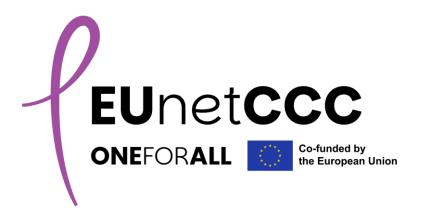




Work Package 4 and 6

Readiness Assessment Checklist for candidates EU Comprehensive Cancer Centres: A 30-item evaluation (RACCC-30) to identify baseline capacities and capabilities



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SUMMARY

The EUnetCCC Joint Action aims to implement a European Network of Comprehensive Cancer Centres (CCCs) to ensure equitable and high-quality cancer care for the entire European population. To achieve this objective, several capacity building activities and tools are planned to strengthen candidate centres' position in view of their future certification as CCC under the framework of **Work Package 6: Strengthening Capacities and Quality in EUCCC.**

In this vein, it is essential to consider the initial readiness of candidate centres besides the standards' themselves, that is, focusing on centres' baseline capacities and capabilities as well as their framework conditions. To that end, it was developed the *Readiness Assessment Checklist for EUCCC candidate*, a structured framework of analysis aiming to focus on the readiness of candidate CCCs before starting the certification process. This 30-item evaluation checklist (RACCC-30) should enable identifying the strengths and gaps considered as decisive to succeed in the certification as a Comprehensive Cancer Centre. The use of this checklist obeys to the purpose of strengthening the preparatory processes as well as of tailoring capacity-building processes.

The development of the checklist followed a multi-step process, including a literature review, focus groups plus a co-creation and revision phase with members of different WPs as well as a pilot phase to validate the tool in a wide sample of candidate CCCs together with the MM testing.

The RACCC-30 includes 30 items, structured across the following thematic areas:

- → Leadership and open attitudes toward change (7 items)
- → Organisational development (9 items)
- → Data management and IT standardisation (6 items)
- → Policy and institutional framework (8 items)

Completion is ideally carried out through consensus-building by 2-3 professionals from candidate centres with a wide view on the areas dealt with. Each item is rated using a 5-point Likert scale. The results of the RACCC-30 will provide a global score, thematic sub-scores, and a relative position across candidate CCCs, offering an overview of each centre that supports WP6 in guiding capacity-building efforts.

All data collected will be handled confidentially, in compliance with the General Data Protection Regulation (GDPR), and will be accessible only to authorised teams involved in capacity-building activities.





GLOSSARY USED IN THE CHECKLIST

- EUCCC Certification scheme: To be completed.
- **EUnetCCC Standards**: Set of Standards developed during the CraNE Joint Action... (TBC).
- Constituent institutions of the CCC: Care provider/s, research institution/s and university/es needed to institutionalise a Comprehensive Cancer Centre.
- Candidate CCC: Organisation configured as a comprehensive cancer centre that has been
 officially supported by the Ministry of Health to be engaged in the EUnetCCC Certification
 pathway.
- Maturity Model (MM): Tool that enables assessment of the level of organisational maturity, gap analysis along the path to maturity, identification of development directions for certification purposes, and benchmarking of CCC units.
- Core Team of the Certification: Task force that should lead the certification process
 through intense communication and coordination interactions with the services and
 institutions making up the CCC as well as with the certification operators.
- 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 (CraNE Joint Action).





1. Introduction and justification

Cancer is a complex disease that requires high-quality, multidisciplinary, and patient-centred care, with access to advanced diagnostics and innovative treatments (1). To support this goal, over the past years, various frameworks, such as the Organisation of European Cancer Institutes (OECI) and the Deutsche Krebshilfe (DKH) in Germany, have been established to designate Comprehensive Cancer Centres (CCC), specialised healthcare institutions that provide high-quality multidisciplinary cancer care, combined with clinical and translational research, education, technological innovation, clinical trials, and patient support services (2)(3)(4).

The Europe's Beating Cancer Plan (EBCP) establishes, within its strategic priority number 5, the need to implement a European network of CCC to ensure equitable and high-quality cancer care for the entire population (1). The European Network of Comprehensive Cancer Centres (EUnetCCC) Joint Action, funded by the EU4Health programme, continues the work initiated by the CraNE Joint Action (2022–2024) and aims to achieve this objective (5). This network is designed to ensure that all European citizens, regardless of their geographical location, have equitable access to evidence-based, high-quality cancer care throughout the entire care continuum. Moreover, the initiative establishes a shared framework for advancing research, promoting effective integration between clinical practice and research, as well as access to innovation and training. The EUnetCCC Joint Action involves 163 institutions across 31 countries, promoting the exchange of knowledge, resources, and best practices among centres. It also supports the creation of sustainable alliances through a common affiliation structure, the adoption of a shared certification system (EUCCC), and the development of capacity-building mechanisms to assist candidate CCC (5).

Successfully becoming a CCC requires candidate centres ensuring access to all relevant diagnostics and treatments modalities, providing care for all tumour groups, connect to a wide range of cancer-related research and integrate education and training for all major stakeholders involved in the care and research process. This process presents significant challenges, as it requires continuous institutional improvement and development, along with an effective coordination across these dimensions with a strong foundation in leadership, institutional strategy, infrastructure, and governance, in line with the standards established in the CraNE Joint Action (6).

Within the EUnetCCC Joint Action, WP6 aims to support candidates CCC at different stages of development. Activities will be tailored to different types of centres with varying legal organizational structure, degrees of maturity, resource availability, size and type of healthcare system of the country or region. Therefore, the readiness assessment is essential to understand the baseline capacities and framework conditions of candidate centres at the outset of the certification journey. The readiness refers to the extent to which a centre has the professionals, strategies, processes, infrastructure, and resources in place to successfully adopt and sustain a comprehensive-like certification.

In response to this need, WP6 presents a specific assessment tool to help centres understand which structural and operational components are most critical for creating the right conditions to succeed in certification.





2. Purpose

The Readiness Assessment Checklist is a practical evaluation tool devoted to support candidate CCC in understanding their level of readiness before starting the EUCCC certification process.

Specifically, its purpose is to:

- 1. Provide a structured overview of candidate CCC baseline capacities and capabilities as well as key insights on framework conditions.
- 2. Facilitate candidate CCC reflection in aligning its development strategy with the certification goals.
- 3. Articulate a structured dialogue with WP6 regarding the practical level of preparedness, thereby contributing to inform and guide tailored capacity-building activities.

3. Methodology

The development of the checklist has been carried out in three phases:

- a) Literature review and 4 focus groups to define the thematic areas and the initial items of the checklist (period February-May 2025);
- b) Co-creation and evaluation of the tool's components (thematic areas, items, and scoring system) with the participation of experts; and c) Validation with candidate CCCs under the framework of the MM pilot testing, including diverse European countries and the three main CCC configurations, namely, institutional, consortium and interregional CCCs.
- d) Review by CCC Coordinators (expert centres from WP6)
- d) Publication (TBC).

The co-creation and evaluation process of the checklist involved healthcare professionals from different European countries, with experience in care, healthcare management, research, and certification processes.

The final version of the checklist will be reviewed by JA WP leaders and the Joint Action Coordinator Team.

See annex 1 for more details regarding the methodology.





4. Checklist Components

4.1 Concept

The checklist is based on the principle that readiness for certification depends not only on compliance with specific standards but also on the underlying capacities and capabilities that enable sustainable implementation. For this reason, the checklist items are expressed as assumptions (e.g., "The candidate CCC has..."), each reflecting a key component considered essential for embarking on a comprehensive-like certification process.

4.2 Thematic areas and items

The checklist is composed by 30 items organized into four thematic areas, each addressing a critical dimension of readiness:

- → **Leadership and open attitudes toward change (7 items):** Focuses on institutional leadership, commitment, and the capacity to drive organizational transformation.
- → **Organisational development (9 items):** Covers governance structures, multidisciplinary collaboration, quality management systems, and workforce development.
- → Data management and IT standardization (6 items): Assesses the availability of reliable data systems, digital infrastructures, interoperability, and standardized IT processes.
- → Policy and institutional framework (8 items): Examines alignment with national/regional policies, regulatory environment, financial frameworks, and institutional support.

4.3 Evaluation system

The RACCC-30 uses a 5-point Likert scale to capture the degree of readiness for each of the 30 items. Each item is phrased as an assumption (e.g., "The candidate CCC has...") and must be rated according to how well it reflects the current situation of the candidate CCC.

On a scale from 1 to 5, can we <u>assume</u> that the candidate CCC has the assessed item <u>in place</u> in preparation for the EUnetCCC certification?

- → Strongly agree (n=5 points)
- → Agree (n=4 points)
- → Neither Agree nor Disagree (n=3 points)
- → Disagree (n=2 points)
- → Strongly disagree (n=1 point)

As an alternative method, another direct rating scale like Likert-Type Scales composed of multiple, typically 4 to 10, related Likert items (7).

4.4 Calculating scores





The total score and the sub-score by thematic area will be calculated as the average of all items values. For this checklist, we assume that all items carry equal weight.

The results of the RACCC-30 will provide information at different levels:

- → Global scoring: the total score across all 30 items to understand the degree of readiness of the candidate CCC to cope with the process of certification.
- → Scoring per thematic area: sub-scores are calculated for each of the four thematic areas, providing a clear orientation to the centre on their baseline capacities and capabilities by them.
- → Relative position across all candidate CCC that will provide a comparative and anonymous view and guides WP6 in allocating capacity-building support.

As an alternative method, the total score could also be calculated as the sum of all item scores, assuming there are no missing values.

5. Instructions to fulfil the checklist

To ensure the RACCC-30 provides a reliable and comprehensive picture of readiness, careful attention must be paid to how the checklist is completed and by whom.

Consensus approach

- Completion of the checklist is ideally carried out through consensus-building among the selected informants, with two or three representatives who have a wide view on the candidate's overall situation. Thus, it is highly recommended that participants reach consensus on the scoring of each item.
- Discussion among informants ensures that different perspectives are considered and that responses reflect the collective reality of the centre, rather than individual viewpoints.

Full completion

• All 30 items should be completed.

Confidentiality

- The information provided through the RACCC-30 will be treated confidentially and anonymously. There will be no public mention of the centre's name and of the professionals involved. Only the teams engaged in the capacity building activities (under the framework of EUnetCCC JA) will have access to the data.
- All data will be stored in accordance with the General Data Protection Regulation (GDPR) on the EUnetCCC IT portal.





6. Readiness Assessment Checklist (RACCC-30)

- Based on your perspective, please assign a score by answering the following question:
 On a scale from 1 to 5, can we <u>assume</u> that the candidate CCC has the assessed item <u>in place</u> in preparation for the EUnetCCC certification?
 - o Strongly agree (5 points)
 - o Agree (4 points)
 - o Neither Agree nor Disagree (3 points)
 - o Disagree (2 points)
 - o Strongly disagree (1 point)

em	atic area 1: Leadership and openness toward change	
		Value
1.	Formalisation of the governance structure . A formal Cancer Centre Board (the governing body of the CCC) is in place, or is being established with clear structures to ensure institutional alignment among the institutions that make up the candidate CCC.	
2.	Patients' representative role. There is broad acceptance of patients having a role in the governance of the candidate CCC, and some related actions have been implemented.	
3.	Attitudes toward change. A positive attitude toward change is present across all relevant organisational units (including non-oncological ones), and no major resistance is envisaged.	
4.	<i>Culture of quality evaluation.</i> The constituent institutions of the CCC have previous certification experience or routinely collect and use quality data to support organisational improvement.	
5.	Top-management commitment and leverage . Candidate centre's director (or transversal leadership in the case of a consortium) has formally granted legitimacy to the "core team" managing the certification, as well as to specific leverage mechanisms (e.g., involvement of heads of services).	





6.	Formalisation of the certification team's task . A project leader and a "core team" are engaging and supporting all professionals involved in the certification (including clinical-, quality- and IT departments), while avoiding over-reliance on individual relationships, informal meetings and ad hoc approaches.	
7.	Communication framework . A communication framework promotes the EUnetCCC certification across all constituents of candidate CCC, fostering shared understanding and reducing organizational silos in alignment with centre's strategic plan.	
Them	atic area 2: Organisational development	
		Value
8.	Integration of healthcare providers, universities, and research institutions. The constituents of the CCC share common goals and plan joint activities beyond merely having professionals who conduct clinical or research work across the different institutions.	
9.	Resources' mobilisation . Sufficient resources are expected to be mobilised to effectively manage the certification process, including workforce support with the necessary competencies and skills.	
10.	<i>Infrastructures in place</i> . The candidate' healthcare services encompass all the care and research infrastructures needed to meet the EUnetCCC Standards and enable their full development.	
11.	<i>Care pathways' activation</i> . No significant resistance is anticipated in developing diseased-based care pathways, including assigning roles and responsibilities to the relevant departments, collecting data and ensuring active monitoring.	
12.	Centrality of multidisciplinary teams in clinical decision-making. Multidisciplinary team (MDT) meetings for each cancer type are well established and plays a central role in reviewing diagnosis and making therapeutic decisions for most cancer patients. Where needed, a multicentric approach is adopted in consortia settings or international collaboration in the case of small countries.	
13.	Presence of advanced nursing roles. Advanced practice nurses (APN)* have been formally recognised and introduced as an essential part of the healthcare workforce. *An APN is a nurse who has acquired clinical competencies and advanced decision-making skills, through additional education, for expanded nursing clinical practice (ICN, 2008).	





14. <i>Access to molecular tumour board</i> . Access to a molecular tumour board - whether in-house, regional/national or cross-border - has been ensured. In addition, local professionals are in place to bridge knowledge gaps in interpreting results and to correctly adapt patients' clinical management.	
15. <i>Education opportunities</i> . The relationship between the healthcare setting and medical education providers is established and in good position to enable the delivery of continuous education at all levels of the CCC, creating training and development opportunities for all professional groups.	
16. <i>Protected research time</i> . Healthcare professionals are given protected time for research activities.	
Thematic area 3: Data management and IT standardisation	
	Value
17. Data sharing . The candidate CCC's data protection policy and the national legal framework (including patient liability provisions) allow data sharing and ensure continuity of data flows necessary for indicator collection across all constituents of the candidate CCC.	
18. Standardised IT tools and structured data . A regional or national plan for IT development supports the creation of standardised IT tools (such as a unique Electronic Health Record across organizations), semantic standardisation of data and common data models (structured, named and stored), enabling interoperability, cross-centre data exchange and future international data sharing.	
19. <i>Data retrieval</i> . Cancer patient data can be retrieved, implying data from all constituents of the candidate CCC or delimited to cancer patients. Data retrieval may be automatic or performed manually.	
20. Data quality control . Data quality control mechanisms are being developed (e.g., indicators at the centre and diagnosis level, and dashboards supporting candidate CCC governance and quality improvement) to ensure the reliability of data used for monitoring and research.	
21. Data accessibility across the constituents of the candidate CCC. The candidate CCC's IT infrastructure enables the efficient generation, and retrieval of all data types required for the certification. It also ensures access to data from independent system within the constituents of the candidate CCC, including electronic healthcare records, clinical trials data systems, population based-cancer registries, human recourse systems, and others.	





22. Use of data not retrievable from the constituents of the candidate CCC. An agreement is in place between the constituents of the candidate CCC and other regional or national institutions to enable the use of other data for quality and research purposes (e.g., survival from a national cancer registry, Central Registry of Insured Persons).

Thematic area 4: Policy and institutional framework Value 23. *Compatibility of certification*. The EUCCC Certification process is compatible with other regional, national and international requirements and targets (e.g., waiting times, surgeons' caseload). 24. Framework conditions. Factors such as geographic distances, low population density and/or a high number of CCC components have been identified, and mitigation strategies are in place. 25. *Healthcare coverage*. The national level of healthcare coverage (including technology, treatments and infrastructure) does not pose a major obstacle to the deployment of EUnetCCC Standards. 26. *Support from health authorities*. Recognition and support from regional and/or national health authorities is ensured, if needed. 27. **Societal value of the certification**. The value of the EUnetCCC certification has been communicated to citizens, communities, healthcare professionals and providers beyond the CCC through the Ministry of Health, public agencies or bodies, National Support Groups or Cancer Mission Hubs. 28. Access to innovative diagnostics and therapies. Supply chain challenges and/or market constraints (e.g., access to innovative drugs) do not pose a significant barrier to developing the full potential of the candidate CCC. 29. **Positioning of CCCs within the health system**. A national body (e.g., national cancer institute, hospital federation, health authority, or national insurance) is engaged to align the various healthcare providers involved in cancer under a single strategy or it is anticipated that the CCC will assume this coordinating role itself. 30. *Policy alignment*. The level of coordination between the Ministries involved in the certification process (e.g., health, social security, science, education) provides a sufficient basis for integrating the shared activity and resources of care providers, universities and research institutions within the CCC framework.





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ANNEX 1. Checklist development methodology

The checklist development follows a mixed-methods approach, combining qualitative and quantitative methodologies (8)(9) and is structured into three phase.

The first phase is qualitative and documentary, aiming to build the conceptual foundation. The second phase continues with a qualitative approach to define the checklist. The third phase combines qualitative and quantitative methods and focuses on validating the assessment tool.

• Phase 1: Identification of thematic areas and items

- → The checklist development begins with a literature review to identify previous experiences related to institutional readiness assessments at the beginning of a certification or development process. This review serves as a basis for the initial definition of thematic areas that represent institutional readiness, and the identification of potential items to include in the checklist. The search includes scientific databases such as PubMed and grey literature sources.
- → Thematic areas are validated in an initial expert meeting involving professionals with experience in evaluation processes and certification systems for CCC.
- → Next, focus groups are conducted based on the previously identified thematic areas to identify relevant items for each. Participants are selected through purposive sampling, based on their expertise in oncology care, health system management, research, and oncology certification schemes, while ensuring geographical diversity, with experts from various EU Member States or associated countries.

• Phase 2: Checklist development

- → The research team structures the items gathered during the focus groups and conducts a complementary literature review to identify the most suitable scoring method.
- → All components of the checklist are submitted for review to experts from the focus groups, members of WP6, and professionals experienced in CCC certification schemes in Europe (notably from OECI and DKH).
- → Experts provide feedback to improve the clarity, relevance, and feasibility of the items and scoring system. The research team integrates the proposed modifications into the checklist.

• Phase 3: Checklist validation

→ The checklist development includes a pilot test in a representative sample of European centres that are candidates for EUCCC certification (at least 10 centres). Centres are selected according to the following criteria:

Inclusion criteria:

Centres representing different European regions from at least three EU Member
 States or associated countries.





 Centres with varying institutional configurations, including institutional, consortium and Interregional CCCs, some of them involved local networks of providers (not certified but associated to the CCC through territorial integration mechanisms, such as integrated care pathways).

Exclusion criteria:

o Centres in a mature position towards a CCC-like certififcation.

Limitations

Although the checklist development is designed to ensure methodological rigour and expert engagement, it presents some inherent limitations related to the study type and context. First, the use of purposive sampling for selecting participants and pilot centres may introduce selection bias. Additionally, since participation is voluntary, this may further impact representativeness, particularly if geographical or institutional diversity is insufficient across EU Member States or associated countries.

Furthermore, even though the qualitative validation process follows a systematic approach, it depends on subjective expert judgment, which may be influenced by healthcare system contexts, professional experience, or personal interpretations of the CCC concept. Lastly, although the checklist is built on general items and for all CCC configurations, it may require context-specific adaptations in regional or national settings with significant structural differences.