission of their self-assessment report. The centre should therefore focus on document additions, rightful completion of the forms and the addition of precision to facilitate the preparation of the on-site audit. At this stage, the Applicant Centre can also be oriented towards the capacity building activities of the WP6 of EU Net CCC.	
Option 1: • ***Information about the next steps after a go decision*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*	
Option 2: • ***Information about the next steps after a no-go decision*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*	

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3.19 Step 9.2: Preparation of the on-site audit

~ Estimated execution time: 6 to 8 weeks ~

→ Step 9.2 is part of the preparation of the on-site audit and should be started during the Final Go/No-go decision and finalized after the Certification Board's final decision.

During this step, the Applicant Centre will work on the completion of the on-site audit agenda and will prepare its team internally. On the other hand, the EU CCC Certification Program Coordinator ensures the Audit team has all the documents and necessary elements to prepare for the on-site audit and helps them prepare if needed. Finally, the Audit team will hold an internal preparation meeting prior to the on-site audit.

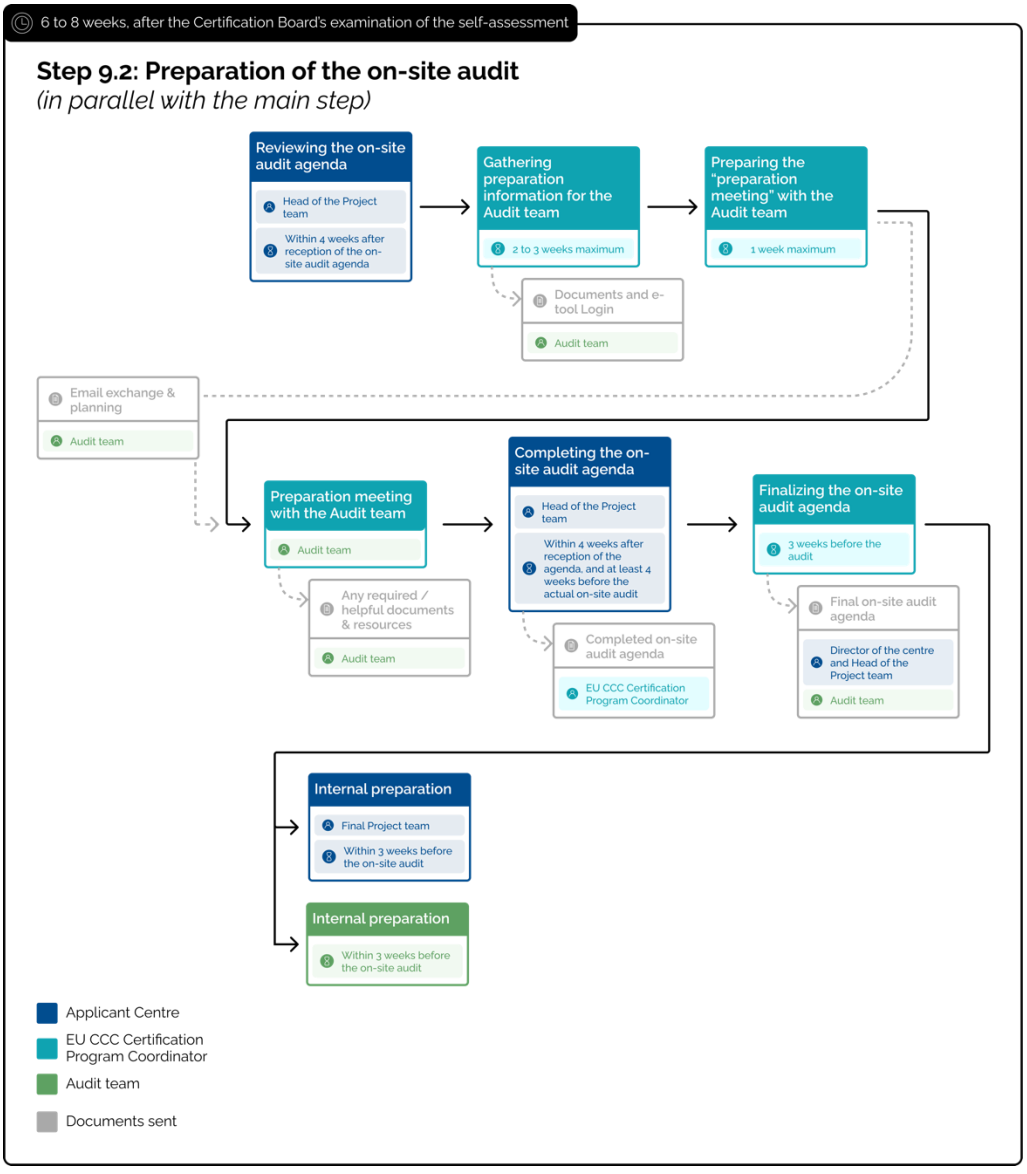

Figure III-12 – Step 9.2: Preparation of the on-site audit

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Reviewing the on-site audit agenda	
Head of the Project team	Within 4 weeks after reception of the on-site audit agenda
Upon reception of the on-site audit agenda from the EU CCC Certification Program, the Head of the Project team will review and analyse it. The objective for the Applicant Centre is to complete the agenda based on their capacities and upon the availability of the Project team members.	

Gathering preparation information for the Audit team	
EU CCC Certification Program Coordinator	2 to 3 weeks maximum
The EU CCC Certification Program Coordinator sends to the Audit team all the necessary information, documents, e-tool login, etc... that they will need to prepare for the on-site audit. *[detail on the type of information and documents they may receive?]*	
Documents and e-tool Login: *sent through the e-mail, from the EU CCC Certification Program Coordinator to the Audit team*	

Preparing the "preparation meeting" with the Audit team	
EU CCC Certification Program Coordinator	A week maximum
The EU CCC Certification Program Coordinator prepares the "preparation meeting", which needs to take place at least 3 weeks before the on-site audit. This meeting is meant to ensure the Audit team is ready for the on-site audit, that they have all the information they need and that they do not have any other need prior to the audit.	
Email exchange & planning: *from the EU CCC Certification Program Coordinator to the Audit team.*	

Preparation meeting with the Audit team
EU CCC Certification Program Coordinator
The EU CCC Certification Program Coordinator and the Audit team participate in a teleconference meeting. This meeting is made to ensure that all the administrative and logistics details have been

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handled *[detail of the administrative and logistics to handle will be refined in the next Joint Action].* The EU CCC Certification Program Coordinator may give a list of pre-requisites to the auditors to facilitate their preparation.
Any required / helpful documents & resources: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*

Completing the on-site audit agenda	
Head of the Project team	Within 4 weeks after reception of the agenda, and at least 4 weeks before the actual on-site audit
At least 4 weeks before the on-site audit, The Head of the Project team will ensure the rightful completion of the on-site audit agenda. It needs to provide the list of employees to interview and the locations / rooms for the interviews, as well as any complementary information auditors may need during their audit.	
Completed on-site audit agenda: *sent through the e-tool, from the Head of the Project team to the EU CCC Certification Program Coordinator.*	

Finalizing the on-site audit agenda	
EU CCC Certification Program Coordinator	3 weeks before the audit
The EU CCC Certification Program Coordinator makes sure the on-site audit agenda responds to all the proper criteria and finalizes it. If necessary, they may need to contact the Head of the Project team or the Centre Coordinator to complete some missing information.	
Final on-site audit agenda: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team, the Head of the Project team and the Centre Coordinator.*	

Internal preparation (Applicant Centre)	
Final project team	Within 3 weeks before the on-site audit
The Applicant Centre's Project Team must prepare for the on-site audit, implicating: • Organisation of the practical logistics for the audit. • Preparation and organisation of the Project team members and potential other contributors.	

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- Internal communication details, to ensure the whole centre/institute is aware of the ongoing certification process.

Internal preparation (Audit team)	
Audit team	Within 3 weeks before the on-site audit

Following the reception of the final on-site audit agenda, the Audit team should hold a preparation meeting to dispatch the preparation tasks between all the Audit team members. Amongst the elements to review we will find:

- The documentation review.
- The pre-requisites and conformity check.

Once they have settled on the repartition, they should collectively work on the preparation of the audit.

Finally, it is advised for the Audit team to have a physical meeting day, prior to the on-site audit. This moment should ensure a proper cohesion during the peer-review audit.

3.20 Step 10: Payment

~ Estimated execution time: 2 to 4 weeks ~

This administrative step involves the Liaison Office and the Applicant Centre. These steps will be refined in the next Joint Action, as it was determined that the EU Net CCC Certification Program will require a payment, but the person or organisation responsible for payment has not yet been identified, nor have the basis for the contract and contractors.

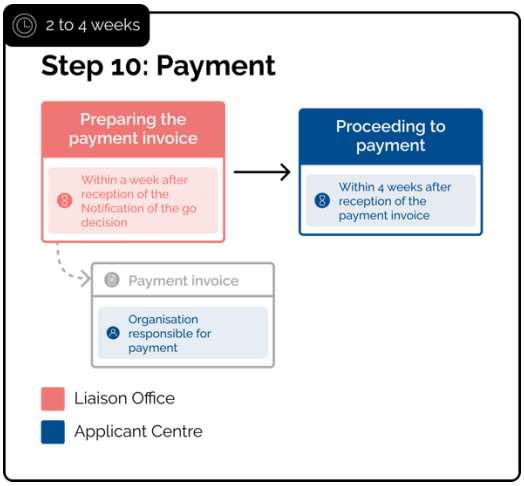

Figure III-13 – Step 10: Payment

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Preparing the payment invoice	
Liaison Office	Within a week after reception of the Notification of the go decision
After reception of the signed contract from the Applicant Centre, the Liaison Office will prepare and send a payment invoice to *the organisation responsible for payment*	
Payment invoice: *sent through the e-tool or email, from the Liaison Office to the organisation responsible for payment.*	

Proceeding to payment	
Organisation responsible for payment	Within 4 weeks after reception of the payment invoice
Following the reception of the invoice, the organisation responsible for payment will proceed to pay the fees indicated in the invoice. This action will allow the centre to move on to the next steps of the process: the on-site audit.	

3.21 Step 11: On-site audit

~ Estimated execution time: 1 to 2 weeks ~

The on-site audit involves interactions between the Applicant Centre's Project team and the Audit team who will conduct observations and interviews, while the Head of the Project team should ensure the auditors are provided will all the necessary elements and orientations while on site.

The on-site audit should be peer-reviewed; hence the composition of the Audit team will be arranged to cover all the areas of expertise and of analysis demanded for the on-site audit.

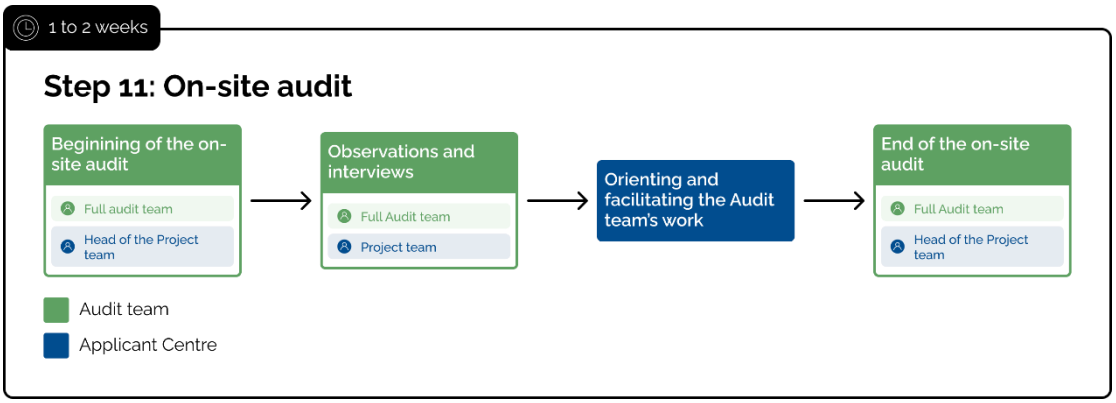

Figure III-14 – Step 11: On-site audit

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Beginning of the on-site audit
Head of the Project team and Audit team
Upon their arrival on site, the Audit team should be welcomed by the Head of the Project team. Together, they will review the agenda and ensure that everything is properly managed and planned for the complete duration of the audit. At this stage, if the auditors foresee any missing elements from the agenda, they should mention it to the Head of the Project team to evaluate the possibility of including these elements in the planning.

Observations and interviews
Audit team, Head of the Project team, Centre Coordinator and Members of the Project Team
Throughout the on-site audit, the auditors will observe a range of facilities, processes and means displayed by the Applicant Centre. The Audit team may visit several sites of the Applicant Centre during this period. They will also conduct group interviews with staff members to gather their perspective on the conformity of the centre. The interviewed staff members should be members of the final Project team, thus, they should be prepared for these interactions and clearly informed of the purpose and stakes of the on-site audit. Finally, throughout the on-site audit, the Head of the Project team and Centre Coordinator should facilitate and help orienting the Audit team on the grounds of the centre or institute.

End of the on-site audit
Head of the Project team and Audit team
At the end of the on-site audit, the Audit team holds a meeting with the Head of the Project team to give them a rapid overview of their observations and remind them of the next steps of the certification process and give them some visibility on the deadlines.

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3.22 Step 12: Reporting and Improvement plan definition

~ Estimated execution time: 10 to 14 weeks ~

Reporting: *~ Estimated execution time: 6 to 8 weeks ~*

After the on-site audit, the auditors will add their observation notes in the e-tool which will allow the EU CCC Certification Program Coordinator to draft a report. Following several exchanges between the EU CCC Certification Program Coordinator and Chairperson of the Audit team, the Applicant Centre will receive and react upon the draft report. Once all the contributors involved have given their comments, the report will be finalized.

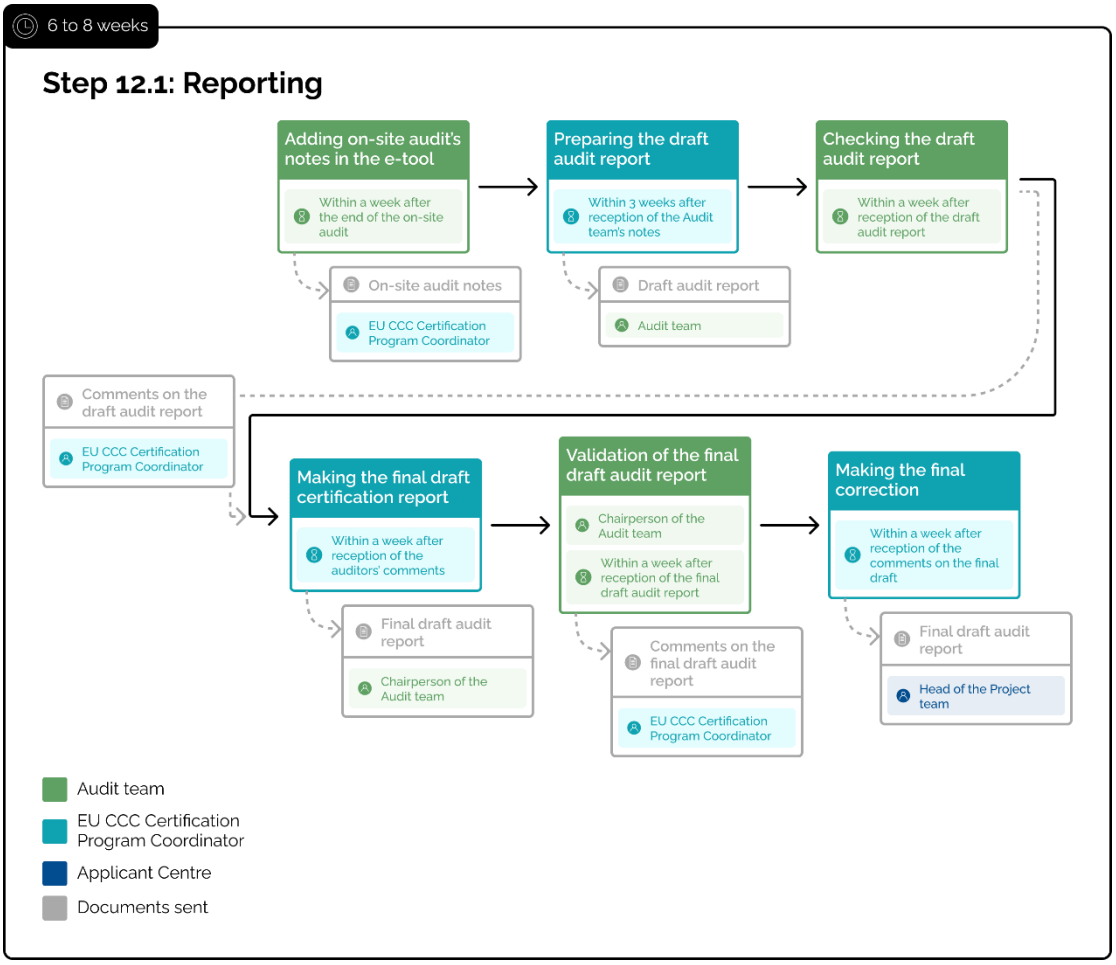

Figure III-15 – Step 12.1: Reporting

Adding on-site audit notes in the e-tool	
Audit team	Within a week after the end of the on-site audit
Following the on-site audit, the members of the Audit team integrate their notes in the e-tool, for the EU CCC Certification Program Coordinator to consult them and prepare a draft audit report.	
On-site audit notes: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator*	

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Preparing the draft audit report	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the Audit team's notes
Based on the auditors' on-site audit notes the EU CCC Certification Program Coordinator starts a draft audit report. The report should contain the standards reviewed during the on-site audit with the scores of the Applicant Centre from the self-assessment, the scores of the auditors, and the findings of the auditors supporting the scores, the general remarks, strengths and opportunities they have identified. Once the first draft is finalized, the EU CCC Certification Program will send it to the Audit team.	
Draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	

Checking the draft audit report	
Audit team	Within a week after reception of the draft audit report
Upon reception of the draft audit report from the EU CCC Certification Program Coordinator, the auditors will review it to add their comments and suggestions. The objective of this cross analysis is to ensure all the observations from the on-site audit were rightfully transcribed and are intelligible. All the auditors will be able to add their comments in their own e-tool account and will validate their review for the EU CCC Certification Program Coordinator to consult.	
Comments on the draft audit report: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator*	

Making the final draft certification report	
EU CCC Certification Program Coordinator	Within a week after reception of the auditors' comments
The EU CCC Certification Program Coordinator finalizes the draft of the audit report. The final draft does not present the conclusion, description of the certification process' findings not the decision for attribution of the certification. However, the report will be used as evidence in the final validation instance with the Certification Board.	

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Once the EU CCC Certification Program Coordinator finalized the final draft, they will send it back to the Chairperson of the Audit team for last comments.
Final draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*

Validation of the final draft audit report	
Chairperson of the Audit team	Within a week after reception of the final draft audit report
Upon reception of the final draft audit report, the Chairperson of the Audit team verifies the final draft audit report and sends its final comments to the EU CCC Certification Program Coordinator	
Comments on the final draft audit report: *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	

Making the final correction	
EU CCC Certification Program Coordinator	Within a week after reception of the comments on the final draft
Upon reception of the Chairperson of the Audit team's comments, the EU CCC Certification Program Coordinator produces the final correction of the draft audit report and submits it to the Applicant Centre for review.	
Final draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*	

Improvement plan definition: ~ *Estimated execution time: 4 to 6 weeks* ~

In this step, the Applicant centre's Project team work on their improvement plan. If needed, they can reach out to the EU CCC Certification Program Coordinator for a discussion prior to the finalisation of the improvement plan.

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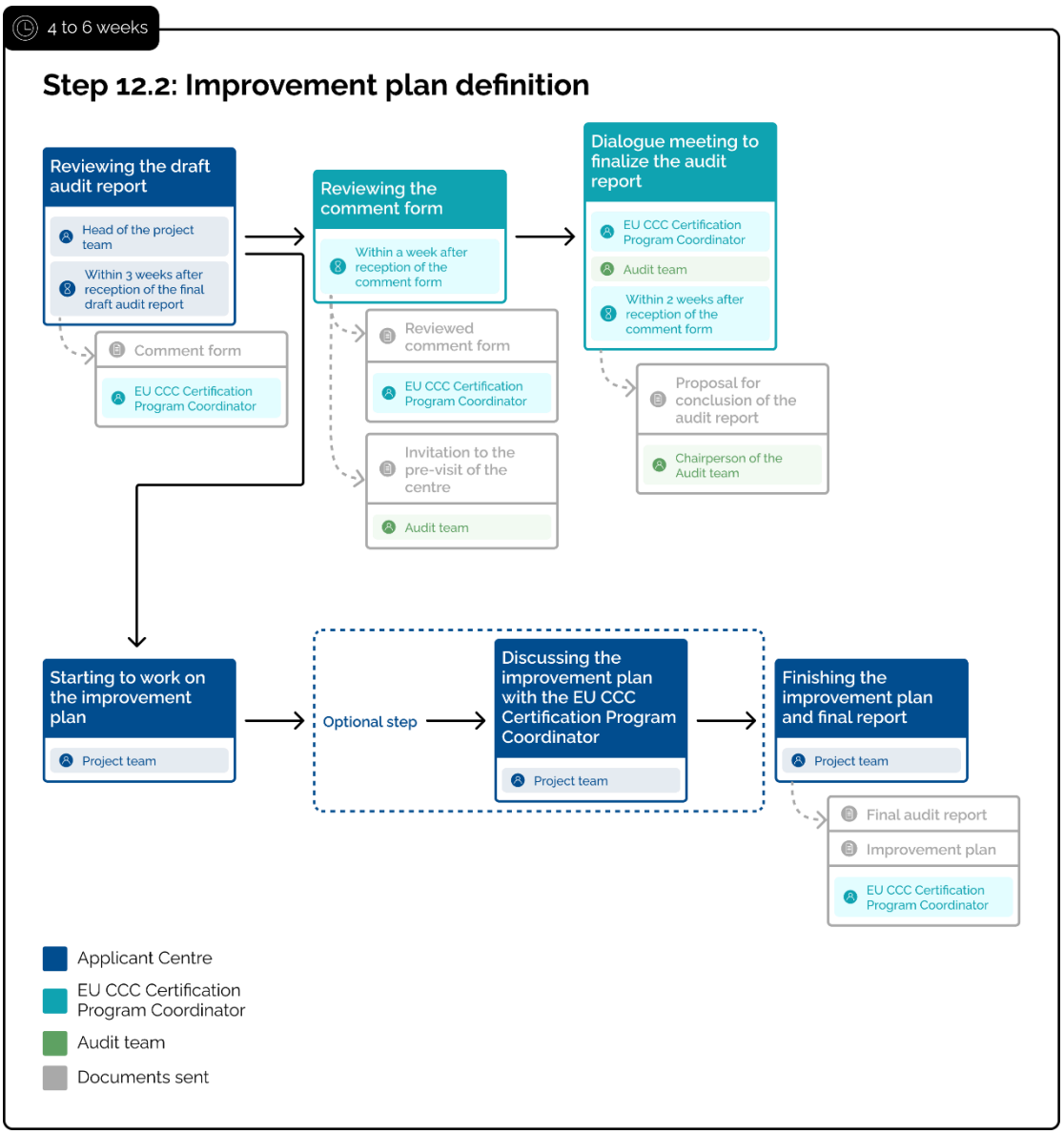

Figure III-16 – Step 12.2: Improvement plan definition

Reviewing the draft audit report	
Head of the Project team	Within 3 weeks after reception of the final draft audit report
Upon reception of the Final draft audit report, the Head of the Project team will review the report on factual inaccuracies. They should complete the dedicated comment form in the e-tool before the deadline. Their comment form will be sent to the EU CCC Certification Program Coordinator, analysed and discussed with the Audit team before the finalisation of the actual report.	
Comment form: *sent through the e-tool, from the Head of the Project team to the EU CCC Certification Program Coordinator*	

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Reviewing the comment form	
EU CCC Certification Program Coordinator	Within a week after reception of the comment form
The EU CCC Certification Program Coordinator reviews the comment form before transferring it to the Audit team. The EU CCC Certification Program Coordinator should also address a meeting invitation to the Audit team to discuss the Applicant Centre's comment form and finalize the audit report.	
Reviewed comment form: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Invitation to the pre-visit of the centre: *from the EU CCC Certification Program Coordinator to the Audit team*	

Dialogue meeting to finalize the audit report	
EU CCC Certification Program Coordinator and Audit team	Within 2 weeks after reception of the comment form
Upon reception of the comment form and invitation from the EU CCC Certification Program Coordinator, the auditors will prepare their potential comments prior to the dialogue meeting. Following the reaction meeting, both the EU CCC Certification Program Coordinator and Chairperson of the Audit team should provide a proposal for conclusion of the audit report, with a description of the on-site audit findings.	
Proposal for conclusion of the audit report: *completed in the e-tool by the EU CCC Certification Program Coordinator and Chairperson of the Audit team.*	

Starting to work on the improvement plan
Project team
Based on the elements from the draft final audit report, the Project team of the Applicant Centre, starts working on its improvement plan. The objective is to identify their areas of improvements and to define an action plan for the next 12 to 24 months. The definition of the improvement plan should not be neglected, as it is key to the potential granting of the EU CCC Certification.

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Optional step below. If the Applicant Centre does not require a meeting, they will directly move to the 'Finishing the improvement plan and final report' step.

Discussing the improvement plan with the EU CCC Certification Program Coordinator
Project team
Upon request from the Head of the Project team, the EU CCC Certification Program Coordinator can hold a meeting to discuss the definition of their improvement plan. The coordinator can challenge the Applicant Centre's draft plan so that it can be improved. However, the Applicant Centre must be the complete owner of this improvement plan which should not be directed by the EU CCC Certification Program Coordinator.

Finishing the improvement plan and final report
Project team
Once the improvement plan is finalized, the Head of the Project team and Centre Coordinator should complete the dedicated form in the e-tool, before submitting it to the EU CCC Certification Program Coordinator.
Improvement plan: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*
Final audit report: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

3.23 Step 13: Final review validation

~ Estimated execution time: 1 month ~

In this final step, the EU CCC Certification Program Coordinator will review all the documents (i.e. improvement plan, final audit report and proposal for conclusion of the audit report) and submit it to the Audit team, which will either approve or reject the centre's final audit report. The EU CCC Certification Program Coordinator will then transfer the final audit report, the Audit team's decision and his advice on the report to the Certification Board.

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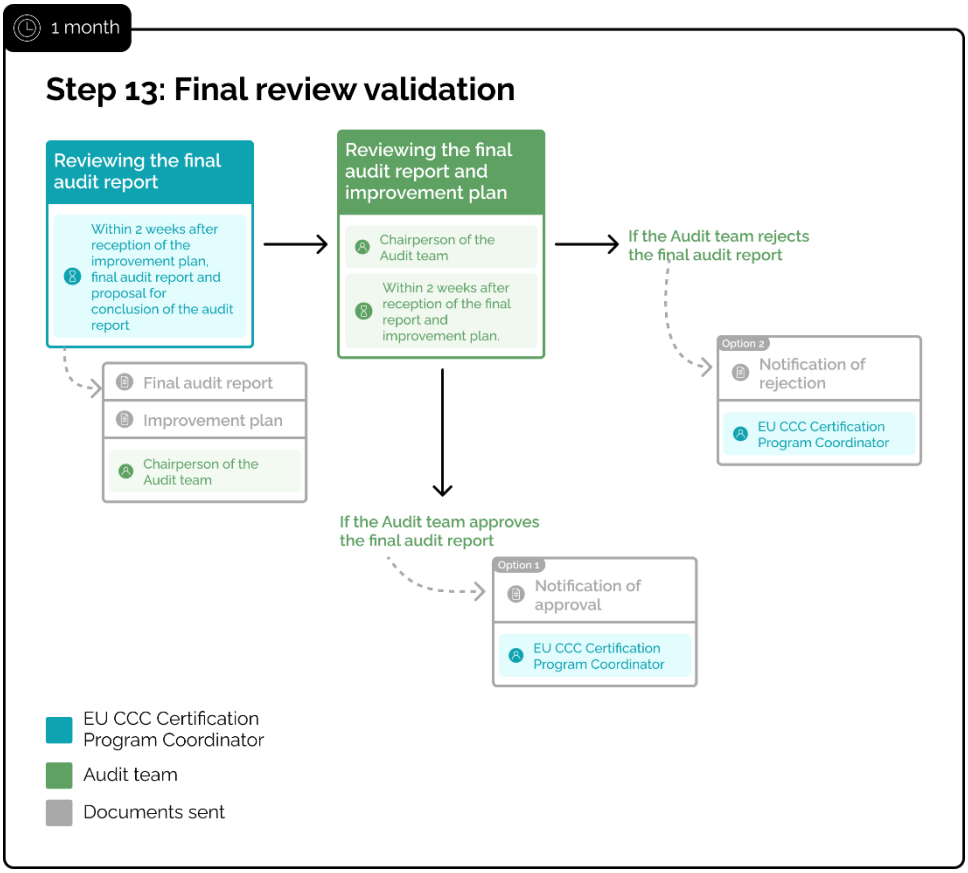

Figure III-17 - Step 13: Final review validation

Reviewing the final audit report	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the improvement plan, final audit report and proposal for conclusion of the audit report
The EU CCC Certification Program Coordinator reviews the final audit report and writes the conclusion. Then, they should validate the final report and improvement plan in the e-tool before transferring it to the Chairperson of the Audit team.	
Final audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team*	
Improvement plan: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team*	

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Reviewing the final audit report and improvement plan	
Audit team	Within 2 weeks after reception of the final report and improvement plan.
The Chairperson of the Audit team reviews the final audit report and the Applicant Centre's improvement plan. Based on the content, the Chairperson can either approve or reject the final audit report and improvement plan. *Option 1: The Chairperson of the Audit team approves the final audit report and improvement plan* In this case, they will issue a notification of approval for the EU CCC Certification Program Coordinator. *Option 2: The Chairperson of the Audit team rejects the final audit report and improvement plan* In this case, they will issue a notification of rejection for the EU CCC Certification Program Coordinator.	
Option 1: • ***Notification of approval:*** *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	
Option 2: • ***Notification of rejection:*** *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	

3.24 Step 14: Certification

~ Estimated execution time: 2 to 4 months ~

This final step can be divided in two main parts. On the one hand it is decisive, as the EU CCC Certification Program Coordinator and Certification Board will review the Audit team's on-site audit report and Applicant Centre's improvement plan. On the other hand, it is ceremonial, as once the certification is granted, several documents will be sent, and a celebration will take place.

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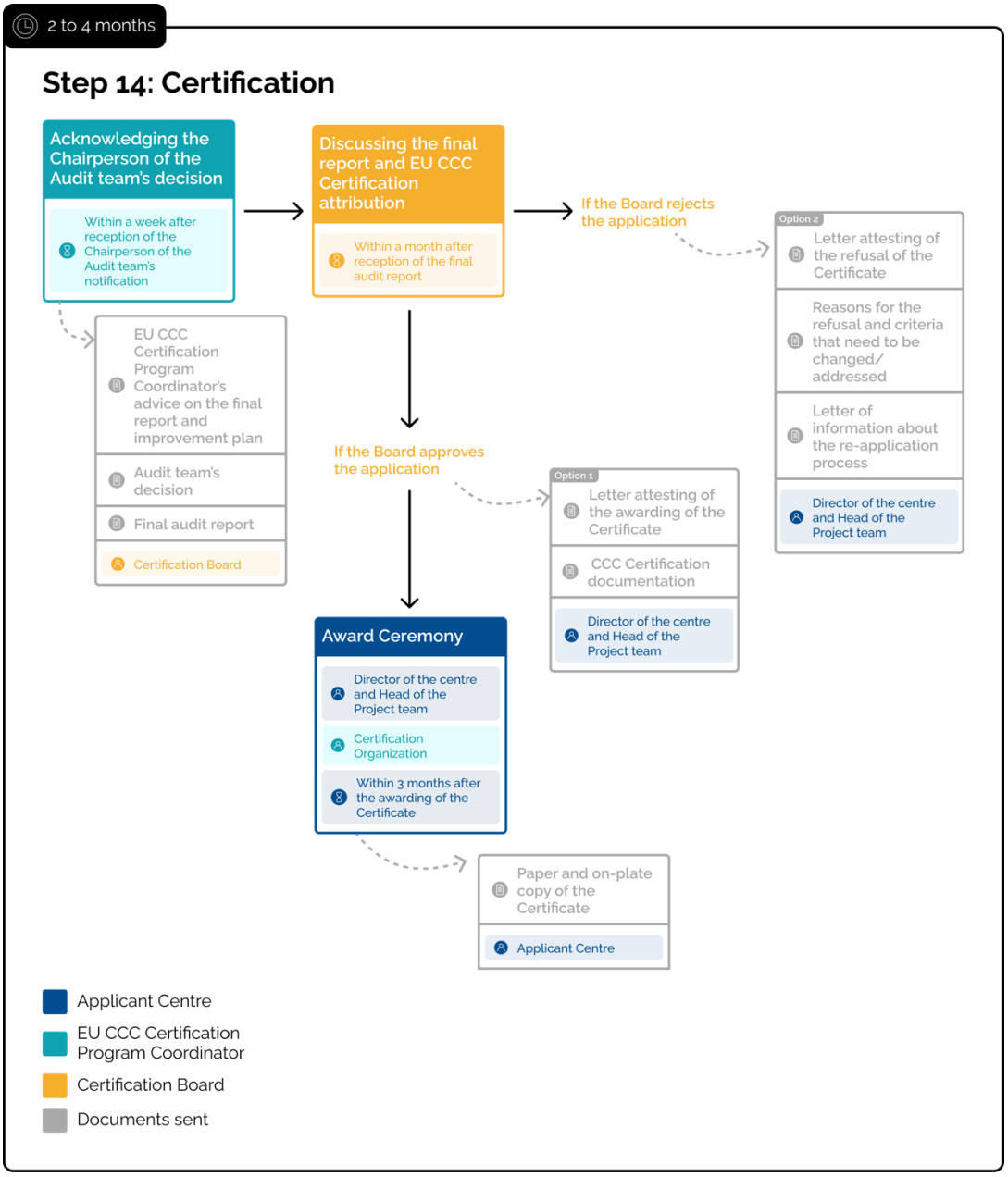

Figure III-18 - Step 14: Certification

Acknowledging the Chairperson of the Audit team's decision	
EU CCC Certification Program Coordinator	Within a week after reception of the Chairperson of the Audit team's notification
The EU CCC Certification Program Coordinator receives the Chairperson of the Audit team's decision and prepares some advice for the Certification Board, which will be responsible for the final certification attribution decision	
Final audit report: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*	

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Audit team's decision: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
EU CCC Certification Program Coordinator's advice on the final report and improvement plan: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

Discussing the final report and EU CCC Certification attribution	
Certification Board	Within a month after reception of the final audit report
The Certification Board reviews the Audit team's decision, the final audit report, the Applicant Centre's improvement plan and the EU CCC Certification Program Coordinator. Based on their review, they will decide upon the acceptance or rejection of the Applicant Centre's certification application. *Option 1: The Certification Board approves the Applicant Centre's certification application* The Centre Coordinator, Head of the Project team and Director of the centre will receive confirmation of the EU CCC Certification attribution. *Option 2: The Certification Board rejects the Applicant Centre's certification application* The Centre Coordinator, Head of the Project team and Director of the centre will receive information regarding the rejection of their certification application and information about the repeat process, if they wish to re-attempt the certification process.	
Option 1: • ***Letter attesting of the awarding of the Certificate:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.* • ***EU CCC Certification documentation:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*	
Option 2: • ***Letter attesting of the refusal of the Certificate:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.* • ***Document regarding the reasons for the refusal and criteria that need to be changed/addressed:*** *sent through official communication channels of the*	

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Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team. • ***Letter of information about the re-application process:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*

Award Ceremony	
Applicant Centre and Certification Organisation	Within 3 months after the awarding of the Certificate
During an award ceremony, the newly certified EU Comprehensive Cancer Centre receives an on-plate copy of the Certificate.	
Option 1: • ***Paper and on plate copy of the Certificate:*** *attributed during the Award Ceremony to the Director of the centre and Head of the Project team.*	

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IV. Detail of the follow-up and improvement plan implementation

3.25 Step 1: Feedback follow-up

~ Estimated execution time: 2 to 4 months ~

In this first step, the EU CCC Certification Program Coordinator will contact the newly certified centre or institute to collect their feedback and experience of the certification process. The objective of the feedback form collection is to ensure the Certification Body to remain in constant improvement of its practices and processes, the same way the EU CCC Certification demands constant and continuous improvement and evolution from its Certified Centres.

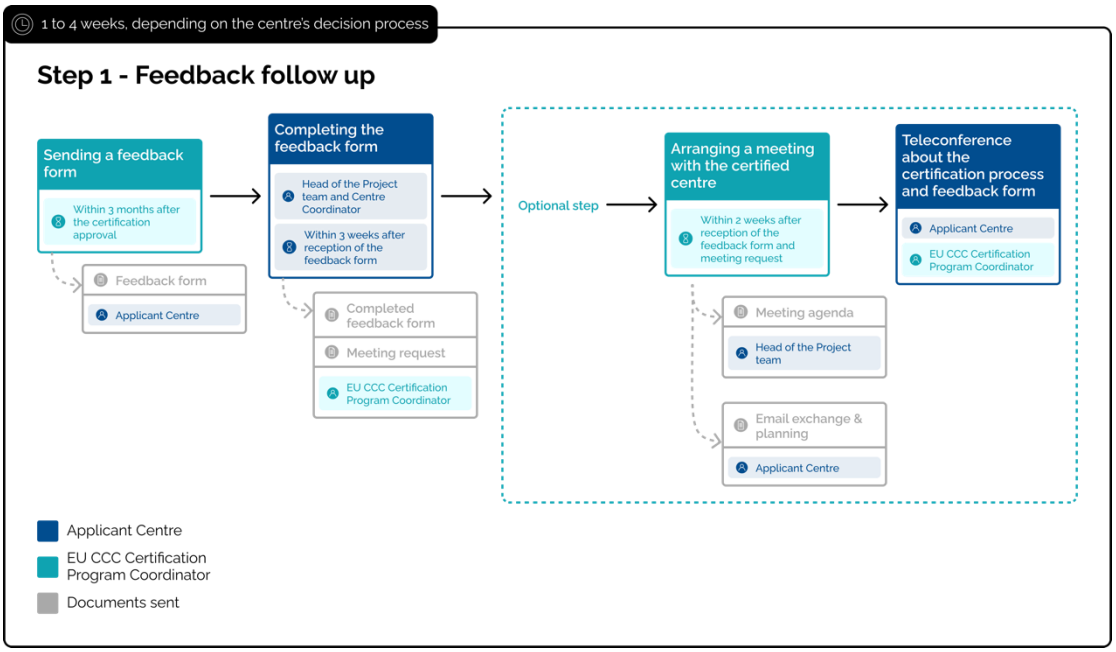

Figure IV-1 - Step 1: Feedback follow-up

Sending a feedback form	
EU CCC Certification Program Coordinator	Within 3 months after the certification approval
The EU CCC Certification Program Coordinator sends a feedback form to the Centre Coordinator and Head of the Project team of the now certified centre. The objective of this form is to allow the certification body to remain in constant improvement of its practices and processes. *[Content of the feedback form will be refined in the next Joint Action]*	
Feedback form: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	

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Completing the feedback form	
Head of the Project team and Centre Coordinator	Within 3 weeks after reception of the feedback form
The Head of the Project team and Centre Coordinator, complete the feedback form and sends it back to the coordinator through the e-tool. The Head of the Project team is encouraged to contact the members of the Project team and any other contributors in the certification process to gather their inputs. Finally, if the centre wishes to elaborate on their experience, they can request a meeting with the EU CCC Certification Program Coordinator.	
Completed feedback form: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*	
Meeting request: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*	

Optional steps below. If the Applicant Centre does not require a follow-up meeting, they will directly move to "Step 2: Progress report on the improvement plan".

Arranging a meeting with the certified centre	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the feedback form and meeting request
Upon the Centre Coordinator's request, the EU CCC Certification Program Coordinator will arrange a meeting with the certified centre to have a larger discussion regarding their certification process experience and the feedback form they have completed.	
Meeting agenda: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	
Email exchange & planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator.*	

Teleconference about the certification process and feedback form
Applicant Centre and EU CCC Certification Program Coordinator
During this optional meeting, the main speaker should remain the certified centre, as the Certification Organisation should benefit from the most honest feedback. Nonetheless, should the meeting need to be led by the EU CCC Certification Program Coordinator, the following topics can be discussed: • From an organisational and practical standpoint:

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- What is the centre's feedback and identified areas of improvement for future applicant or for their potential renewal?
- What did they like and would absolutely keep in the current certification process?

- Inputs regarding their use of the available documents, information and the e-tool:
  - Did they encounter any issue with the available resources? With the e-tool specifically?
  - What are the elements that were particularly useful and/or helpful for their experience?
- Regarding the criteria, standards and evaluation criteria:
  - Do they see any missing criteria that should pertain in the criteria and standards for the EU CCC Certification? (especially in time with medical and technological evolutions)
- Any elements from the feedback form that the EU CCC Certification Program Coordinator would like to elaborate.

3.26 Step 2: Progress report on the improvement plan

~ Estimated execution time: to the centre's discretion, within a year after the obtention of the EU CCC Certification~

In this second step, the Certified Centre starts working on the implementation of the improvement plan defined after the on-site audit. The Centre will have 12 months after the approval of their EU CCC Certification to work on their improvement points, prior to the submission of a progress report to their EU CCC Certification Program Coordinator.

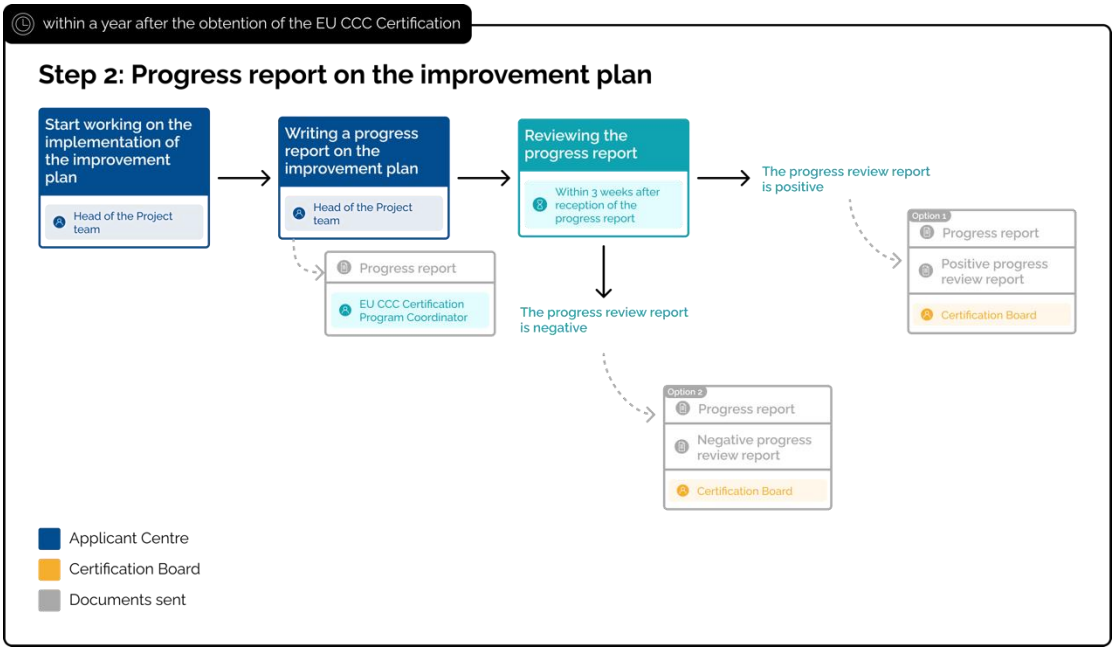

Figure IV-2 - Step 2: Progress report on the improvement plan

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Start working on the implementation of the improvement plan
Head of the Project team
Shortly after the granting of the EU CCC Certification, the Certified Centre should start working on the implementation of their improvement plan. It should be reminded to the centres that they have taken an engagement for the completion of said improvement plan, and that they will be required to report to the Certification Organisation regularly.

Writing a progress report on the improvement plan
Head of the Project team
Before the 12 months deadline, the Certified Centre should send a progress report on the implementation of their improvement plan to the Certification Organisation. The content of the progress report may depend on the centre's maturity and their improvement plan. Nonetheless, if necessary, the centre can find a report template on the e-tool. Once it is finalized, the Head of the Project team will submit the centre's progress report for the EU CCC Certification Program Coordinator.
Progress report: *sent through the e-tool, from the Head of the Project team to the EU CCC Certification Program Coordinator.*

Reviewing the progress report	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the progress report
Upon reception of the Certified Centre's progress report, the EU CCC Certification Program Coordinator will review the document, in comparison with the improvement plan they had previously engaged on. Following the review, the EU CCC Certification Program Coordinator should write a progress review report to the attention of the Certification Board. This review can either be positive or negative. The EU CCC Certification Program Coordinator reviews the progress report on the improvement plan submitted by the Certified Centre.	

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<u>Option 1: The progress review report is positive</u> If the progress review report is positive, it means that the EU CCC Certification Program Coordinator, through his review, judges as sufficient the amount and quality of improvements executed by the Centre. *<u>Option 2: The progress review report is negative</u>* If the progress review report is negative, it means that the EU CCC Certification Program Coordinator, through his review, judges as insufficient the amount and quality of improvements executed by the Centre.
Progress report: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
<u>Option 1:</u> • ***Positive progress review report:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
<u>Option 2:</u> • ***Negative progress review report:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

3.27 Step 3: Certification Board review of the progress report

~ Estimated execution time: 1 month~

In this step, the Certification Board will review the Certified Centre's progress report as well as the EU CCC Certification Program Coordinator's review. Depending on the Certification Board's final decision, the centre will either pursue a regular journey or will enter a probation period and be required to produce another progress report. The definition of the probation time's length is up to the Certification Board.

The 2nd progress report will be reviewed and evaluated like their first report. However, if the Centre does not meet the requirements after the second submission, sanctions may apply. The conditions and requirements will be refined in the next Joint Action EU Net CCC.

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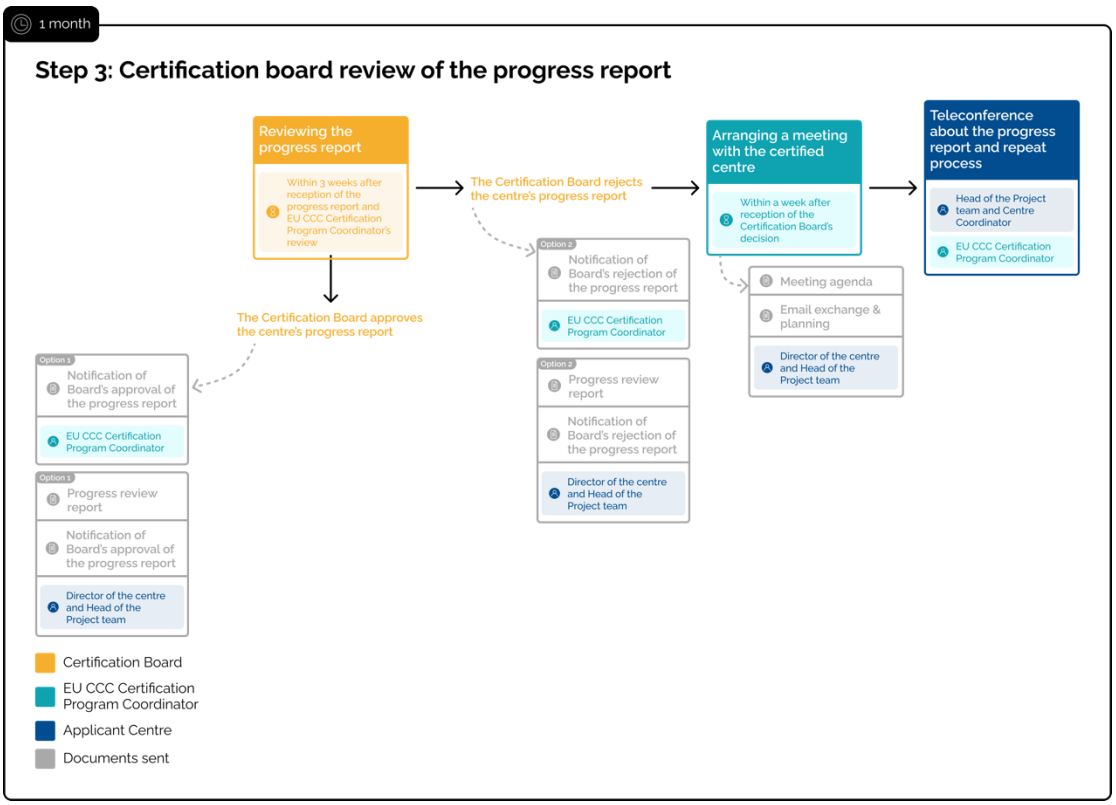

Figure IV-3 - Step 3: Certification Board review of the progress report

Reviewing the progress report	
Certification Board	Within 3 weeks after reception of the progress report and EU CCC Certification Program Coordinator's review

The Certification Board reviews the documents transferred by the coordinator. Following the review, the Certification Board will issue a decision.

Its decision can defer from the EU CCC Certification Program Coordinator's progress review report's advice and is left to the interpretation of the Certification Board.

Option 1: The Certification Board approves the centre's progress report

If the Certification Board approves the centre's progress report, it means that they accept the centre's progress report, judges as sufficient the amount and quality of improvements executed by the Centre and clears them the rest of their certification time.

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Option 2: The Certification Board rejects the centre's progress report If the Certification Board rejects the centre's progress report, it means that they do not accept the centre's progress report, judges as insufficient the amount and quality of improvements executed by the Centre and does not clear them for the rest of their certification time. The Certification Board will therefore give the centre a probation period of 12 months to implement the required improvements and submit another progress report. The length of the probation period is determined by the Certification Board and can be up to 12 months.
Progress review report: *sent through the e-tool, from the Certification Board to the Head of the Project team.*
Option 1: • ***Notification of Board's approval of the progress report:*** *sent through the e-tool, from the Certification Board to (1) the Head of the Project team and (2) the EU CCC Certification Program Coordinator.*
Option 2: • ***Notification of Board's rejection of the progress report:*** *sent through the e-tool, from the Certification Board to (1) the Head of the Project team and (2) the EU CCC Certification Program Coordinator.*

Arranging a meeting with the certified centre (option 2)	
EU CCC Certification Program Coordinator	Within a week after reception of the Certification Board's decision
Upon reception of a notification of Board's rejection of the progress report, the EU CCC Certification Program Coordinator will arrange a meeting with the Head of the Project team and Centre Coordinator to discuss their report and the improvements that need to be done during the probation period.	
Meeting agenda: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	
Email exchange & planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator.*	

Teleconference about the progress report and probation period (option 2)
Certified Centre and EU CCC Certification Program Coordinator
During this meeting, the EU CCC Certification Program Coordinator should go over the following topics with the Certified Centre:

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- The centre's progress report.
- The decision issued by the Certification Board.
- Their probation period and the expected improvements.

The EU CCC Certification Program Coordinator should be able to answer any questions from the centre to guide them through their probation period.

3.28 Step 4: Yearly updates and events

~ Estimated execution time: To the centre's discretion~

This step details on the one hand the yearly obligations of the centres to submit an annual report, as well as the content, documentation and events that will be proposed to them on a regular basis.

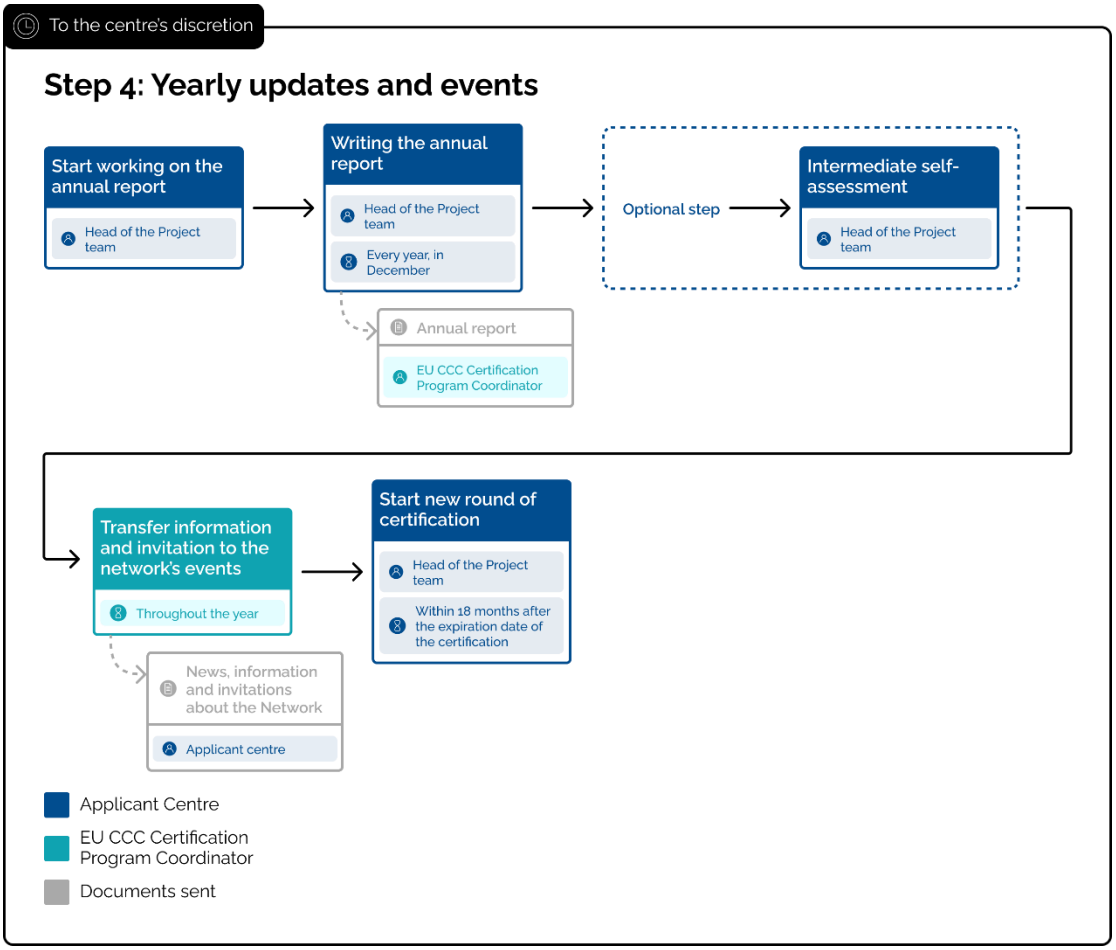

Figure IV-4 - Step 4: Yearly updates and events

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Start working on the annual report
Head of the Project team
Every year, the Certified Centre should work on an annual report. This annual report is more flexible in its structure than the progress report. The objective of the report is to allow EU Net CCC to communicate and have an overview of what the centres do and create interactions between them. This report should enhance collective continuous improvement and peer exchanges.

Writing the annual report	
Head of the Project team	Every year, in December
Before the deadline, the Certified Centre should send its annual report to the Certification Organisation. This report should mention: • Key figures and numbers from the Centre's year of action. • Completed or initiated actions from the Centre's improvement plan • Potential innovations, research project and initiatives, and other elements the centre should wish to share. The annual report's content may depend on the centre's maturity and their improvement plan. Finally, the template format for the annual report will be available in the e-tool. Even if the template format should be respected by every centre, the content can be modified at the centre's discretion, as long as it still contains the key requirements.	
Annual report: *sent through the e-tool, from the Applicant Centre to the EU CCC Certification Program Coordinator*	

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Optional step below. The execution of an intermediate self-assessment is left to the centre's discretion.

Intermediate self-assessment
Head of the Project team
During the 5 years of validity of their certification, the Certified Centre will still have access to the self-assessment template. In this regard, centres can decide to perform an intermediate self-assessment to evaluate their improvements based to the EU Net CCC criteria and standards. It is to be noted that the EU Net CCC criteria and standards will be reviewed periodically, to ensure the Certification integrates the medical and technical evolutions and maintains its relevance and quality of care.

Transfer information and invitation to the network's events	
EU CCC Certification Program Coordinator	Throughout the year
Regularly, the EU CCC Certification Program Coordinator will communicate with the Certified Centre to share information, news and events about the Network. These will ensure a link between certified centres and contribute to the interest and collective improvement of the whole network.	
News, information and invitations about the Network: *sent through e-mail, from the EU CCC Certification Program Coordinator to the Head of the Project team.*	

Start new round of certification	
Applicant Centre	Within 18 months after the expiration date of the certification
At the end of the certificate validity period, the Centre should start a new round of certification, within 18 months after the expiration date of the Certification. If the Centre does not meet this deadline, they should undergo the full initial certification process.	

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V. Detail of the renewal process

3.29 Step 1: Preparation and completion of the application renewal form

~ Estimated execution time: To centre's discretion~

In this step, the Applicant Centre should only verify its profile information in the e-tool and will then directly proceed to the completion of its application renewal form.

This step is dealt within the centre and does not involve any interactions.

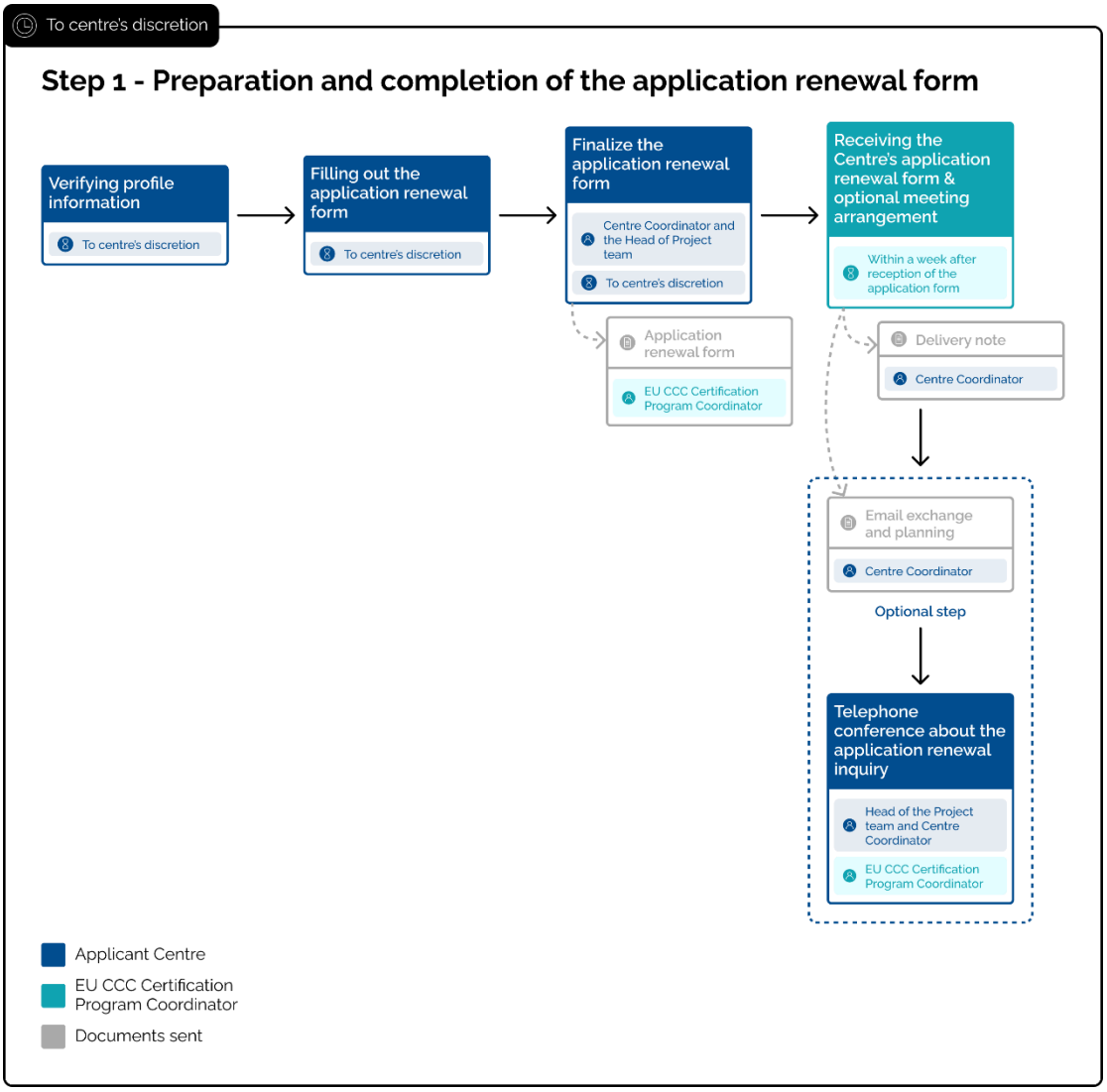

Figure V-1 - Step 1: Preparation and completion of the application renewal form

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Verifying profile information	
Centre Coordinator	To centre's discretion
The Applicant Centre connects to its account on the EU CCC Certification Program e-tool. If they forgot their login information, they should follow the recovering password process. *[The process should be defined and included here].* Once they are logged in, they can verify their information and correct and/or complete them.	

Filling out the application renewal form	
Centre Coordinator and Head of the Project team	To centre's discretion
The Centre Coordinator starts completing the application renewal form on the EU CCC Certification Program e-tool. *The questions, mandatory information and required documents to provide are yet to be determined.*	

Finalize the application renewal form	
Centre Coordinator and Head of the Project team	To centre's discretion
Once the centre finalized the application renewal form, the Centre Coordinator will validate it on the e-tool. Before validation, the Applicant Centre should verify that: • All questions have been answered. • All mandatory documents have been added to the application form. The application renewal form will be automatically submitted to the EU CCC Certification Program Coordinator.	
Application renewal form: *sent through the e-tool, from the* Centre Coordinator *to the EU CCC Certification Program Coordinator*	

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Receiving the Centre's Application renewal form & optional meeting arrangement	
EU CCC Certification Program Coordinator	Within a week after reception of the application renewal form
Upon reception of the centre's application renewal form, the EU CCC Certification Program Coordinator will send a delivery note to the Centre Coordinator. In addition, and upon the centre's request, the EU CCC Certification Coordinator can arrange a telephone call with them to ensure they have properly understood the upcoming steps for the application renewal.	
Delivery note: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the* Centre Coordinator.	
Email exchange and planning (optional): *from the EU CCC Certification Program Coordinator to the Centre Coordinator*	

Optional step below, left to the centre's discretion.

Telephone conference about the application renewal inquiry
EU CCC Certification Program Coordinator, Centre Coordinator and Head of the Project team of the Applicant Centre
The EU CCC Certification Program Coordinator, the Centre Coordinator and the Head of the Project team participate in a call to validate the submission of the application renewal form and discuss the upcoming steps for the renewal of the centre's certification.

3.30 Step 2: Initial review

~ Estimated execution time: 2 weeks ~

The initial review of the application renewal form is used to evaluate the readiness of the centre for full accomplishment of the certification renewal process. It allows the EU CCC Certification Program coordinator to identify the gaps the Applicant Centre faces to meet the initial requirements.

The initial review can either be positive or negative. In both cases, the EU CCC Certification Program Coordinator will issue an advice and a report for the Certification Board.

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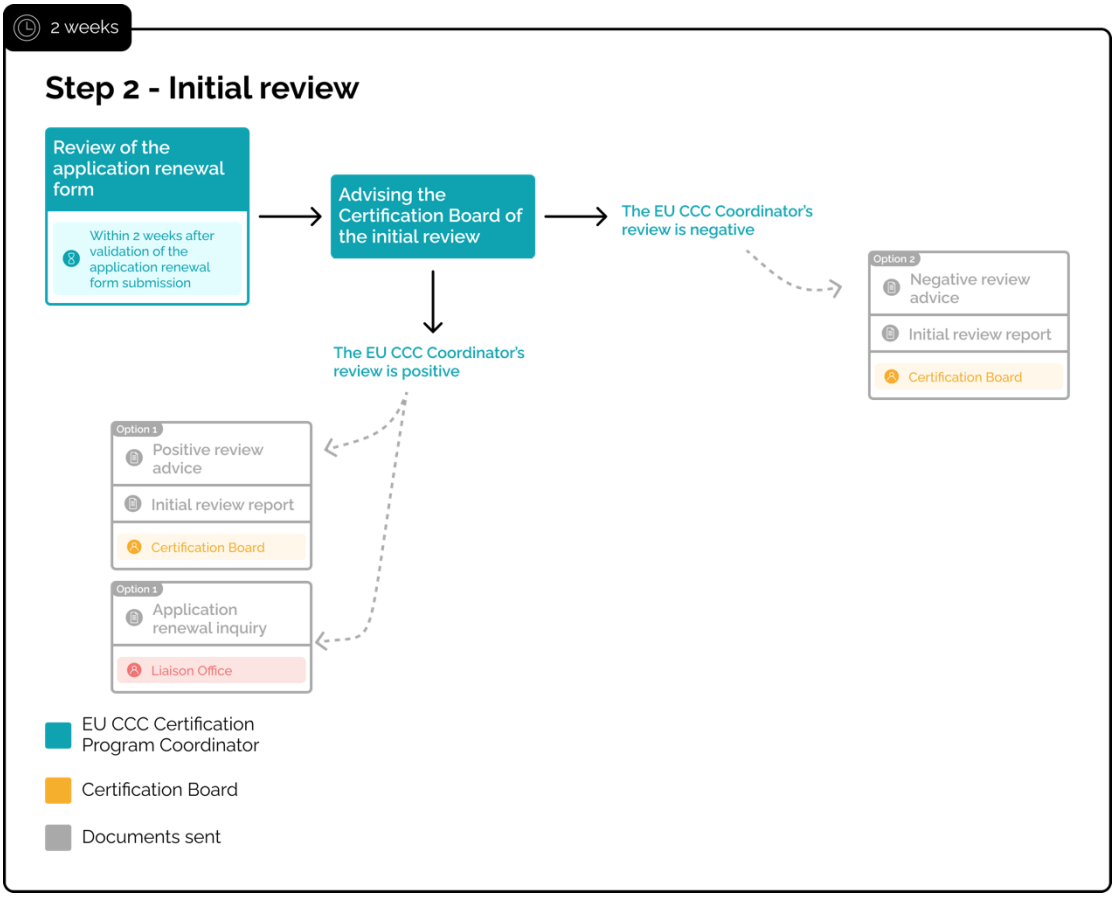

Figure V-2 - Step 2: Initial review

Review of the application renewal form	
EU CCC Certification Program Coordinator	Within 2 weeks after validation of the application renewal form submission

The EU CCC Certification Program Coordinator reviews the application renewal form to evaluate the readiness of the centre for full accomplishment of the certification renewal process. This step is meant to allow the coordinator to identify the gaps the centre faces to meet the initial requirements.

Option 1: The review is positive

If the initial review of the application renewal form is positive, it means that the Applicant Centre's meets the initial requirements to undergo the full certification renewal process.

Option 2: The review is negative

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If the initial review of the application renewal form is negative, it means that the Applicant Centre's is yet to meet some of the requirements to undergo the full certification renewal process.

Advising the Certification Board of the initial review
EU CCC Certification Program Coordinator
Depending on the outcome of the initial review, the EU CCC Certification Program Coordinator will notify and advise the Certification Board with an initial review report and either a positive review advice (*option 1*) or a negative review advice (*option 2*). As it is an inquiry for the renewal of the certification, the EU CCC Certification Program Coordinator will directly notify the Liaison Office so that they can start working on the contract proposal.
Initial review report: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
Application renewal inquiry: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Liaison Office.*
Option 1: • ***Positive review advice:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
Option 2: • ***Negative review advice:*** *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

3.31 Step 3: Application examination

~ Estimated execution time: 2 to 4 weeks ~

Based on the elements the Certification board received from the EU CCC Certification Program Coordinator, they will either provide a favourable or unfavourable opinion on the Applicant Centre's application renewal.

Then, the EU CCC Certification Program Coordinator will write a notification for the Centre Coordinator and discuss the results over a telephone conference with them.

This call should also be used to discuss the improvements the Applicant Centre needs to make to be able to successfully complete the process. As it is the certification renewal process, regardless of the Certification Board's opinion, the Applicant Centre will be allowed to go on with the rest of the process.

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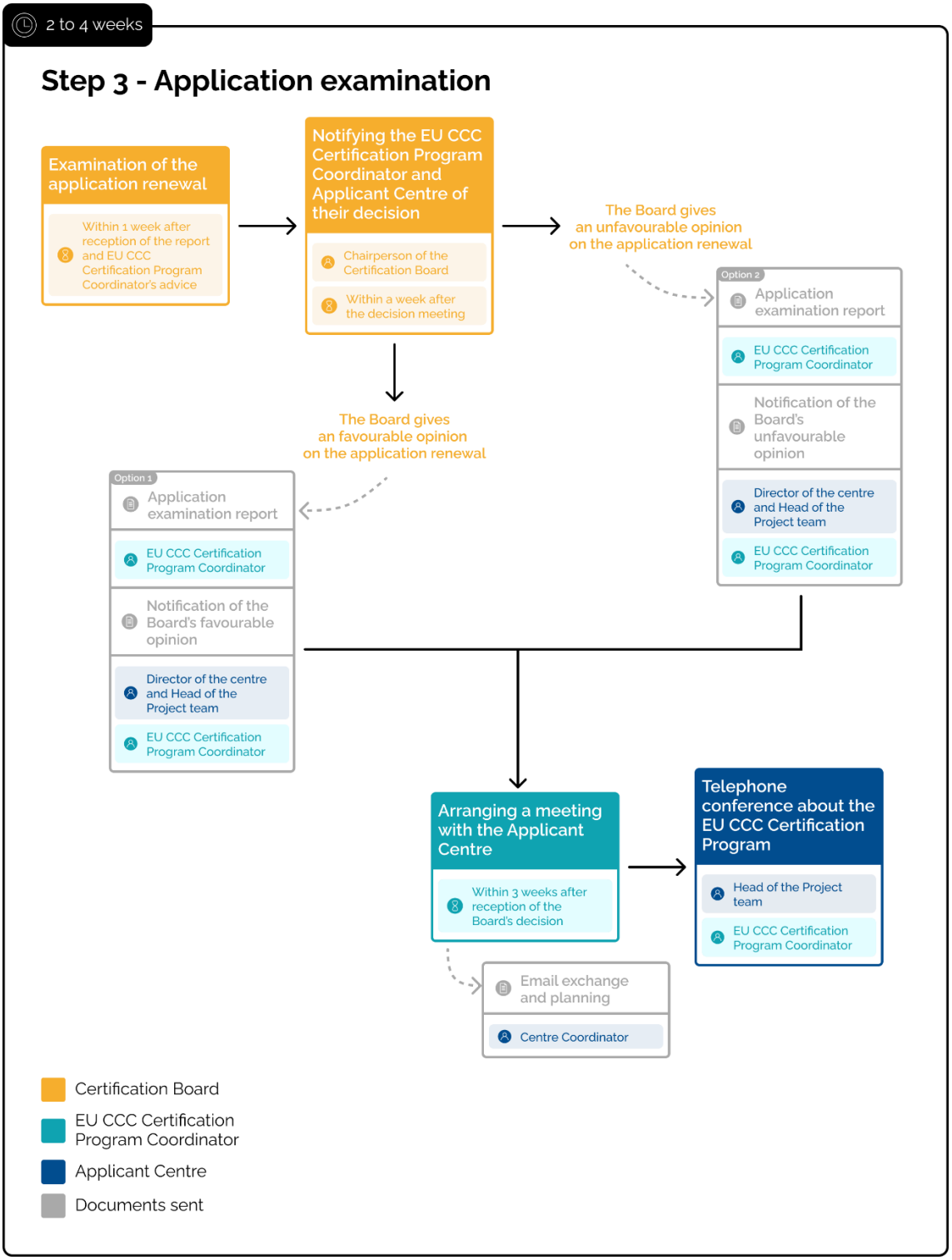

Figure V-3 - Step 3: Application examination

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Examination of the application renewal	
Certification Board	Within a week after reception of the report and EU CCC Certification Program Coordinator's advice

The Board examines the EU CCC Certification Program Coordinator's initial review report and its associated advice to give an opinion on the ability or inability for the centre to preserve the certification.

Its opinion can defer from the EU CCC Certification Program Coordinator's advice and is left to the interpretation of the Certification Board.

As it is an inquiry for the renewal of the certification the Certification Board gives an opinion, meaning that it is informative, not eliminatory.

Option 1: Favourable opinion on the application renewal

The Board gives a favourable opinion on the application submitted by the Applicant Centre.

This means that they believe the Applicant Centre has a high probability of obtaining the renewal of its certification.

Option 2: Unfavourable opinion on the application renewal

The Board gives an unfavourable opinion on the application submitted by the Applicant Centre.

This means that the Applicant Centre has a significant probability of not obtaining the renewal of its certification.

Notifying the EU CCC Certification Program Coordinator and Applicant Centre of their decision	
Chairperson of the Certification Board	Within a week after the decision meeting.

Depending on the outcome of the Board's examination of the application, the Chairperson of the Certification Board will notify and advise the EU CCC Certification Program Coordinator with an application examination report and either a notification of the Board's favourable opinion for the renewal of the certification (*option 1*) or a notification of the Board's unfavourable opinion for the renewal of the certification (*option 2*).

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As it is an inquiry for the renewal of the certification, the Certification Board will also directly notify the Applicant Centre's Coordinator.
Application examination report: *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to the EU CCC Certification Program Coordinator.*
Option 1: • ***Notification of the Board's favourable opinion:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the EU CCC Certification Program Coordinator and (2) the Director of the centre and the Head of the Project team.*
Option 2: • ***Notification of the Board's unfavourable opinion:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the EU CCC Certification Program Coordinator and (2) the Director of the centre and the Head of the Project team.*

Arranging a meeting with the Applicant Centre	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the Board's opinion
Regardless of the Certification Board's decision, the coordinator arranges an appointment with the Centre Coordinator.	
Email exchange and planning: *from the EU CCC Certification Program Coordinator to the Centre Coordinator.*	

Telephone conference about the EU CCC Certification Renewal Program
EU CCC Certification Program Coordinator, Centre Coordinator and Head of the Project team of the Applicant Centre
Regardless of the Certification Board's decision, the EU CCC Certification Program Coordinator and the Head of the Project team will have a meeting. They participate in a telephone conference and discuss the following topics: • The Certification Program and the potential evolutions that occurred since their initial or previous certification. • The planning and organisation of the certification renewal process (next steps). • The improvements and development the centre will have to tackle, based on the Certification Board's report.

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3.32 Step 4: Contractualisation and Payment

~ Estimated execution time: one month~

This step, mostly administrative, involve the Liaison Office and the Applicant Centre. These steps will be refined in the next Joint Action, as it was determined that the EU Net CCC Certification Program will require a payment, but the person or organisation responsible for payment has not yet been identified, nor have the basis for the contract and contractors.

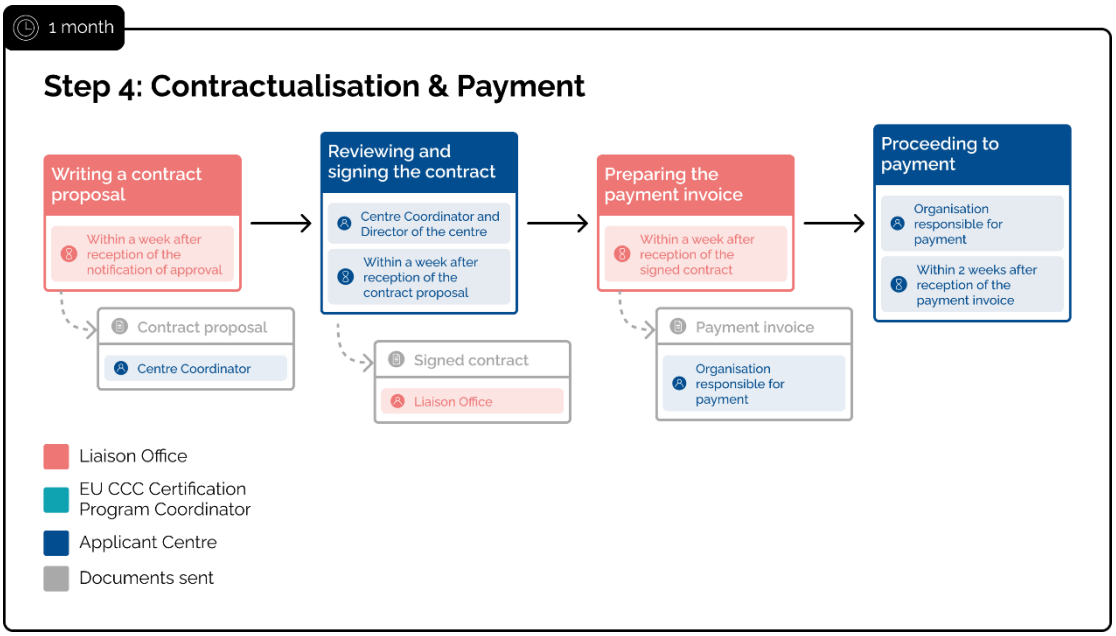

Figure V-4 - Step 4: Contractualisation and Payment

Writing a contract proposal	
Liaison Office	Within a week after reception of the notification of approval
Following the reception of the application renewal inquiry[22], the Liaison Office writes a contract proposal for the Applicant Centre. This contract is based on the general standard contract that is publicly accessible, amended with the specific information pertaining to the Applicant Centre. The terms of the contract contain the commitments the centre agrees to when entering the Certification Program and the following process. Once it is finalized, the Liaison Office can send the contract proposal to the Centre Coordinator.	
Contract proposal: *sent through the e-tool, from the Liaison Office to the Centre Coordinator.*	

[22] See Step 2: Initial review, *Advising the Certification Board of the initial review*.

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Reviewing and signing the contract	
Centre Coordinator and Director of the centre	Within a week after reception of the contract proposal
Following the reception of the contract, the Applicant Centre proceeds to the review and signature of the contract. In the eventuality of questions, the Applicant Centre can contact the EU CCC Certification Program Coordinator or use the help system included in the Program's e-tool. Once the centre finalized the review and signed the contract, they will send it back to the Liaison Office.	
Signed contract: *sent through the e-tool, thanks to digital signature from the Centre Coordinator to the Liaison Office.*	

Preparing the payment invoice	
Liaison Office	Within a week after reception of the signed contract
After reception of the signed contract from the Applicant Centre, the Liaison Office will prepare and send a payment invoice to *the organisation responsible for payment*	
Payment invoice: *sent through the e-tool or email, from the Liaison Office to the organisation responsible for payment.*	

Proceeding to payment	
Organisation responsible for payment	Within 2 weeks after reception of the payment invoice
Following the reception of the invoice, the organisation responsible for payment will proceed to pay the fees indicated in the invoice. This action will allow the centre to move on to the next steps of the process.	

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3.33 Step 5: Core team set-up and planning

~ Estimated execution time: 2 to 4 weeks ~

In this step, the Centre Coordinator and Head of the Project team meet will start preparing for the self-assessment.

At this stage, the Applicant Centre should therefore compose a core Project team, organize, plan and structure their work to ensure the proper execution of the process. Since it is a certification renewal, it is likely the Applicant Centre will already have a pre-identified Project Team. Nonetheless, they should not neglect the potential evolutions that could have occurred in the certification process and the assessed criteria for example, and therefore will need to make sure their team is composed of the rights experts and contributors.

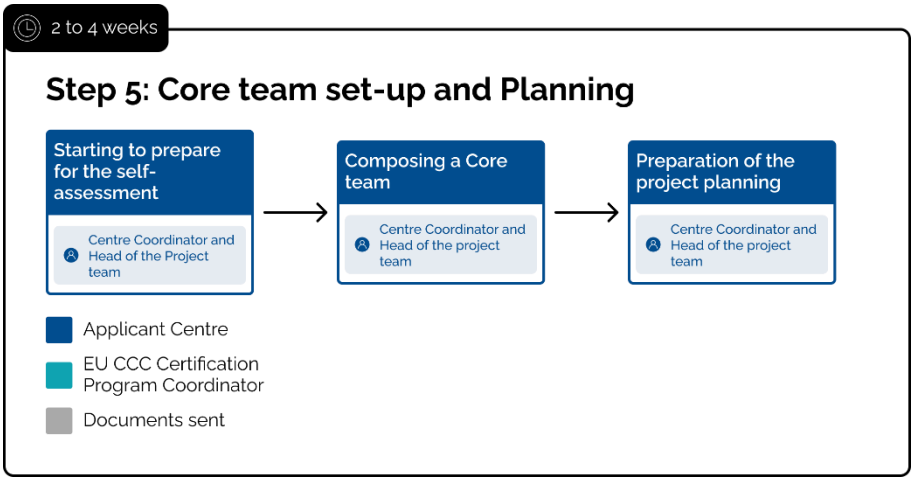

Figure V-5 - Step 5: Core team set-up and planning

Starting to prepare for the self-assessment
Centre Coordinator and Head of the Project team
The Applicant Centre starts preparing for the upcoming steps thanks to the information available on the e-tool. They should particularly be aware of the following resources: • List of Criteria and Standards • Glossary • Additional information notice • List of evidence

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Composing a Core team
Centre Coordinator and Head of the Project team
The Centre Coordinator and Head of the Project team work on the composition of a Core team in their cancer centre/institute. The Core team should be composed of the people who will be leading the certification process and coordination alongside the Head of the Project team and Centre Coordinator.

Preparation of the project planning
Centre Coordinator and Head of the Project team
The Centre Coordinator and the Head of the Project team should oversee the project planning. Hence, they should notably: • Set meetings to follow the progress on the forms' completion. • Define a concrete schedule and deadlines. • Set up a timeline and methodology to ensure the centre's staff (i.e. Core team and other contributors) is involved in the Certification process. • Identify experts and other contributors. • Anything the centre identifies as necessary for its internal organisation.

3.34 Step 6: Detailed self-assessment

~ Estimated execution time:1 to 2 months ~

The self-assessment period is dedicated to the Applicant Centre. During this step, they will fill out the required forms, provide any required documents and work on non-compliances and improvement points. Once the centre is ready, they will submit a draft version of the self-assessment to the EU CCC Certification Program Coordinator through the e-tool.

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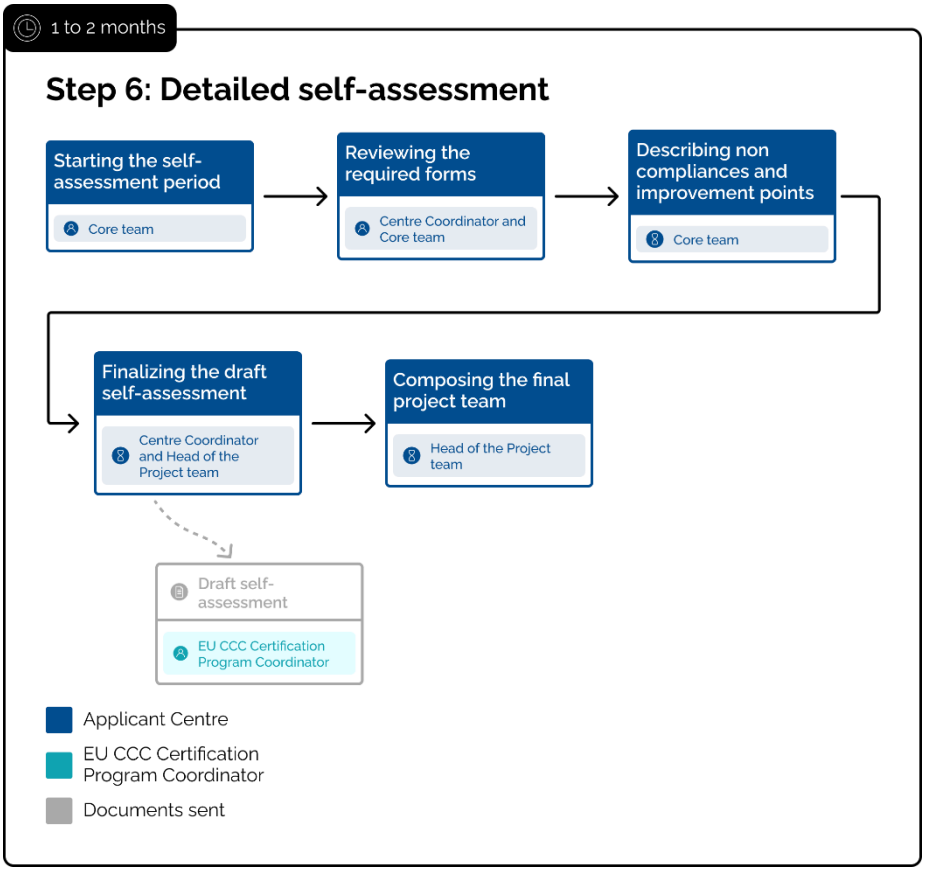

Figure V-6 - Step 6: Detailed self-assessment

Starting the self-assessment period
Core team
The Applicant Centre starts its self-assessment period and checks the information and requirement on the e-tool. All the forms can be completed in the e-tool. Documents, responding to the eligible formats, can also be uploaded directly in the e-tool and associated to their related criteria, standards or additional question. At this stage, it is essential to ensure all the members of the Core team are fully involved in the process, to facilitate the completion of the self-assessment and ensure the reliability of all the answers and documents provided by the centre.

Reviewing the required forms
Centre Coordinator and Core team
The Applicant Centre starts reviewing and completing the forms in the e-tool. They are required to make notes and comments to explain their scores and answers, in line with the recommended lines for evidence. If necessary, they can be asked to provide documents to justify their answers.

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Finally, the Applicant Centre must attach all the required documents to their self-assessment. [*The list of evidence is yet to be defined. It will depend on the criteria, standards and additional information documents.]*

Describing non compliances and improvement points

Core team

The Applicant Centre must describe the potential non-compliances and improvement points in the e-tool.

By improvement points, we imply all the complementary information the centre may provide to justify their answer or score to one or several of the criteria, standard, or additional information.

For instance, if a centre answered 'partly' to one of the items but is currently implementing an internal plan or improvement strategy, this should be mentioned and justified using the related evidence in this part.

Similarly, if the data used in the additional information document is dated and the numbers have significantly evolved, this should be described and justified in this part.

These descriptions and additional justifications will be used to build the improvement plan and transferred to the Audit team prior to the on-site audit.

Finalizing the draft self-assessment

Centre Coordinator and Head of the Project team

The Applicant Centre reviews the self-assessment forms and documents before submission. They must ensure all the questions have been properly answered and all the required documents have been uploaded in the right categories.

The e-tool should also give them indications of the questions that may require further elaboration, or areas of mis completion to facilitate their review.

Draft self-assessment: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

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Composing the final project team
Head of the Project team
The Head of the Project team and Centre Coordinator compose the final Project team. This team's composition should respond to the on-site audit's requirements and involve people who will be able to and should contribute to the completion of the self-assessment and to the on-site audit.

3.35 Step 6.2: Composing and preparing the Audit team

~ Estimated execution time: 6 weeks~

→ Step 6.2 is part of the preparation of the on-site audit and should be executed around the self-assessment step.

In this step, the EU CCC Certification Program Coordinator will work on the composition of the Audit team and make sure there are no conflicts of interests between the chosen team and the Applicant Centre.

Even if it the on-site audit is for a renewal of the certification, a new audit team should be appointed to ensure complete impartiality. However, the new audit team should have access to the notes and report from the initial application, as it may facilitate their understanding of the centre's evolutions.

This step should be initiated about 4months before the on-site audit, based on the Applicant Centre's level of self-assessment.

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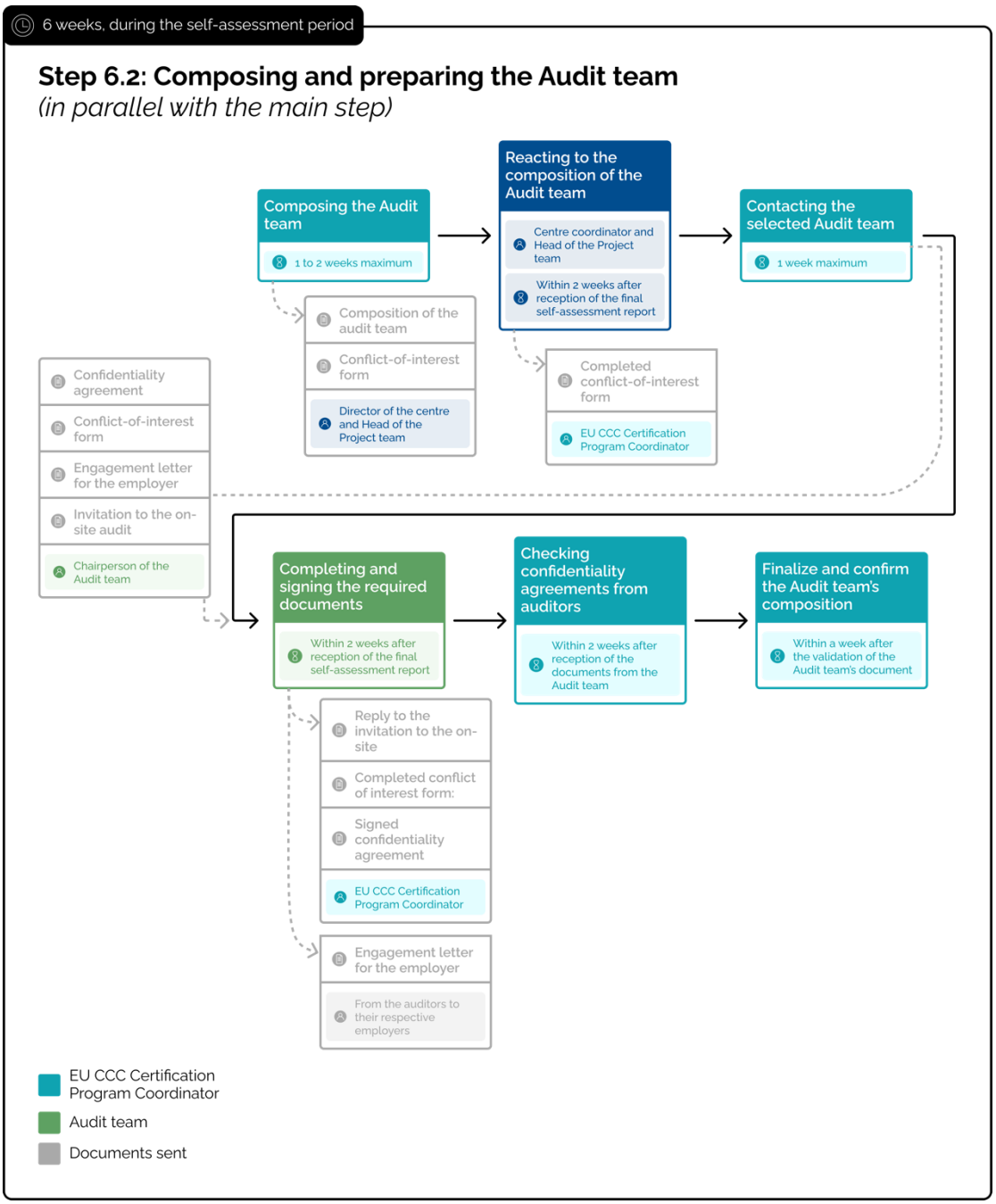

Figure V-7 - Step 6.2: Composing and preparing the Audit team

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Composing the Audit team	
EU CCC Certification Program Coordinator	1 to 2 weeks maximum
The EU CCC Certification Program Coordinator composes the Audit team for the on-site audit of the Applicant Centre. The Audit team should be composed of peers. The composition of the team should therefore be arranged to cover all the areas of expertise and of analysis demanded for the on-site audit and the assessment of the centre on the required Criteria and Standards of the EU CCC Certification.	
Composition of the Audit team: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	
Conflict-of-interest form: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	

Reacting to the composition of the Audit team	
Centre Coordinator and Head of the Project team	Within 2 weeks after reception of the Audit team composition
The Centre Coordinator and Head of the Project team can, if necessary, express any potential conflict of interest against one or more of the Audit team members. To do so, the Applicant Centre should complete the conflict-of-interest form associated to the list of the Audit team members that they received in the e-tool.	
Completed conflict of interest form: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator*	

Contacting the selected Audit team	
EU CCC Certification Program Coordinator	A week maximum
The EU CCC Certification Program Coordinator prepares the invitation for the Audit team, as well as all the documents they will need to fill before the on-site audit: • Confidentiality agreement. • Conflict-of-interest form. • Engagement letter for the employer.	
Confidentiality agreement: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Conflict-of-interest form: *sent through the e-tool from the EU CCC Certification Program Coordinator to the Audit team.*	
Engagement letter for the employer: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	

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Invitation to the on-site audit: *from the EU CCC Certification Program Coordinator to the Audit team.*

Completing and signing the required documents	
Audit team	Within 2 weeks after reception of the documents
The members of the Audit team received an invitation to take part in a certification process. If they accept the invitation, they should complete and sign all the documents sent by the EU CCC Certification Program Coordinator.	
Reply to the invitation to the on-site audit: *from the Audit team to the EU CCC Certification Program Coordinator.*	
Completed conflict of interest form: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*	
Signed confidentiality agreement: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*	
Engagement letter for the employer: *from the Audit team to their respective employers.*	

Checking confidentiality agreements from auditors	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the documents from the Audit team
The EU CCC Certification Program Coordinator checks that the documents received from the Audit team were carefully completed and signed. If some of the documents were mis-completed or mis-signed, the EU CCC Certification Program Coordinator should contact the Audit team members as soon as possible to validate this step.	

Finalize and confirm the Audit team's composition	
EU CCC Certification Program Coordinator	Within a week after the validation of the Audit team's document
The EU CCC Certification Program Coordinator verifies that there is not any conflict of interests between the Applicant Centre and the elected Audit team members to finalize the composition of the team and initiate the next preparation step.	

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3.36 Step 7: Progress monitoring

~ *Estimated execution time:* 2 to 8 weeks, depending on the centre's choice to ask for a pre-visit ~

This step has two main goals. The first one is to review and assess the centre's self-assessment to identify areas for improvement and send them to the Applicant Centre before the finalisation.

The second one is an optional pre-visit of the centre by the EU CCC Certification Program Coordinator and Chairperson of the Audit team, before the submission from the centre of the final self-assessment.

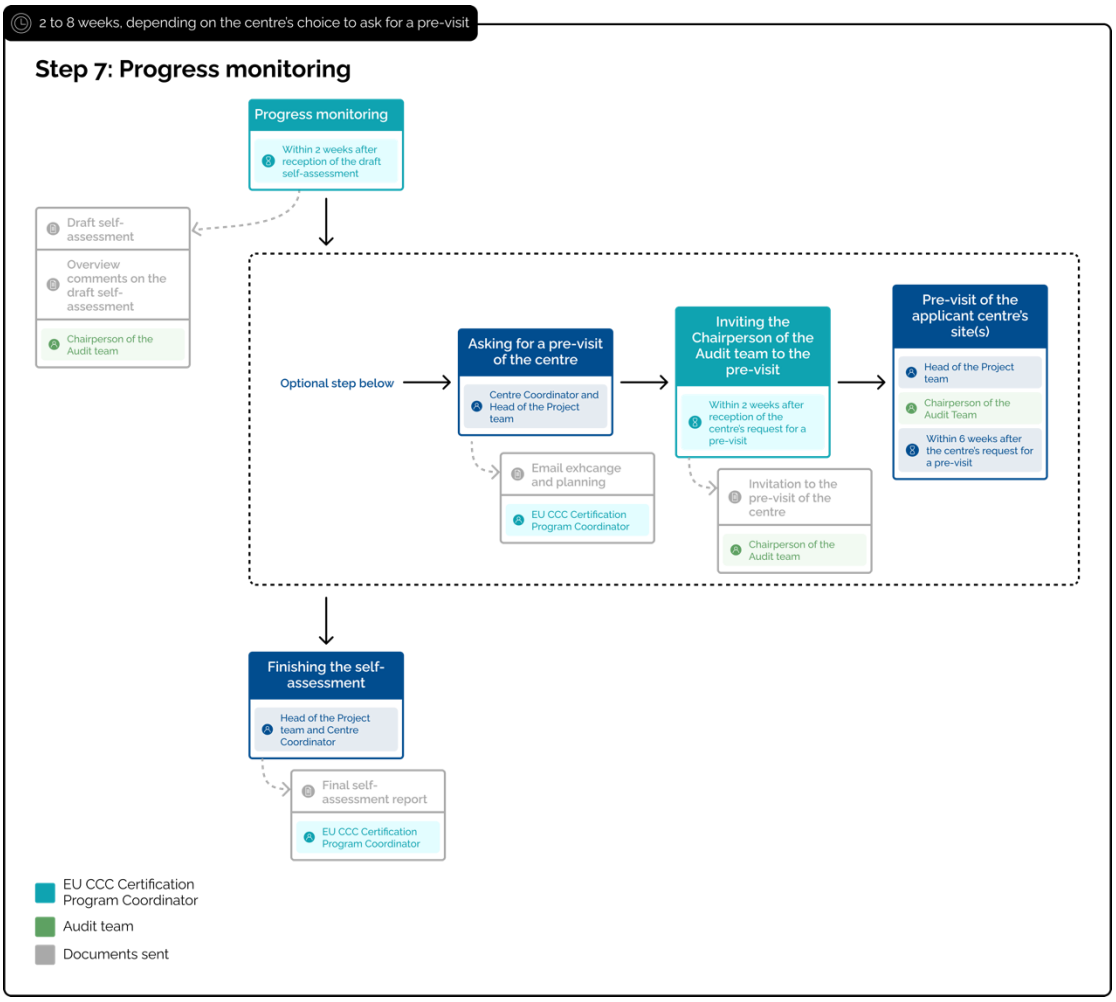

Figure V-8 - Step 7: Progress monitoring

Progress monitoring	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the draft self-assessment
The EU CCC Certification Program Coordinator reviews the draft self-assessment and produces a list of overview comments. It is to be noted that this review should be technical, hence, made to identify any technical	

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deficiencies in the self-assessment, or information that can be further elaborated before the final submission. This review is not meant to identify improvements points within the centre's organisation, or current capacities based on their answers in the forms. The draft self-assessment, as well as the EU CCC Certification Program Coordinator's comments will be transferred to the Chairperson of the Audit team
Draft self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*
Overview comments on the draft self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*

Optional steps below. If the Applicant Centre does not require a pre-visit, they will directly move to the 'Finishing the self-assessment step'.

Asking for a pre-visit of the centre
Centre Coordinator and Head of the Project team
The Head of the Project team and the Centre Coordinator can ask for an appointment with the EU CCC Certification Program Coordinator to request a pre-visit of their centre before finalizing the self-assessment.
Email exchange and planning: *from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

Inviting the Chairperson of the Audit team to the pre-visit	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the centre's request for a pre-visit
Upon reception of the Applicant Centre's request, the EU CCC Certification Program Coordinator sends an invitation to the Chairperson of the Audit team, to invite them to the pre-visit of the Applicant Centre's site(s).	
Invitation to the pre-visit of the centre: *from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

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Pre-visit of the Applicant Centre's site(s)	
EU CCC Certification Program Coordinator, Head of the Project team, Chairperson of the Audit team	Within 6 weeks after the centre's request for a pre-visit
The EU CCC Certification Program Coordinator, the Chairperson of the Audit team and the Head of the Project team meet for a pre-visit of the centre. This pre-visit can be useful for in person support during the self-assessment period and in some cases to manage the centre's expectations regarding the certification obtention. At the end of the pre-visit, the Head of the Project should have a moment of debriefing with the EU CCC Certification Program Coordinator and the Chairperson of the Audit team. This debriefing should help the Head of the project gather all the necessary inputs before the finalisation of the Applicant Centre's self-assessment. The costs of the visit should be covered by the centre.	

Finishing the self-assessment
Head of the Project team and Centre Coordinator
Upon the feedback received in the progress monitoring review and the optional pre-visit, the Head of the Project team and Centre Coordinator will amend and finalize the self-assessment in the e-tool. Once they have checked all the information, forms and documents, they can validate the self-assessment and submit it directly on the e-tool.
Final self-assessment report: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

3.37 Step 7.2: Composing the on-site audit agenda

~ Estimated execution time: 2months ~

→ Step 7.2 is part of the preparation of the on-site audit and should be executed around the progress monitoring step.

Following the composition and validation of the Audit team, the EU CCC Certification Program Coordinator will work on a draft agenda for the on-site audit in collaboration with the Chairperson of the Audit team.

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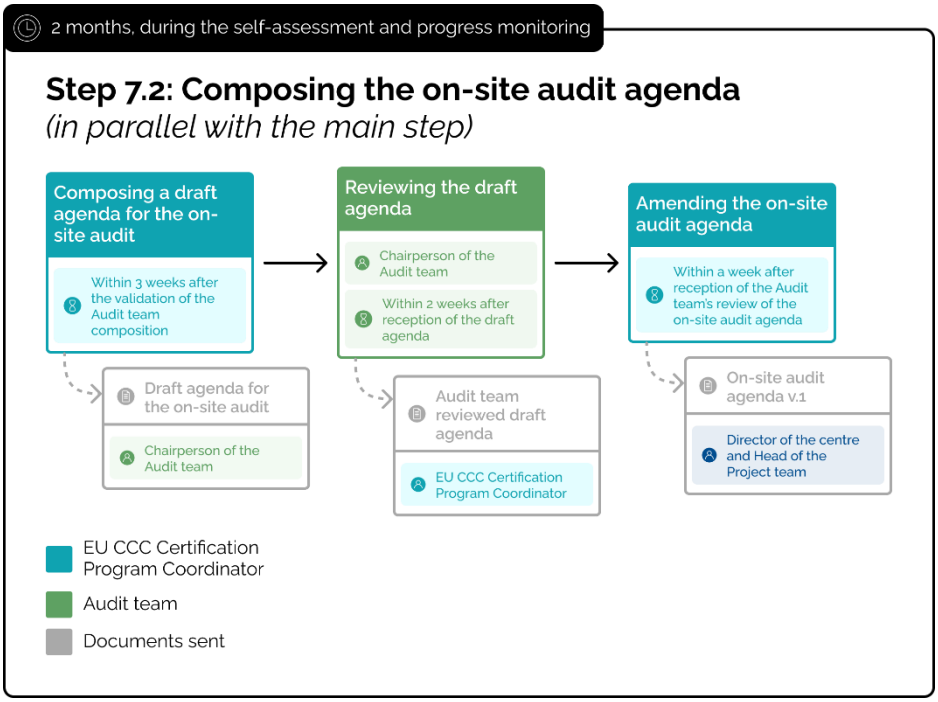

Figure V-9- Step 7.2: Composing the on-site audit agenda

Composing a draft agenda for the on-site audit	
EU CCC Certification Program Coordinator	Within 3 weeks after the validation of the Audit team composition
The EU CCC Certification Program Coordinator starts a draft agenda for the on-site audit. The agenda will be based on a template agenda, which they will be to access in the e-tool.	
Draft agenda for the on-site audit: *sent through the e-tool, from the EU CCC Certification Program to the Chairperson of the Audit team.*	

Reviewing the draft agenda	
Chairperson of the Audit team	Within 2 weeks after reception of the draft agenda
Upon reception of the draft agenda for the on-site audit, the Chairperson of the Audit team will review the agenda and amend it, if necessary, before sending back his comments and approval to the EU CCC Certification Program Coordinator.	
Audit team reviewed draft agenda: *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	

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Amending the on-site audit agenda	
EU CCC Certification Program Coordinator	Within a week after reception of the Audit team's review of the on-site audit agenda.
Upon reception of the Chairperson of the Audit team's review of the draft agenda, the EU CCC Certification Program Coordinator will, if necessary, amend the agenda, before sending a first version to the Head of the Project team and the Centre Coordinator.	
On-site audit agenda v.1: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team and Centre Coordinator.*	

3.38 Step 8: Final Go/No go decision

~ Estimated execution time: 6 to 8 weeks ~

Following the reception of the final self-assessment, the EU CCC Certification Program Coordinator will review and issue some advice for the Certification Board.

The Certification Board will discuss the self-assessment and notify the Head of the Project team of the Applicant Centre and the EU CCC Certification Program Coordinator with a go or a no-go decision, based on the rightful completion of the self-assessment and presence of appropriate evidence for the on-site audit.

The Applicant Centre will then be in contact with the EU CCC Certification Program Coordinator to discuss the next steps, including a second payment stage.

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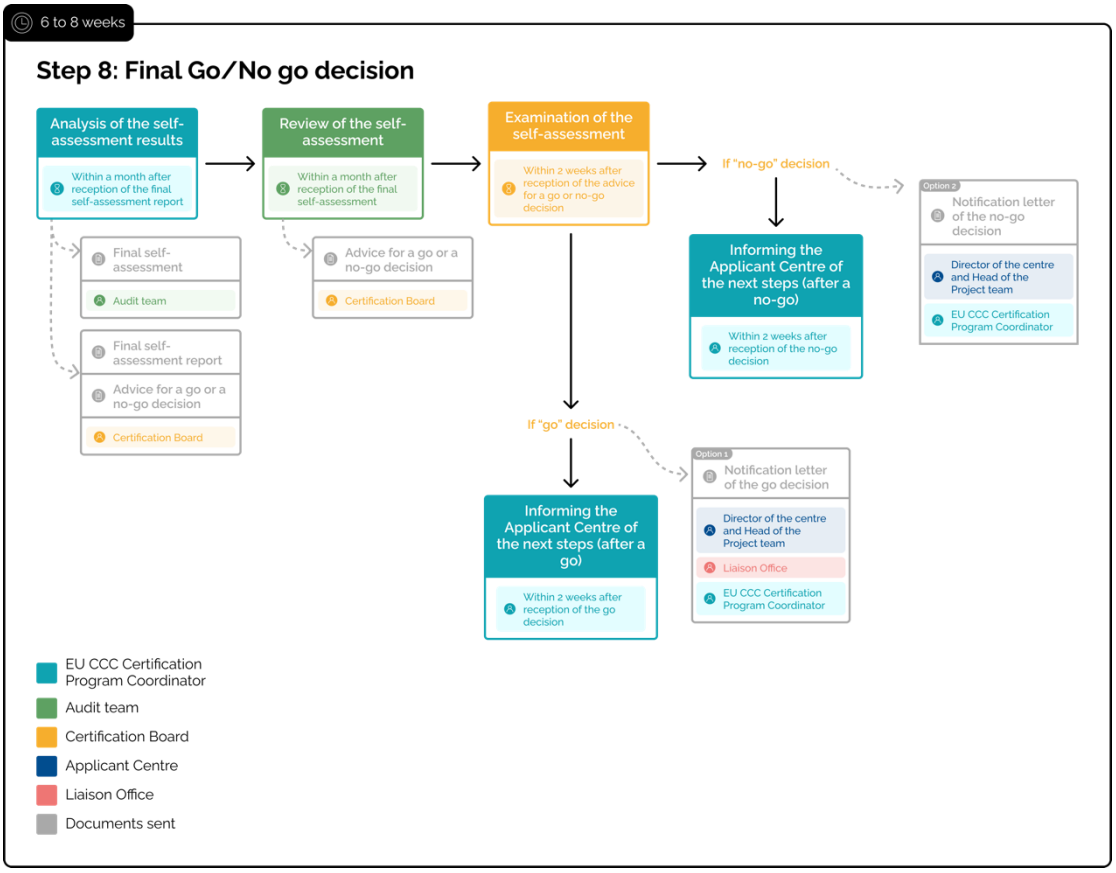

Figure V-10 - Step 8: Final Go/No go decision

Analysis of the self-assessment results	
EU CCC Certification Program Coordinator	Within a month after reception of the final self-assessment report

The EU CCC Certification Program Coordinator analyses and examines the final self-assessment report before the on-site audit.

This analysis should be carried on in the e-tool, as it will provide the EU CCC Certification Program Coordinator with a pre-analysis of the results. Then, they should review the notes, comments and elements that could not be automatically verified by the e-tool.

Upon reception and after a preliminary verification, the EU CCC Certification Program Coordinator should transfer the final self-assessment report to the Audit team.

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Once they have finalized their review and analysis, the EU CCC Certification Program Coordinator will issue some advice for a go or a no-go decision and send it to the Certification Board.
Final self-assessment: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*
Final self-assessment report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Certification Board.*
Advice for a go or a no-go decision: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

Review of the self-assessment	
Audit team	Within a month after reception of the final self-assessment
The Audit team reviews the self-assessment to submit some advice to the board before their go- or no-go decision. This review should be carried on in the e-tool, as it will provide the auditors with a pre-analysis of the results and particularly focus on the elements and documents they will need to prepare their on-site audit. Once they have finalized their review and analysis, the Chairperson of the Audit team will issue some advice for a go or a no-go decision and send it to the Certification Board.	
Advice for a go or a no-go decision: *sent through official communication channels of the Certification Organisation, from the Audit team to the Certification Board.*	

Examination of the self-assessment	
Certification Board	Within 2 weeks after reception of the advice for a go or no-go decision
Upon reception of the advice for a go or a no-go decision from the EU CCC Certification Program Coordinator and the Chairperson of the Audit team, the Certification Board will examine all the elements and take the final decision. By the end of the examination, the Certification Board will have recommended either for a 'go' or a 'no-go' decision, regarding the centre's application at this stage of the process, and their readiness for the on-site audit.	

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Option 1: The Certification Board recommends a go decision If the Board's final decision is a go, it means that all the items in the self-assessment were scored and completed, and that the information and documents provided are sufficient for the Audit team to prepare for the on-site audit. *Option 2: The Certification Board recommends a no-go decision* If the Board's final decision is a no-go, it means that the information and documents provided are not sufficient for the Audit team to prepare for the on-site audit. The final decision is left to the interpretation of the Certification Board, hence, may differ from the EU CCC Certification Program Coordinator's and Chairperson of the Audit team's advice. The Chairperson of the Certification Board will directly notify the following contributors of their decision: • The Head of the Project team • The EU CCC Certification Program Coordinator • The Audit team • The Liaison Office (if it is a go decision)
Option 1: • ***Notification letter of the go decision:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the Director of the centre and the Head of the Project team, (2) the EU CCC Certification Program Coordinator and (3) the Liaison Office.*
Option 2: • ***Notification letter of the no-go decision:*** *sent through official communication channels of the Certification Organisation, from the Chairperson of the Certification Board to (1) the Director of the centre and the Head of the Project team, and (2) the EU CCC Certification Program Coordinator.*

Informing the Applicant Centre of the next steps	
EU CCC Certification Program Coordinator	Within a week after reception of the Certification Board's decision for a go or no-go
Upon reception of the Certification Board's decision, the EU CCC Certification Program Coordinator will contact the Head of the Project team and Centre Coordinator to inform them of the steps awaiting them. *Option 1: If the Applicant Centre received a go decision*	

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The EU CCC Certification Program Coordinator will inform the Head of the Project team of the elements they will need to upload in the e-tool as well as any other pre-requisites for the on-site audit, and the associated deadlines. *Option 2: If the Applicant Centre received a no-go decision* The EU CCC Certification Program Coordinator will inform the Head of the Project team of the reasons that led to the no-go decision following their self-assessment report. Thus, they should discuss the elements the centre needs to review, the documents they should add, and the modification they should do prior to a 2nd submission of their self-assessment report. The centre should therefore focus on document additions, rightful completion of the forms and the addition of precision to facilitate the preparation of the on-site audit. At this stage, the Applicant Centre can also be oriented towards the capacity building activities of the WP6 of EU Net CCC.
Option 1: • ***Information about the next steps after a go decision:*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*
Option 2: • ***Information about the next steps after a no-go decision:*** *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*

3.39 Step 8.2: Preparation of the on-site audit

~ Estimated execution time: 6 to 8 weeks ~

→ Step 8.2 is part of the preparation of the on-site audit and should be started during the Final Go/No-go decision and finalized after the Certification Board's final decision.

During this step, the Applicant Centre will work on the completion of the on-site audit agenda and will prepare its team internally. On the other hand, the EU CCC Certification Program Coordinator ensures the Audit team has all the documents and necessary elements to prepare for the on-site audit and helps them prepare if needed. Finally, the Audit team will hold an internal preparation meeting prior to the on-site audit.

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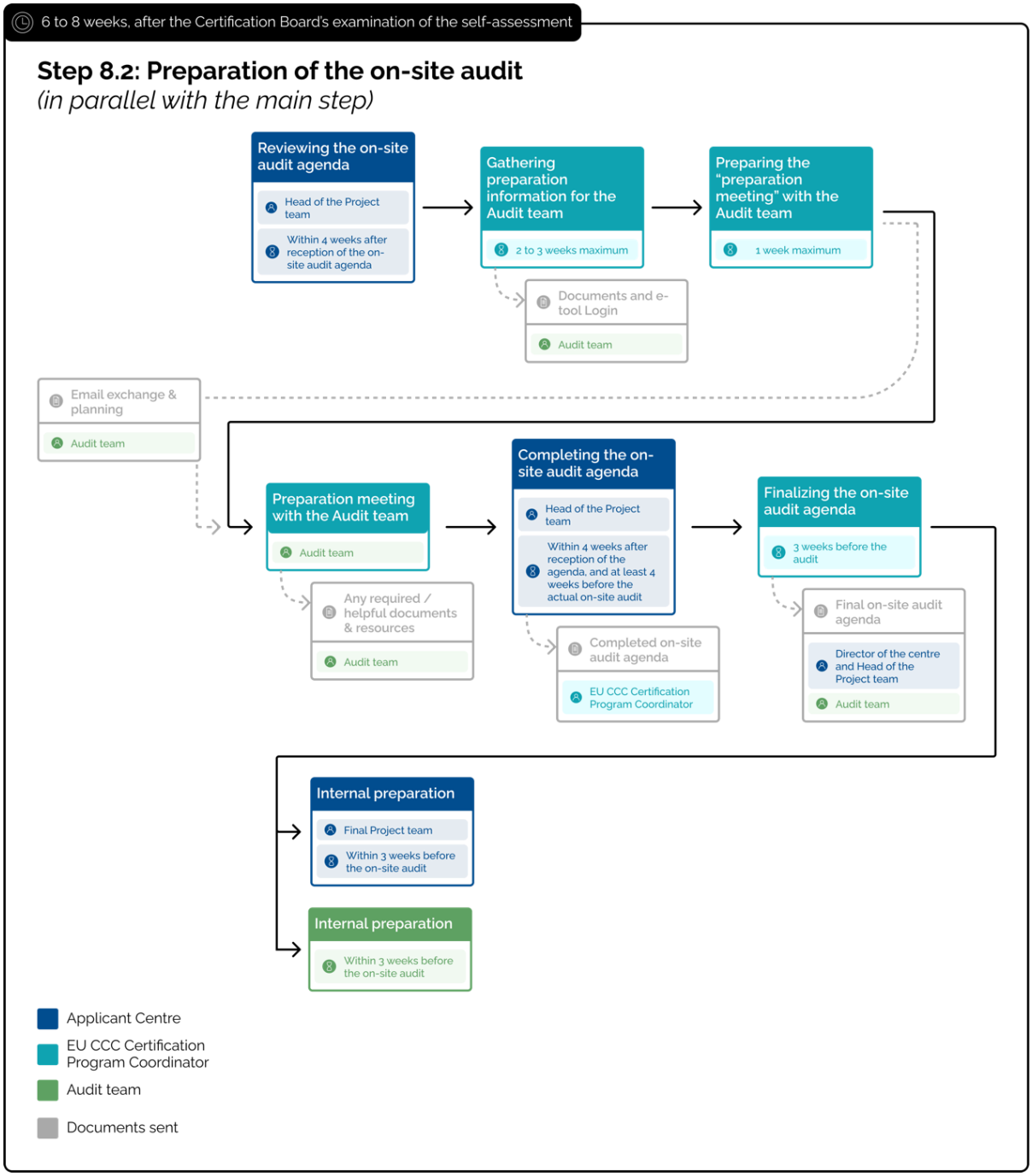

Figure V-11 - Step 8.2: Preparation of the on-site audit

Reviewing the on-site audit agenda

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Head of the Project team	Within 4 weeks after reception of the on-site audit agenda
Upon reception of the on-site audit agenda from the EU CCC Certification Program, the Head of the Project team will review and analyse it. The objective for the Applicant Centre is to complete the agenda based on their capacities and upon the availability of the Project team members.	

Gathering preparation information for the Audit team	
EU CCC Certification Program Coordinator	2 to 3 weeks maximum
The EU CCC Certification Program Coordinator sends to the Audit team all the necessary information, documents, e-tool login, etc... that they will need to prepare for the on-site audit. *[detail on the type of information and documents they may receive?]*	
Documents and e-tool Login: *sent through the e-mail, from the EU CCC Certification Program Coordinator to the Audit team*	

Preparing the "preparation meeting" with the Audit team	
EU CCC Certification Program Coordinator	A week maximum
The EU CCC Certification Program Coordinator prepares the "preparation meeting", which needs to take place at least 3 weeks before the on-site audit. This meeting is meant to ensure the Audit team is ready for the on-site audit, that they have all the information they need and that they do not have any other need prior to the audit.	
Email exchange & planning: *from the EU CCC Certification Program Coordinator to the Audit team.*	

Preparation meeting with the Audit team
EU CCC Certification Program Coordinator
The EU CCC Certification Program Coordinator and the Audit team participate in a teleconference meeting. This meeting is made to ensure that all the administrative and logistics details have been handled *[The detail of the administrative and logistics to handle will be refined in the next Joint Action].*

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The EU CCC Certification Program Coordinator may give a list of pre-requisites to the auditors to facilitate their preparation.
Any required / helpful documents & resources: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*

Completing the on-site audit agenda	
Head of the Project team	Within 4 weeks after reception of the agenda, and at least 4 weeks before the actual on-site audit
At least 4 weeks before the on-site audit, The Head of the Project team will ensure the rightful completion of the on-site audit agenda. It needs to provide the list of employees to interview and the locations / rooms for the interviews, as well as any complementary information auditors may need during their audit.	
Completed on-site audit agenda: *sent through the e-tool, from the Head of the Project team to the EU CCC Certification Program Coordinator.*	

Finalizing the on-site audit agenda	
EU CCC Certification Program Coordinator	3 weeks before the audit
The EU CCC Certification Program Coordinator makes sure the on-site audit agenda responds to all the proper criteria and finalizes it. If necessary, they may need to contact the Head of the Project team or the Centre Coordinator to complete some missing information.	
Final on-site audit agenda: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team, the Head of the Project team and the Centre Coordinator.*	

Internal preparation (Applicant Centre)	
Final project team	Within 3 weeks before the on-site audit
The Applicant Centre's Project Team must prepare for the on-site audit, implicating: • Organisation of the practical logistics for the audit. • Preparation and organisation of the Project team members and potential other contributors. • Internal communication details, to ensure the whole centre/institute is aware of the ongoing certification process.	

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Internal preparation (Audit team)	
Audit team	Within 3 weeks before the on-site audit

Following the reception of the final on-site audit agenda, the Audit team should hold a preparation meeting to dispatch the preparation tasks between all the Audit team members. Amongst the elements to review we will find:

The documentation review.

The pre-requisites and conformity check.

Once they have settled on the repartition, they should collectively work on the preparation of the audit.

Finally, it is advised for the Audit team to have a physical meeting day, prior to the on-site audit. This moment should ensure a proper cohesion during the peer-review audit.

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3.40 Step 9: Payment

~ Estimated execution time: 2 to 4 weeks ~

This administrative step involves the Liaison Office and the Applicant Centre. These steps will be refined in the next Joint Action, as it was determined that the EU Net CCC Certification Program will require a payment, but the person or organisation responsible for payment has not yet been identified, nor have the basis for the contract and contractors.

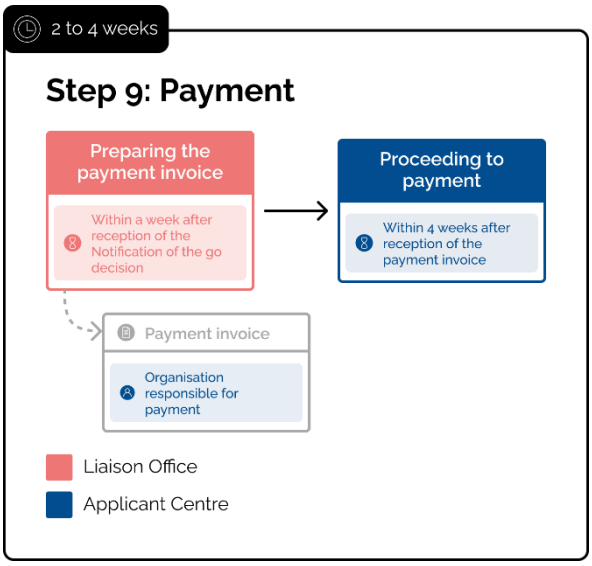

Figure V-12 - Step 9: Payment

Preparing the payment invoice	
Liaison Office	Within a week after reception of the Notification of the go decision
After reception of the signed contract from the Applicant Centre, the Liaison Office will prepare and send a payment invoice to *the organisation responsible for payment*	
Payment invoice: *sent through the e-tool or email, from the Liaison Office to the organisation responsible for payment.*	

Proceeding to payment	
Organisation responsible for payment	Within 4 weeks after reception of the payment invoice
Following the reception of the invoice, the organisation responsible for payment will proceed to pay the fees indicated in the invoice. This action will allow the centre to move on to the next steps of the process: the on-site audit.	

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3.41 Step 10: On-site audit

~ Estimated execution time: 1 to 2 weeks ~

The on-site audit involves interactions between the Applicant Centre's Project team and the Audit team who will conduct observations and interviews, while the Head of the Project team should ensure the auditors are provided will all the necessary elements and orientations while on site.

The on-site audit should be peer-reviewed; hence the composition of the Audit team will be arranged to cover all the areas of expertise and of analysis demanded for the on-site audit.

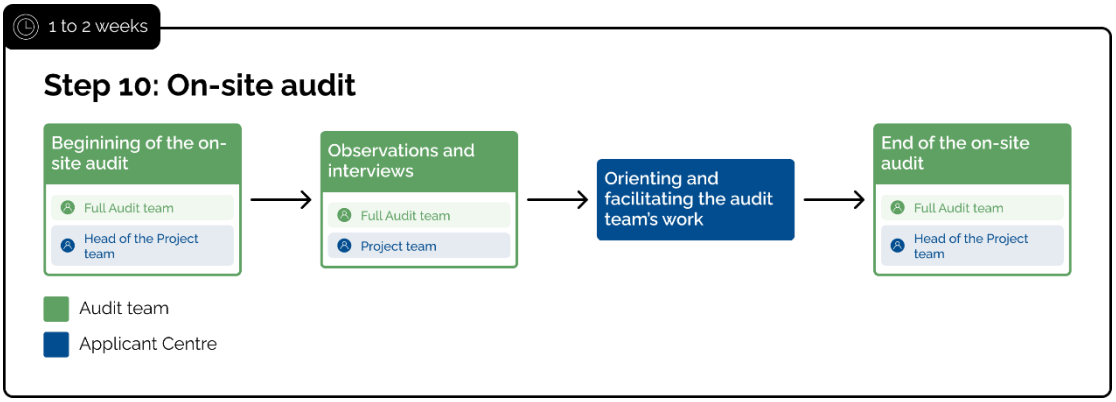

Figure V-13 - Step 10: On-site audit

Beginning of the on-site audit
Head of the Project team and Audit team
Upon their arrival on site, the Audit team should be welcomed by the Head of the Project team. Together, they will review the agenda and ensure that everything is properly managed and planned for the complete duration of the audit. At this stage, if the auditors foresee any missing elements from the agenda, they should mention it to the Head of the Project team to evaluate the possibility of including these elements in the planning.

Observations and interviews
Audit team, Head of the Project team, Centre Coordinator and Members of the Project Team
Throughout the on-site audit, the auditors will observe a range of facilities, processes and means displayed by the Applicant Centre. The Audit team may visit several sites of the Applicant Centre during this period.

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They will also conduct group interviews with staff members to gather their perspective on the conformity of the centre. The interviewed staff members should be members of the final Project team, thus, they should be prepared for these interactions and clearly informed of the purpose and stakes of the on-site audit. Finally, throughout the on-site audit, the Head of the Project team and Centre Coordinator should facilitate and help orienting the Audit team on the grounds of the centre or institute.

End of the on-site audit
Head of the Project team and Audit team
At the end of the on-site audit, the Audit team holds a meeting with the Head of the Project team to give them a rapid overview of their observations and remind them of the next steps of the certification process and give them some visibility on the deadlines.

3.42 Step 11: Reporting and Improvement plan definition

~ Estimated execution time: 10 to 14 weeks ~

Reporting: *~ Estimated execution time: 6 to 8 weeks ~*

After the on-site audit, the auditors will add their observation notes in the e-tool which will allow the EU CCC Certification Program Coordinator to draft a report. Following several exchanges between the EU CCC Certification Program Coordinator and Chairperson of the Audit team, the Applicant Centre will receive and react upon the draft report. Once all the contributors involved have given their comments, the report will be finalized.

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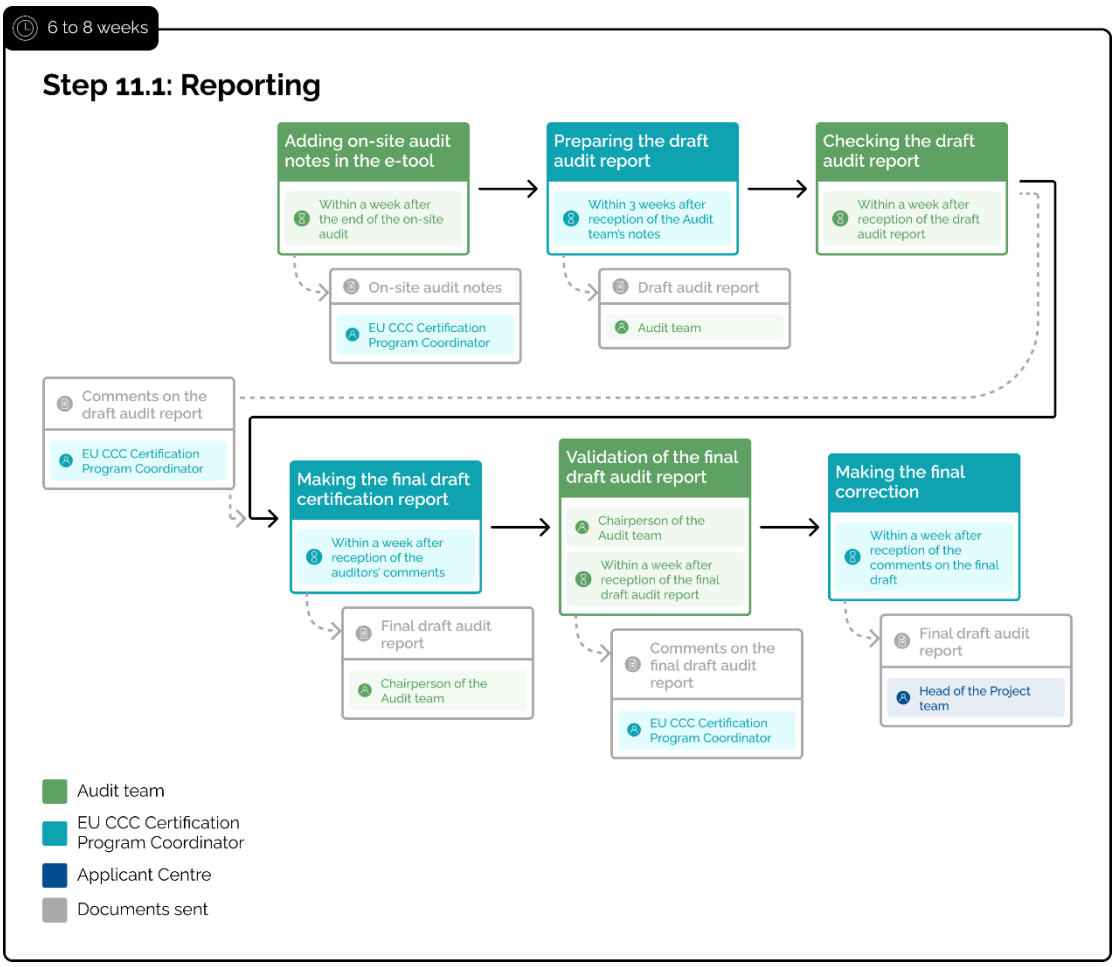

Figure V-14- Step 11.1: Reporting

Adding on-site audit notes in the e-tool	
Audit team	Within a week after the end of the on-site audit
Following the on-site audit, the members of the Audit team integrate their notes in the e-tool, for the EU CCC Certification Program Coordinator to consult them and prepare a draft audit report.	
On-site audit *notes:* *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*	

Preparing the draft audit report	
EU CCC Certification Program Coordinator	Within 3 weeks after reception of the Audit team's notes
Based on the auditors' on-site audit notes the EU CCC Certification Program Coordinator starts a draft audit report.	

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The report should contain the standards reviewed during the on-site audit with the scores of the Applicant Centre from the self-assessment, the scores of the auditors, and the findings of the auditors supporting the scores, the general remarks, strengths and opportunities they have identified. Once the first draft is finalized, the EU CCC Certification Program will send it to the Audit team.
Draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*

Checking the draft audit report	
Audit team	Within a week after reception of the draft audit report
Upon reception of the draft audit report from the EU CCC Certification Program Coordinator, the auditors will review it to add their comments and suggestions. The objective of this cross analysis is to ensure all the observations from the on-site audit were rightfully transcribed and are intelligible. All the auditors will be able to add their comments in their own e-tool account and will validate their review for the EU CCC Certification Program Coordinator to consult.	
Comments on the draft audit report: *sent through the e-tool, from the Audit team to the EU CCC Certification Program Coordinator.*	

Making the final draft certification report	
EU CCC Certification Program Coordinator	Within a week after reception of the auditors' comments
The EU CCC Certification Program Coordinator finalizes the draft of the audit report. The final draft does not present the conclusion, description of the certification process' findings not the decision for attribution of the certification. However, the report will be used as evidence in the final validation instance with the Certification Board. Once the EU CCC Certification Program Coordinator finalized the final draft, they will send it back to the Chairperson of the Audit team for last comments.	
Final draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

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Validation of the final draft audit report	
Chairperson of the Audit team	Within a week after reception of the final draft audit report
Upon reception of the final draft audit report, the Chairperson of the Audit team verifies the final draft audit report and sends its final comments to the EU CCC Certification Program Coordinator.	
Comments on the final draft audit report: *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*	

Making the final correction	
EU CCC Certification Program Coordinator	Within a week after reception of the comments on the final draft
Upon reception of the Chairperson of the Audit team's comments, the EU CCC Certification Program Coordinator produces the final correction of the draft audit report and submits it to the Applicant Centre for review.	
Final draft audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Head of the Project team.*	

Improvement plan definition: ~ *Estimated execution time: 4 to 6 weeks* ~

In this step, the Applicant Centre's Project team work on their improvement plan. If needed, they can reach out to the EU CCC Certification Program Coordinator for a discussion prior to the finalisation of the improvement plan.

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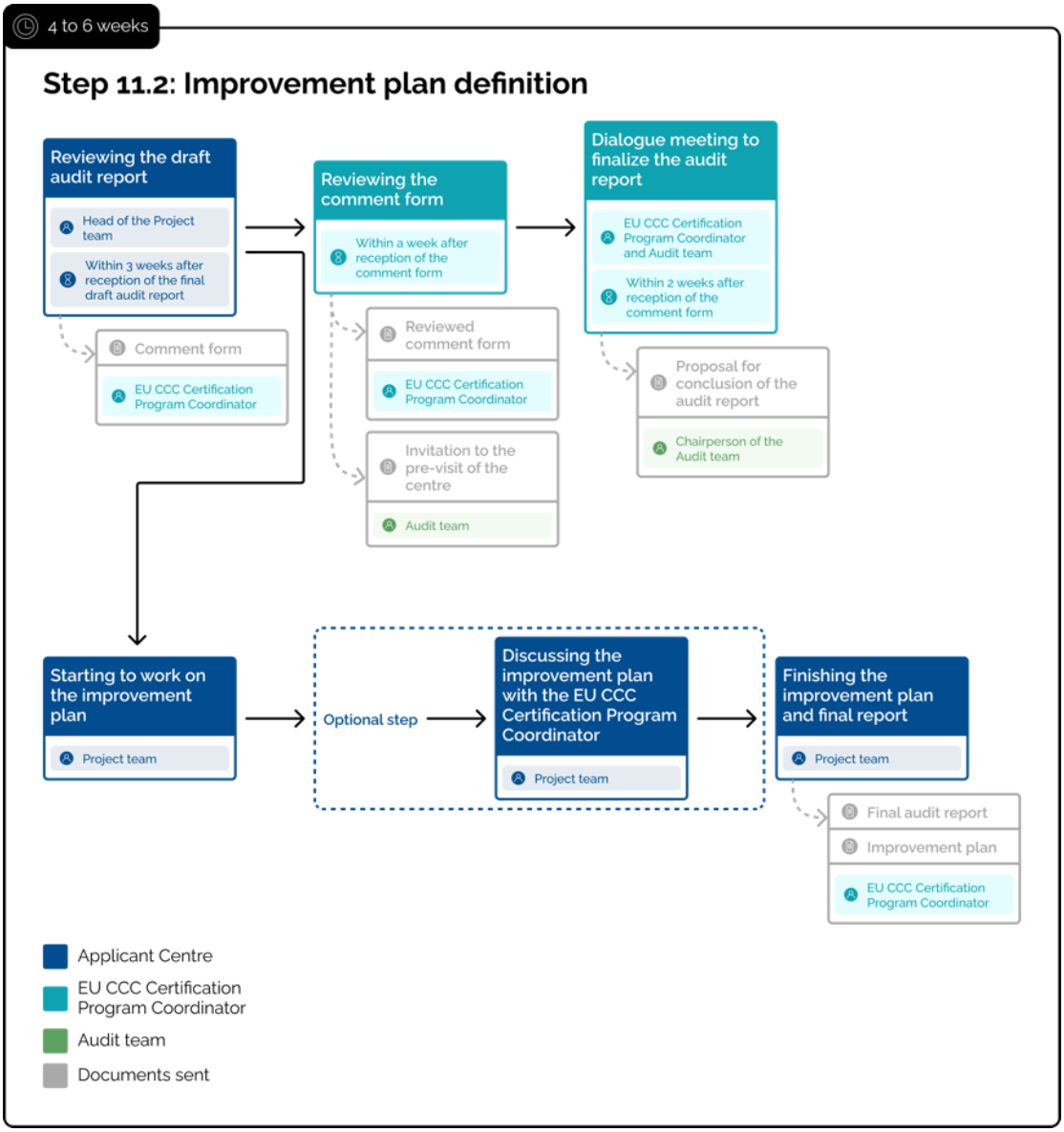

Figure V-15- Step 11.2: Improvement plan definition

Reviewing the draft audit report	
Head of the Project team	Within 3 weeks after reception of the final draft audit report
Upon reception of the Final draft audit report, the Head of the Project team will review the report on factual inaccuracies. They should complete the dedicated comment form in the e-tool before the deadline. Their comment form will be sent to the EU CCC Certification Program Coordinator, analysed and discussed with the Audit team before the finalisation of the actual report.	
Comment form: *sent through the e-tool, from the Head of the Project team to the EU CCC Certification Program Coordinator.*	

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Reviewing the comment form	
EU CCC Certification Program Coordinator	Within a week after reception of the comment form
The EU CCC Certification Program Coordinator reviews the comment form before transferring it to the Audit team. The EU CCC Certification Program Coordinator should also address a meeting invitation to the Audit team to discuss the Applicant Centre's comment form and finalize the audit report.	
Reviewed comment form: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Audit team.*	
Invitation to the pre-visit of the centre: *from the EU CCC Certification Program Coordinator to the Audit team.*	

Dialogue meeting to finalize the audit report	
EU CCC Certification Program Coordinator and Audit team	Within 2 weeks after reception of the comment form
Upon reception of the comment form and invitation from the EU CCC Certification Program Coordinator, the auditors will prepare their potential comments prior to the dialogue meeting. Following the reaction meeting, both the EU CCC Certification Program Coordinator and Chairperson of the Audit team should provide a proposal for conclusion of the audit report, with a description of the on-site audit findings.	
Proposal for conclusion of the audit report: *completed in the e-tool by the EU CCC Certification Program Coordinator and Chairperson of the Audit team.*	

Starting to work on the improvement plan
Project team
Based on the elements from the draft final audit report, the Project team of the Applicant Centre, starts working on its improvement plan. The objective is to identify their areas of improvements and to define an action plan for the next 12 to 24 months. The definition of the improvement plan should not be neglected, as it is key to the potential granting of the EU CCC Certification.

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Optional step below. If the Applicant Centre does not require a meeting, they will directly move to the 'Finishing the improvement plan and final report' step.

Discussing the improvement plan with the EU CCC Certification Program Coordinator
Project team
Upon request from the Head of the Project team, the EU CCC Certification Program Coordinator can hold a meeting to discuss the definition of their improvement plan. The coordinator can challenge the Applicant Centre's draft plan so that it can be improved. However, the Applicant Centre must be the complete owner of this improvement plan which should not be directed by the EU CCC Certification Program Coordinator.

Finishing the improvement plan and final report
Project team
Once the improvement plan is finalized, the Head of the Project team and Centre Coordinator should complete the dedicated form in the e-tool, before submitting it to the EU CCC Certification Program Coordinator.
Improvement plan: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*
Final audit report: *sent through the e-tool, from the Centre Coordinator to the EU CCC Certification Program Coordinator.*

3.43 Step 12: Final review validation

~ Estimated execution time: 1 month ~

In this final step, the EU CCC Certification Program Coordinator will review all the documents (i.e. improvement plan, final audit report and proposal for conclusion of the audit report) and submit it to the Audit team, which will either approve or reject the centre's final audit report. The EU CCC Certification Program Coordinator will then transfer the final audit report, the Audit team's decision and his advice on the report to the Certification Board.

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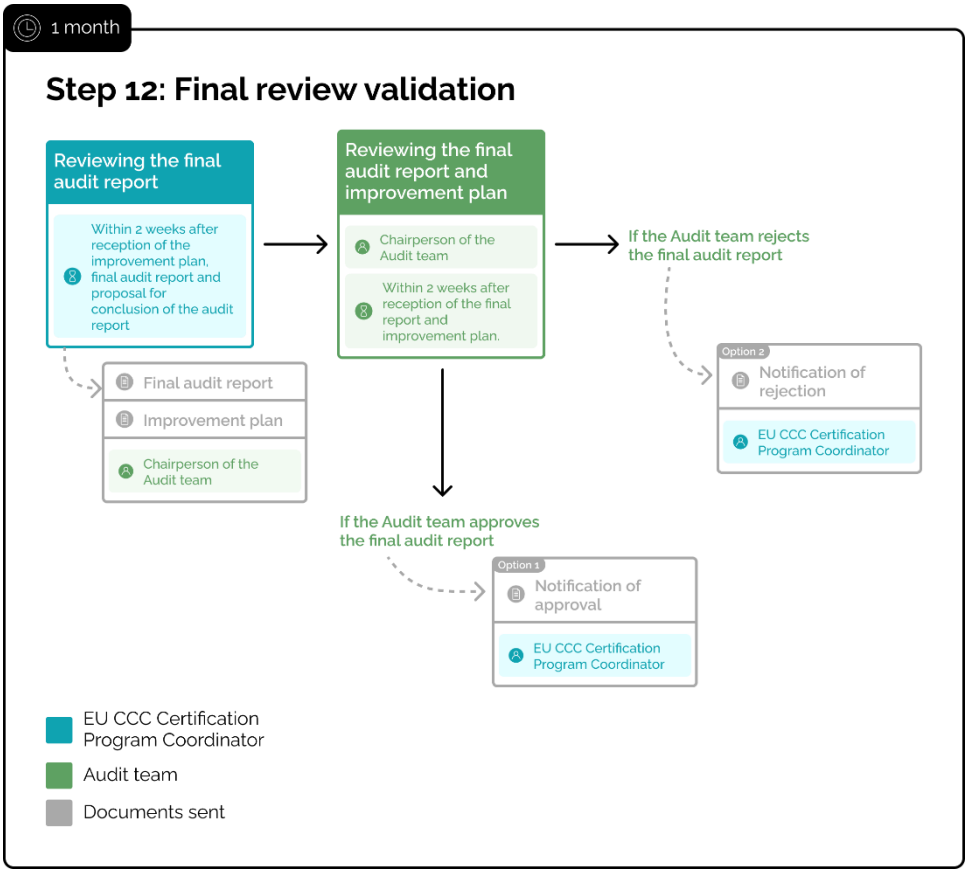

Figure V-16 - Step 12: Final review validation

Reviewing the final audit report	
EU CCC Certification Program Coordinator	Within 2 weeks after reception of the improvement plan, final audit report and proposal for conclusion of the audit report
The EU CCC Certification Program Coordinator reviews the final audit report and writes the conclusion. Then, they should validate the final report and improvement plan in the e-tool before transferring it to the Chairperson of the Audit team.	
Final audit report: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	
Improvement plan: *sent through the e-tool, from the EU CCC Certification Program Coordinator to the Chairperson of the Audit team.*	

Reviewing the final audit report and improvement plan	
Audit team	Delay of treatment
The Chairperson of the Audit team reviews the final audit report and the Applicant Centre's improvement plan.	

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Based on the content, the Chairperson can either approve or reject the final audit report and improvement plan. *Option 1: The Chairperson of the Audit team approves the final audit report and improvement plan* In this case, they will issue a notification of approval for the EU CCC Certification Program Coordinator. *Option 2: The Chairperson of the Audit team rejects the final audit report and improvement plan* In this case, they will issue a notification of rejection for the EU CCC Certification Program Coordinator.
Option 1: • ***Notification of approval:*** *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*
Option 2: • ***Notification of rejection:*** *sent through the e-tool, from the Chairperson of the Audit team to the EU CCC Certification Program Coordinator.*

3.44 Step 13: Certification

~ Estimated execution time: 2 to 4 months ~

This final step can be divided in two main parts. On the one hand it is decisive, as the EU CCC Certification Program Coordinator and Certification Board will review the Audit team's on-site audit report and Applicant Centre's improvement plan. On the other hand, it is ceremonial, as once the renewal of the certification is granted, several documents will be sent, and a celebration will take place.

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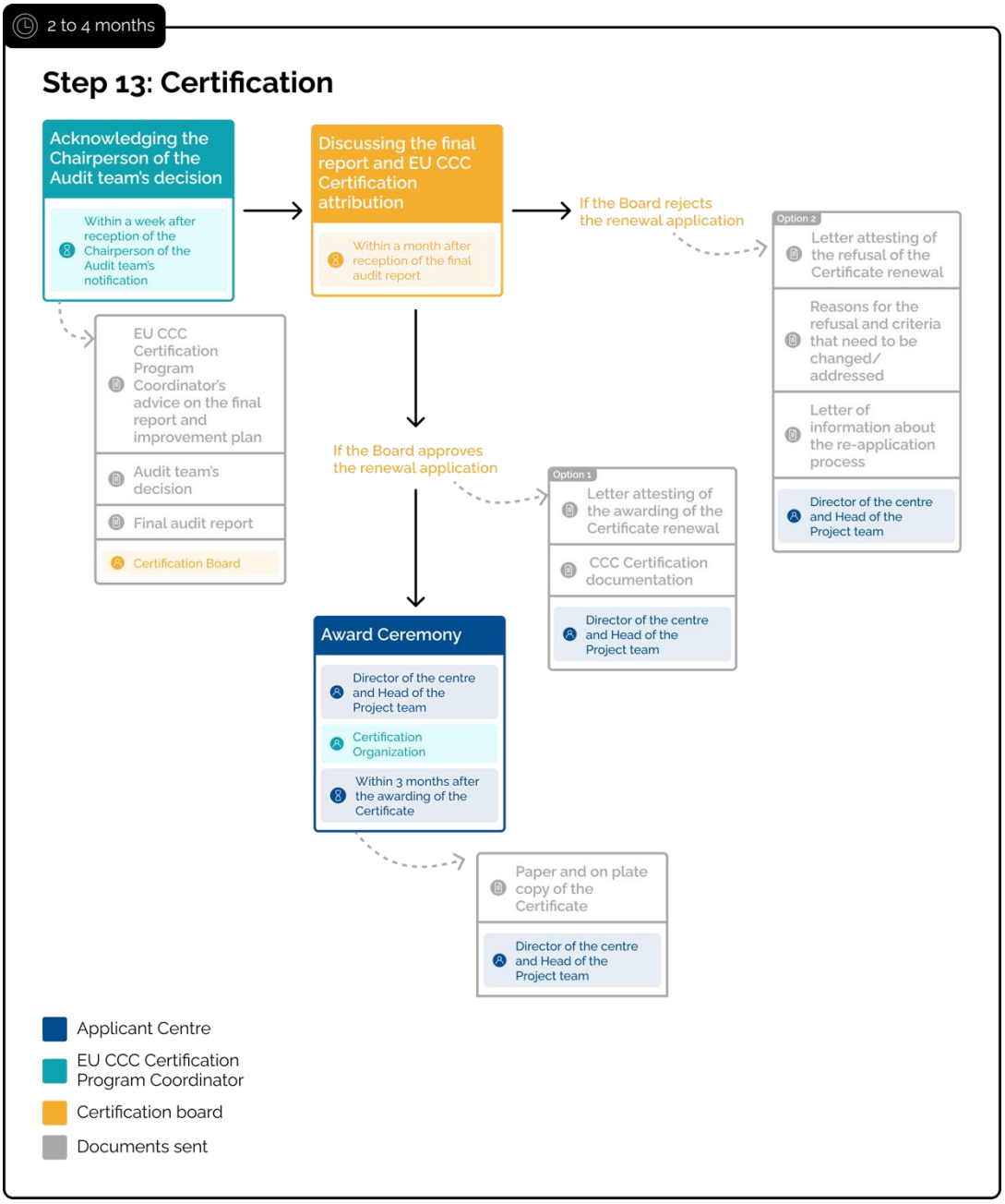

Figure V-17 - Step 13: Certification

Acknowledging the Chairperson of the Audit team's decision	
EU CCC Certification Program Coordinator	Within a week after reception of the Chairperson of the Audit team's notification
The EU CCC Certification Program Coordinator receives the Chairperson of the Audit team's decision and prepares some advice for the Certification Board, which will be responsible for the final certification attribution decision	
Final audit report: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*	

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Audit team's decision: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*
EU CCC Certification Program Coordinator's advice on the final report and improvement plan: *sent through official communication channels of the Certification Organisation, from the EU CCC Certification Program Coordinator to the Certification Board.*

Discussing the final report and EU CCC Certification attribution	
Certification Board	Within a month after reception of the final audit report
The Certification Board reviews the Audit team's decision, the final audit report, the Applicant Centre's improvement plan and the EU CCC Certification Program Coordinator. Based on their review, they will decide upon the acceptance or rejection of the Applicant Centre's certification renewal application. *Option 1: The Certification Board approves the Applicant Centre's certification renewal application* The Centre Coordinator, Head of the Project team and Director of the centre will receive confirmation of the EU CCC Certification attribution. *Option 2: The Certification Board rejects the Applicant Centre's certification renewal application* The Centre Coordinator, Head of the Project team and Director of the centre will receive information regarding the rejection of their certification renewal application and information about the repeat process, if they wish to re-attempt the certification process.	
Option 1: • ***Letter attesting of the awarding of the Certificate renewal:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.* • ***EU CCC Certification documentation:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*	
Option 2: • ***Letter attesting of the refusal of the Certificate renewal:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*	

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- ***Document regarding the reasons for the refusal and criteria that need to be changed/addressed:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*
- ***Letter of information about the re-application process:*** *sent through official communication channels of the Certification Organisation, from the Certification Board to the Director of the centre and the Head of the Project team.*

Award Ceremony	
Applicant Centre and Certification Organisation	Within 3 months after the awarding of the Certificate
During an award ceremony, the Certified EU Comprehensive Cancer Centre receives an on-plate copy of the new Certificate.	
Option 1: • ***Paper and on plate copy of the Certificate:*** *attributed during the Award Ceremony to the Director of the centre and Head of the Project team.*	

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PART IV: Glossary

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Definitions

Advanced Therapy Medicinal Products

ATMPs are medicinal products that are either:

- A gene therapy – Gene therapy is a medical approach that treats or prevents disease by correcting the underlying genetic problem. Gene therapy techniques allow doctors to treat a disorder by altering a person's genetic makeup instead of using drugs or surgery.
- A somatic cell therapy – a technique that transfers the genetic material into cells not involved in reproduction so that they treat the individual but are not passed on to future generations
- A tissue engineered product – a medicine containing engineered cells or tissues, which is intended to regenerate, repair or replace human tissue.

Basic research

Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.

Clinical research

Clinical studies encompass a broader range of research types, whereas clinical trials are specifically focused on testing interventions.

Intervention: Clinical trials always involve an intervention being tested, while clinical studies may or may not involve interventions.

Regulatory Involvement: Clinical trials are often closely regulated and are necessary for the approval of new medical treatments and devices, whereas clinical studies may not always require such stringent regulatory oversight.

Clinical trials

Clinical trials (CT) are a subset of clinical studies that specifically focus on testing the safety, efficacy, and side effects of interventions in humans. These interventions can include new drugs, medical devices, treatments, or diagnostic procedures.

Clinical trial units

The expression applied here means that it could either be an organizational unit within an organization that is a part of the CCC or could be in organization associated with the CCC.

And the core activities within such unit should be demonstrating:

- Experience of coordinating multi-centre randomised controlled trials or other well-designed studies
- A presence of a core team of expert staff to develop studies
- A presence of robust quality assurance systems and processes to meet appropriate regulations and legislation

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- Evidence of longer-term viability of capacity for trials coordination and the development/maintenance of a trial's portfolio

Example: Does not have to be cancer specific. Clinical Trials Units (CTUs) are specialist units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies. (www.ukcrc.org)

Core activities within such unit should be demonstrating:

- experience of coordinating multi-centre randomised controlled trials or other well-designed studies,
- a presence of a core team of expert staff to develop studies,
- a presence of robust quality assurance systems and processes to meet appropriate regulations and legislation,
- evidence of longer-term viability of capacity for trials coordination and the development/maintenance of a trial's portfolio

Complications

Complications related to cancer therapy refer to the adverse effects or problems that can arise from the treatments used to manage cancer, such as chemotherapy, radiation therapy, or surgery. (I.e infections, organ failure, anemia, neuropathy, lymphoedema, ...)

Complication rate

The complication may be caused by the disease, procedure, or treatment or may be unrelated to them. The complication rate is the number of complications divided by the number of patients treated.

Comprehensive Cancer Centre Board

The comprehensive Cancer Centre Board (CCB) is the management structure that is the main governing body of the CCC.

The role involves following up and monitoring CCC-related strategies and improvement plans, ensuring continuous improvement processes, and taking responsibility for necessary coordination along cancer patient pathways, cancer diagnoses, and across research, education, and care.

The Comprehensive Cancer Centre Board is composed of relevant leaders at the units comprising a CCC (hospital(s), research institutes and others) together having the responsibility for all main ingredients expected to be conducted by a CCC.

Dashboard

Cancer dashboards are interactive tools that provide visualizations and analyses of clinical data related to cancer care. Dashboards present up-to-date information in a user-friendly

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format, enabling real-time monitoring of key metrics such as treatment compliance, data quality, and patient outcomes. This facilitates rapid decision-making and identification of areas for improvement.
Cancer dashboards aggregate data from various sources like cancer registries, hospital records, and treatment databases across multiple facilities or regions. This allows for a cohesive view of cancer statistics, patient outcomes, treatment patterns, and performance metrics.

Formal agreements

We require an official contract, signed by the parties, that specifies the purpose, obligations and effective date we require an official contract, signed by the parties, that specifies the purpose, obligations, and effective date.

Information and Communication Technology

Information and Communication Technology (ICT) is an inclusive term, covering all communication equipment or application software: for example, radio, television, mobile phone, computer, network hardware and software, and satellite system, as well as various services and application software related to it, such as video conference and distance learning. The importance of ICTs is not the technology as such, but its enabling function in facilitating enhanced access to information and communication across large distances. ICTs have been used in many innovative ways to achieve social impacts, such as promoting access to basic services including health, finance, and insurance.

In the field of healthcare, key strategic applications of ICTs include e-Health and m-Health.

E-Health and m-Health are increasingly employed in combination with tools that build capacity and address the quality of care to improve health systems, use resources efficiently, and plan for the progressive adoption of universal health coverage.

Internal / External audit

An internal audit is one that is performed by members of the organization or practice. Some large hospital systems have an internal audit department that is responsible for auditing all aspects of the healthcare system (not just the coding and billing).

An external audit is one that is performed by an individual or group that is not a part of the organization or the practice (usually the government or a commercial insurance company)

Key Performance Indicators

Key Performance Indicators (KPIs) in comprehensive cancer care are standardized measures used to assess and improve the quality of cancer services across various aspects of patient care. KPIs are typically derived from clinical guidelines and best practices in cancer

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management. They are quantifiable metrics that can be tracked and compared over time and across different healthcare settings. KPIs aim to evaluate and monitor the quality, efficiency, and effectiveness of cancer care delivery. They cover the entire cancer care continuum, from screening and diagnosis to treatment, survivorship, and end-of-life care.

Line managers

Line managers are the leaders who have the formal role of head for divisions and departments in the organizational entities comprising the CCC.

Molecular Tumour Board

Molecular tumour boards (MTBs) are specialized multidisciplinary teams that review and discuss the molecular aspects of cancer cases. These boards typically consist of oncologists, pathologists, geneticists, molecular biologists, and other specialists. The primary function of MTBs is to analyze the genetic and molecular data from tumour samples to provide personalized treatment recommendations. MTB recommendations should be derived from a multidisciplinary discussion, including not only specific molecular alterations but all features concerning the patient (e.g., performance status, comorbidities). MTB recommendations should be clearly written on 'ad hoc' designed reports, documenting parameters such as:

- driver mutations/copy number/structural variations, including fusion genes;
- druggable molecular alterations (i.e based on proteomics);
- microsatellite instability;
- tumor mutational burden;
- alterations indicating drug resistance;
- MTB conclusions/recommendations;
- potentially available clinical trials.

Notably, the following three key areas should always be present in MTB reports:

- patient identification;
- reporting style and content (concise reports and clear presentation of results);
- interpretation of results.

Patients discussed in the framework of MTBs are usually those for which therapy based on existing guidelines has been ineffective, all tumour types are potentially eligible for MTB discussion; the discriminant should not be histotype.

Multi-Disciplinary Team and meetings

A multidisciplinary team (MDT) in cancer care is a group of healthcare professionals from different specialties who work together to provide comprehensive, coordinated treatment

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and care for cancer patients. MDTs typically consist of (but not limited to) oncologists (medical, surgical, radiation), pathologists, radiologists, clinical nurse specialists, surgeons, other professionals (e.g., dietitians, physiotherapists, psychologists). MDTs hold regular meetings*, (often weekly), to discuss patient cases, review test results, and plan treatments. The main goals of an MDT meeting are to review and discuss individual patient cases in order to develop personalized treatment plans, ensure coordinated and comprehensive care, improve communication between healthcare providers and enhance decision-making based on collective expertise. MDTs consider various factors in treatment planning, including: cancer type and stage, patient's general health, evidence-based guidelines, patient preferences and circumstances.
MDTs provide ongoing support throughout the patient's cancer journey, from diagnosis through treatment and follow-up care.

*Multi-Disciplinary Teams meetings (MTMs)

Patient centredness

Patient-centredness refers to an approach in healthcare that places the patient at the center of care, respecting their preferences, needs, values, and ensuring care is responsive to their unique circumstances. Key elements are: patients are empowered and involved in decision-making about their care, with a balance of power between patients and providers; Understanding their life situation, social context, and individual experience; Care is well-coordinated across different providers, services, and settings to ensure continuity and integration.

Patient Ombudsman

A privileged interlocutor who acts as a bridge between patients and the Hospital Board.

It is the person who investigates, reports on, and helps settle complaints: an individual affiliated with the centre who serves as an advocate for patients.

Each health centre and hospital has a patient ombudsperson that promotes the rights of the patient. The services of the patient ombudsperson are free of charge. The purpose of the patient ombudsperson is to provide advice and assistance if the patient is unhappy with the care or treatment that he/she has received, for example. The patient ombudsperson can also assist the patient in making a claim, complaint or treatment injury report.

Patient Pathway

A patient pathway is an evidence-based tool that supports the planning and management of the care process of individual patients within a group of similar patients with complex, long-term conditions. It details the phases of care, guiding the whole journey a patient takes by defining goals and milestones, and supports mutual decision-making by the patient and his/her multidisciplinary care team collaborating in a comprehensive network of care providers. *(Richter, Hickmann and Schlieter 2021)*

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Patient Pathway coordinator/nurse coordinator

Identified co-ordinator or manager (or written process for case management) of their pathway from admission until end of follow-up, including the implementation of MDT recommendations and ensure that patients receive treatment as soon as possible and in line with local, regional and/or national targets are met. The key functions are to act as a patient navigator and care coordinator.

Patients newly treated

The number of patients with a diagnosis of cancer who are treated for the first time in the cancer centre/institute in the index year for a particular cancer, regardless of the date and place of the initial diagnosis.

- Treated means that the patient has gone through cancer directed treatment, regardless of type.
- Newly treated means the patient has never been treated before in the cancer centre/institute for the same cancer.
- According to this definition: a patient with a new (second or subsequent) cancer should be counted again; but a patient with a recurrent disease previously treated in the centre/institute should not be counted. The number of patients is counted, not the number of visits.

Peer- Review

Peer review in the certification process refers to a critical evaluation conducted by professionals from similar academic or professional backgrounds to assess the quality and standards of an institution or program. These reviewers are usually experts in the field who are independent of the institution being evaluated, preferable from outside the Member State. Their role is to ensure that the institution or program meets established accreditation standards, guidelines, and best practices.

The reviewers are typically chosen for their expertise in relevant areas, ensuring that their evaluations are informed and credible. Peer reviewers often visit the institution or program in person to gather evidence, review documents, observe operations, and interview key personnel.

The peer review process promotes fairness, transparency, and accountability by engaging experts from outside the institution who offer unbiased assessments. In addition, it serves as a learning process for the institution being under audit, as well as gaining knowledge and learning points for the experts serving as auditor, which are to bring these perspectives into their own practice and environment.

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Principal investigator

Principal investigator (PI) refers to the person(s) in charge of a clinical trial or a scientific research grant. The principal investigator prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The principal investigator also analyses the data and reports the results of the trial or grant research.

Rare Cancer

As defined by the National Cancer Institute, cancer that occurs in fewer than 15 out of 100,000 people each year. Most types of cancer are considered rare, and they are often more difficult to prevent, diagnose, and treat than the more common cancers. Because there are fewer cases, research is difficult. Examples of rare cancers are anal, stomach, and laryngeal cancer.

Satisfying capacities

Refer to the essential qualities and resources needed to effectively meet patient needs and expectations in line with national or regional context, and regulations when in place.

Scientific Advisory Board

An external Scientific Advisory Board (SAB) meets at regular intervals and advises the cancer centre/institute on its cancer research strategy, organisation, infrastructure and overall performance.

Shared decision-making for patient empowerment

Shared decision-making (SDM) is a collaborative process that allows patients and healthcare professionals to make care decisions together, taking into account the best scientific evidence available, as well as patients' values, preferences, life situation and willingness to know about disease process and prognosis. The benefits of SDM are well documented but implementing SDM at institutional level is challenging. Cultural barriers are some of the biggest hurdles among both healthcare professionals as well as patients and relatives.

Supportive care

Care given to improve the quality of life of people who have an illness or disease by preventing or treating, as early as possible, the symptoms of the disease and the side effects caused by treatment of the disease. Supportive care includes physical, psychological, social, and spiritual support for patients and their families. There are many types of supportive care.

Examples include pain management, nutritional support, counselling, exercise, music therapy, meditation, and palliative care. Supportive care may be given with other treatments from the time of diagnosis until the end of life. (NCI)

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Technology Transfer Office

A Technology Transfer Office (TTO) is a specialized unit (organised within or outside an institution), responsible for managing and commercializing intellectual property generated from research activities. TTOs aim to facilitate the transfer of scientific discoveries and innovations from academic research to industry and the wider society. TTOs are tasked with identifying and evaluating commercially viable research outcomes, protecting intellectual property through patents and other means, marketing and licensing technologies to industry partners, facilitating the creation of start-up companies based on research, managing industry partnerships and collaborations, providing guidance to researchers on commercialization processes. Responsibilities: securing and protecting intellectual property. managing patent portfolio, negotiating licensing agreements with industry partners, distributing royalties and other income from commercialization activities. TTOs ensure that technology transfer activities comply with relevant laws and regulations.

Translational research

Translational research aims to convert findings from basic research into practical applications that directly benefit human health and well-being thus bridge the gap between laboratory discoveries and clinical practice, often referred to as "bench to bedside" research.

Translational research includes among other translating basic science discoveries into potential clinical applications, testing these applications in clinical trials and implementing them into medical practice. Translational science studies the translation process itself, aiming to understand the scientific and operational principles underlying each step of translating research into practice.

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