EUnetCCC

Handbook

for

Setting up and Certifying CCCNs

Table of contents

Abbreviations and Acronyms

CanCon	Cancer Control
CCC	Comprehensive Cancer Centres
CCCN	Comprehensive Cancer Care Network
CCIs	Comprehensive Cancer Infrastructures
CraNE	Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking
DS	Data Sheet
EUnetCCC	European Network of Comprehensive Cancer Centres
FAQs	Frequently Asked Questions
iPACC	Innovative Partnership for Action Against Cancer
JA	Joint Action
KPI	Key Performance Indicators
NDA	Non-disclosure agreement
QI	Quality Indictaors
SOP	Standard Operating Procedures
SoS	Set of Standards
WP	Work Package

About the Handbook

The main goal of the Handbook is to give potential CCCNs an overview and additional information to facilitate the setting up of certified Comprehensive Cancer Care Networks (CCCNs).

Figure 1 provides an overview of the steps including its content.

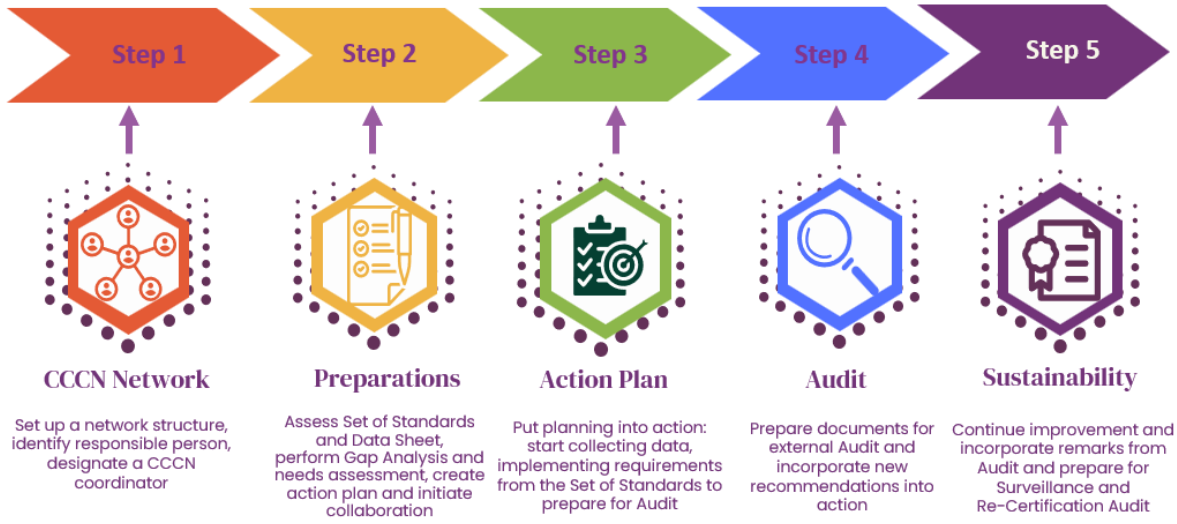


Figure 1: Stepwise approach of the training manual

The Handbook starts with an introduction and contextual backdrop on the CCCN (Comprehensive Cancer Care Network) concept and core elements and continues with chapters covering the 5 overarching steps towards setting up and certifying CCCNs.

Each chapter starts with a short overview of the content and relevant documents, provides examples as well as supporting material.

All documents, templates and other supporting materials can be downloaded in the "Documents Repository" [add Hyperlink]. In addition a Glossary can be found in the Annex [add Hyperlink].

Introduction

1. What is a CCCN?

The updated and currently applied definition of CCCN builds on the theoretical framework and definition developed and agreed during the Joint Action Cancer Control (JA CanCon) [1]. In the light of the emergence of the important role CCCs (Comprehensive Cancer Centres) along with CCCN in the cancer ecosystem, the CCCN definition was jointly further developed in the Joint Action Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking (JA CraNE) to define and acknowledge the interfaces between care (CCCN) and research (CCC). Accordingly, CCCN are defined as follows:

The text highlighted in purple depict the additions that were made to the initial CCCN definition:

- A CCCN consists of multiple units belonging to different institutions dedicated to early detection, diagnosis, treatment, follow-up, supportive and palliative care and rehabilitation for the benefit of cancer patients and cancer survivors. CCCNs encourage the enrolment of their patients in clinical trials conducted within the CCCN or in the co-operating CCC to ensure the integration of research and care
- A CCCN is a collaborative organizational structure united by having joint tumour-specific patient pathways, covering one or more patient pathways.
- A CCCN must have a formal collaboration with a Comprehensive Cancer Centre (CCC), e.g. for complex disease situations, diagnostics and/or research activities. The CCCN can be an extension of the care network of a CCC and/or cooperating with a CCC.
- In a CCCN an inter-professional and multidisciplinary team work together along a tumour-specific, guideline-based patient pathway or along several pathways for the benefit of patients with each particular type of tumour.
- In a CCCN the inter-professional and multidisciplinary team also works together on topics depending on and benefiting from pan-pathway collaboration – like precision cancer medicine, exploiting of diagnostic and treatment capacities, prevention, survivorship, palliation and cancer related education and training.
- The units interact and have a formal agreement to work together in a programmatic and structured way with common governance structure, in order to pursue their goals more effectively and efficiently through collective synergies.
- The CCCN promotes a uniform system of quality assurance and a unified informatics system for optimal exchange of information. It provides both tumour-specific Quality Indicators as well as pan-cancer related Indicators. The Indicators are used by the governmental processes of the CCCN to make the quality of care in the CCCN transparent and to continuously improve it.

- The objective of a CCCN is to provide comprehensive cancer care to all the people living in a specific geographic area and specifically securing access to the advanced services of CCCs to all eligible patients, thus pursuing equality and the improvement of outcomes and quality.

Based on the updated CCCN definition corresponding requirements/standards for the interfaces between CCCN and CCCs were integrated in the Set of Standards for CCCNs.

The network with its functionality is illustrated in the following

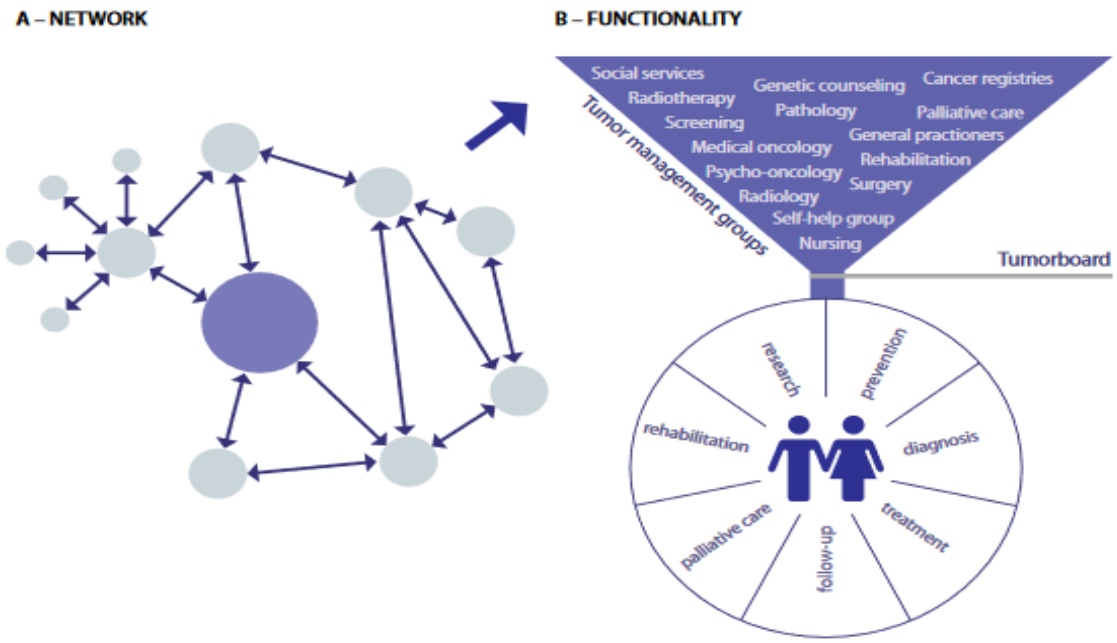


Figure 2.

A – Network: The dots represent units/institutions (e.g. primary care, community hospitals, university hospitals, psychosocial counselling etc.) dedicated to research, prevention, diagnosis, treatment, follow-up, supportive and palliative care and rehabilitation, which work together as a CCCN in a structured way with a common governance

B – Functionality: The tumour management groups within the CCCN are inter-professional, multi-disciplinary and tumour-specific; with the objective to provide comprehensive cancer care to all the people living in a certain geographic area

Notes: The example of a network (A) has arrows to indicate the flow of patients, expertise, data etc. between networking institutions of different sizes, with different roles and at different levels in the health system. These work together in a structured way with a common governance. The dots indicate units/institutions (e.g. primary care, community hospitals, university hospitals. psychosocial counselling) dedicated to research, prevention, diagnosis, treatment, follow-up, supportive and palliative care and rehabilitation. In tumour management groups (B), care-related activities are interprofessional, multidisciplinary and tumour specific. The objective is to provide comprehensive cancer care to the entire population within the catchment area.

Figure 2: EUROPEAN guide on quality improvement in comprehensive cancer control [2]

2. Set of Standards for CCCNs

2.1 Overview

The Set of Standards is the key record where the partners, the structure, collaboration mechanisms and key performance Indicators of CCCNs are laid out.

The Set of Standards consists of 2 documents:

- Word Document: Set of Standards (SoS)
- Excel Document: Data Sheet (DS)

These two elements belong together. The SoS focusses on structural requirements such as structure of the network, qualification of staff, patient pathways etc. whereas the DS focusses on case numbers and Indicators (=Key Performance Indicators (KPIs)/ Quality Indicators (QIs). Together they give an overview over the interdisciplinary and multiprofessional network, the intense cooperation of network partners and the evidence-based treatment in the CCCN

The filled-out SoS and DS must be submitted annually according to the specifications outlined in the certification framework.

Through the SoS, DS and the certification framework a common basis for evaluation in certified networks is established and as such the foundation to identify and reduce differences of quality of care not only between networks, but also between regions and countries is possible.

During the Audits, performance, especially based on the Indicators, is reflected, discussed and if necessary improved by defining and applying suitable actions within the network. The outcomes of these defined measures will then be evaluated during the next Audit.

Moreover, thanks to the established structures and the comprehensive data collection, a Plan-Do-Check-Act-Cycle for continuous improvement can successfully be implemented.

Let's take a closer look at the two documents:

2.1 Word document: Set of Standards

All SoS have the same structure and the same table of content. The chapters include, among others, standards for

- the organisation and processes of the network with a focus on the implementation of interdisciplinary tumour boards,
- the rules and contents of the cooperation between the partners,
- the obligatory disciplines represented in the tumour-specific network,

- the conduct of and access to studies,
- the participation of patients,
- tumour-specific quantitative and qualitative minimum requirements for the expertise of the network partners.

In principle, all requirements outlined in the SoS are to be fulfilled in full.

For some requirements, if a requirement is not (yet) fulfilled by the time of the audit, a concrete plan for its implementation over time must be provided.

If a requirement cannot be fulfilled due to country-specific or health system related constrains, this must be clearly justified. An equivalent solution must be described and agreed.

Each tumour entity has their specific SoS consisting of universal requirements (same for all tumour entities), adapted requirements (same for all tumour entities but with some tumour-specific modifications) and tumour-specific requirements (only applicable for the specific tumours).

Pathologists and Radiotherapist are partners in every CCCN. They should not fill in a separate SoS for every single tumour-specific CCCN they are cooperating with. Therefore a separate SoS for Pathology and Radiotherapy are available, consisting of universal requirements and tumour-specific requirements.

Additionally, there is a SoS for pan-tumour CCCNs. It summarises the non-tumour-specific requirements for a CCCN that has at least 3 tumour-specific CCCNs. SoS addresses overarching governance, streamline standards and process across tumour entities and address cross-tumour collaboration and pathways.

The newest version of the SoS can be downloaded from the Document Collection [*add Hyperlink to Step1*] for the following topics:

- Colorectal and Pancreatic Cancer CCCN
- Gynaecological Cancers CCCN
- Lung Cancer CCCN
- Prostate Cancer CCCN
- Pathology CCCN
- Radiotherapy CCCN

2.2 Excel document: Data Sheet

An essential aspect of the monitoring framework of the CCCNs is to measure and visualize the quality of oncological care in CCCN. The starting point for quality measurements are the DS which are an integral part of the tumour-specific SoS. The DS itemizes the Quality Indicators (QIs), that report to the guideline-appropriate treatment, and other key figures that assess the cooperation within the certified network and the expertise of the main treatment partners.

Most Indicators are tailored to the specific tumour entity and include specific diagnostic or therapy requirements.

The majority of the Key Performance Indicators (KPIs) have target values whereas others have defined plausibility limits in which the certified networks have to give a mandatory statement of reasons as to why the limits were overstepped.

For a successful certification, the cancer car networks must meet the target value or give a plausible explanation in case they are not meeting the value.

The newest version of the DS can be downloaded from the Document Collection Step1 [*Hyperlink to Document Collection Step 1*] for the following topics:

- Colorectal Cancer CCCN
- Pancreatic Cancer CCCN
- Lung Cancer CCCN
- Prostate Cancer CCCN
- Gynaecological Cancers CCCN

2.3 Additional supporting documents

To support and facilitate the implementation of the SoS the following support documents are available:

- CCCN Partner Matrix
- Checklists
- Data Sheets
- Examples / Good Practices
- FAQs
- Information Resource
- Learning Material / Training Material
- Set of Standards
- Templates

These supporting documents can be downloaded from the Document Collection from Step1 to Step 4.

3. How to become a certified CCCN in a nutshell

To apply for certification, all partners of the CCCNs must meet the defined requirements laid out in the SoS across all areas of cancer care: from early detection, diagnosis and treatment to aftercare, research, patient support, follow up, palliation and documentation.

As part of the certification the CCCN has to submit the filled-out SoS. All described standards have to be described and implemented.

Moreover aspiring CCCNs must record the Basic Data and Indicators listed in the Data Sheet for at least six months before applying.

After an initial review of the documents and clarification of critical points, a team of independent oncology experts (Auditors) will visit the CCCN for 1-2 days to confirm compliance with the SoS and discuss possible improvements.

The Auditors make a recommendation as to whether a certificate should be issued. However, the final decision on certification is made by the Certificate Awarding Committee based on the Audit report and recommendations.

Figure 3 shows on the example of a Lung Cancer CCCNs all documents (SoS Lung Cancer CCCN, SoS Pathology, SoS Radiotherapy, DS and CCCN Partner Matrix) that have to be filled-in, implemented and submitted for certification.

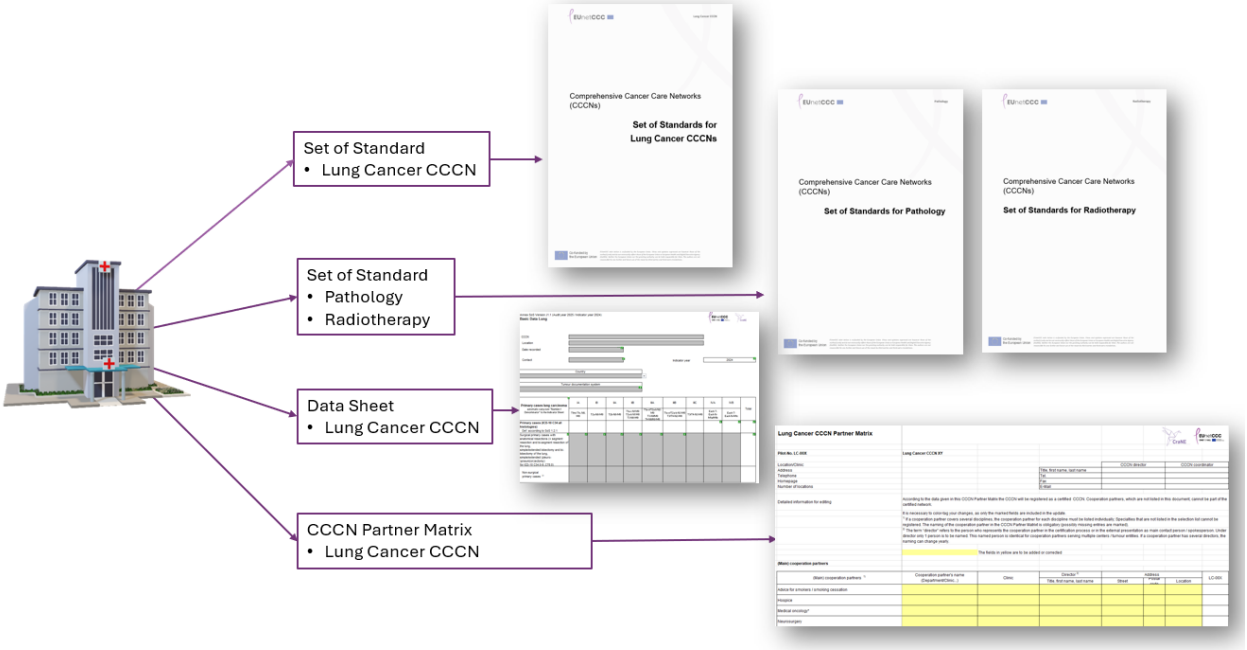


Figure 3: Overview of all documents due for submission (example Lung CCCN)

4. What benefits does the implementation of CCCNs have?

Care of oncological patients always requires cooperation of many disciplines and professional groups. These partners must have sufficient experience for the treatment of the corresponding tumour entity. The SoS for the establishment of CCCN summarise the requirements for all experts involved so that the above-mentioned prerequisites can be met.

Becoming a certified CCCN among many positive aspects will contribute to improve the quality of care, create a uniformly high level of quality care and improve evidence-based practice.

During research conducted amongst already certified CCCNs in the scope of the JA CraNE [3] interviewed CCCN partners highlighted the following aspects that can be positively impacted through the setting up and certification of CCCNs.

Structural level

- implementation of quality procedures
- introduction of new concepts, restructuring processes and updating/development of (new) Standard Operating Procedures (SOPs)
- implement a more structured patient pathway and patient flow
- Improvement on interpersonal level and peer collaboration for instance
    - Better communication and collaboration between different specializations and generate a better understanding why/for what certain measures are necessary
    - Learning from colleagues at the CCCN and from colleagues abroad
    - Becoming a "Breast/Colorectal/Pancreatic Comprehensive Cancer Network" team; develop a common identity

Economic level

- Certification can have positive impact with regard to increasing patient numbers
- First certified CCCN could become a lighthouse project, which helped support discussions at the national level
- Media coverage generated pride in the project, both among the CCCNs and in the wider community

Patient Care level

- Establishing additional cooperation with patient organizations
- Development of additional material for patients including clear structure and steps to follow along the patient pathway / patient centeredness
- Better patient management / flow (i.e. complete information is available, i.e. pathology report)

Moreover, the study identified added value and benefits for different stakeholder groups that are involved in the CCCN concept

- The CCCN concept supports policy makers in establishing national quality-assured CCCN that combines care close to home, if possible, with centralised treatment, if necessary.
- For clinicians, the CCCN concept is helpful in order to implement reliable networks, in which experts work together in a structured way and with this unnecessary diagnostic, time delays and wrong therapy decisions are avoided.
- The CCCN concept gives patients the assurance that they will be treated by experts for their specific disease who will develop and implement the best possible treatment plan for them.

Step 1. CCCN Network – Setting up the Network

First important steps on the journey to an CCCN is setting up the network. This includes (1) deciding on the *tumour entity* and (2) setting up the corresponding *CCCN network*. For the successful setting up of the network the obligatory cooperation partners have to be identified. The CCCN director and the CCCN coordinator must be designated.

All documents relevant to Step 1 are provided in the Document Collection [*add hyperlink*].

1. Structure of the Network – the CCCN Partner Matrix

An essential part of a CCCN is an interdisciplinary network consisting of numerous treatment partners from different specialties and professional groups.

This network can be complex with a wide plexus. It should cover as much of the patient pathway as possible, and its members should be part of a trusted and functioning system. It is the defining character of a CCCN.

The tool to depict that network in the certification process is the CCCN Partner Matrix.

The CCCN Partner Matrix is an Excel document that lists and names the cooperation partners for each tumour-specific CCCN.

It offers an overview of existing cooperations. It contains the information (discipline, name, department, address, mail, etc.) of all mandatory partners of the CCCN that are listed in the Set of Standards.

2. Guiding Principles of CCCN Partner Matrix

When setting up the network and filling in the CCCN Partner Matrix, it is important to keep the points illustrated in Figure 4 in mind.

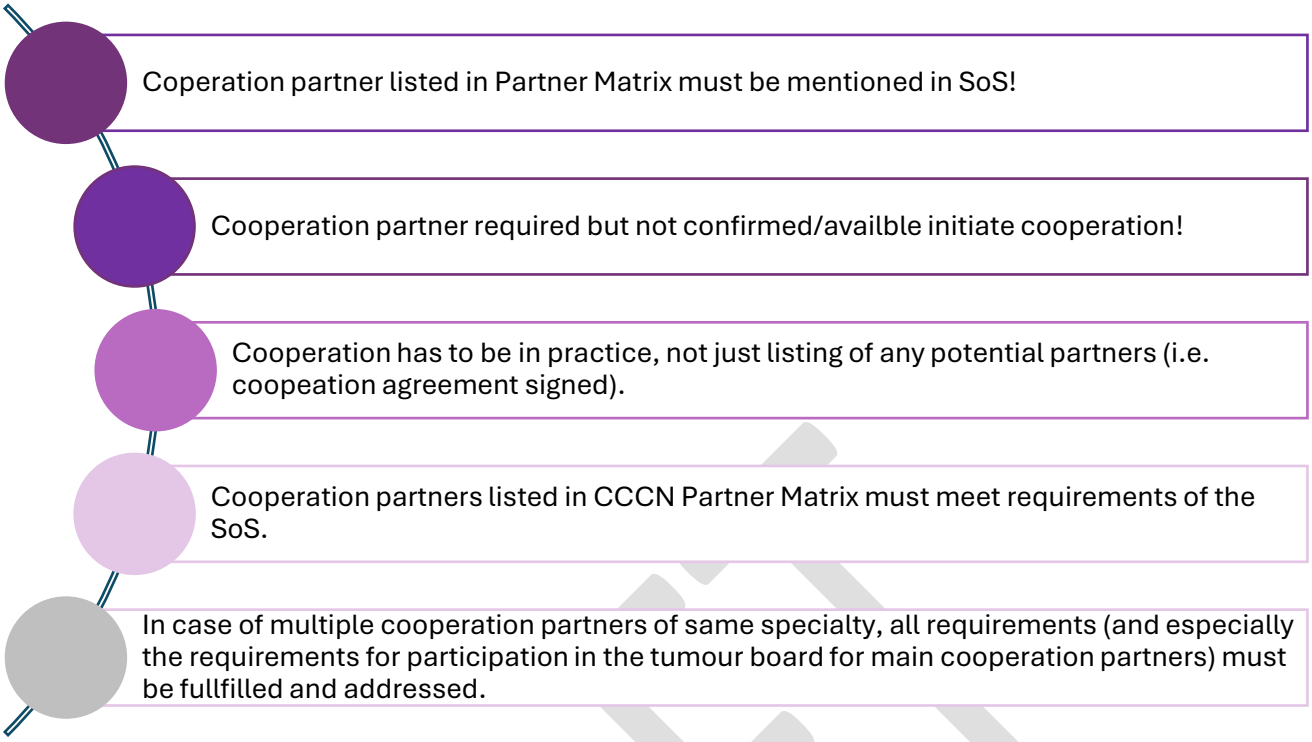


Figure 4: Principles of CCCN Partner Matrix

3. CCCN Director and CCCN Coordinator

Support and encouragement from the management & leadership level and good coordination skills have been identified as key ingredients for successfully set up CCCNs.

3.1 Tasks of the CCCN Director

- **Leadership:** Guiding the CCCN coordinator and other teams and ensuring alignment with the CCCNs mission.
- **Accountability:** Being responsible for (audit-)outcomes, performance, and compliance with the SoS.
- **Representation:** Acting as the face of the CCCN to patients, cooperation partners and other partners.
- **Decision making:** Making high-level decisions that affect budgets, staffing, policies, and operations.
- **Strategic planning:** Setting long-term goals and vision for a the CCCN.
- **Named contact for certification purposes:** maximum two directors, of whom one is a named as the contact person

Finding the right CCCN coordinator has been identified as a key role for success from previous CCCN pilots. CCCN coordinator needs to have sufficient time availability to perform their tasks and should have good standing and strong support from management / leadership team in the CCCN to be able to initiate change/new processes

3.2 Tasks of the CCCN Coordinator

- **Operational:** Coordinating all activities of the CCCN and the CCCN partners, key contact person.
- **Organization & Scheduling:** Arranging meetings (e.g. quality circles), events (e.g. patient information events), or project timelines (certification audit).
- **Communication:** Serving as a link between different teams, departments, or cooperation partners.
- **Implementation:** Making sure that plans, policies, or projects to fulfil the SoS are executed effectively and ensuring compliance with them.
- **Monitoring:** Tracking progress, gathering feedback, and reporting updates to relevant teams, higher management, CCCN Director and auditors.
- **Support Role:** Assisting with administrative or operational tasks, coordination of internal and external audits
- **Contact Person:** Communication interface for all network partners.

4. Definition of cooperation partners

The CCCN differentiates between various categories of cooperation and treatment partners based on their roles, responsibilities, and level of integration within the network.

The following Figure 5 “Representation of a CCCN Network structure “ illustrates the structure of a Lung CCCN, to show how various partners are interconnected to provide coordinated, multidisciplinary cancer care.

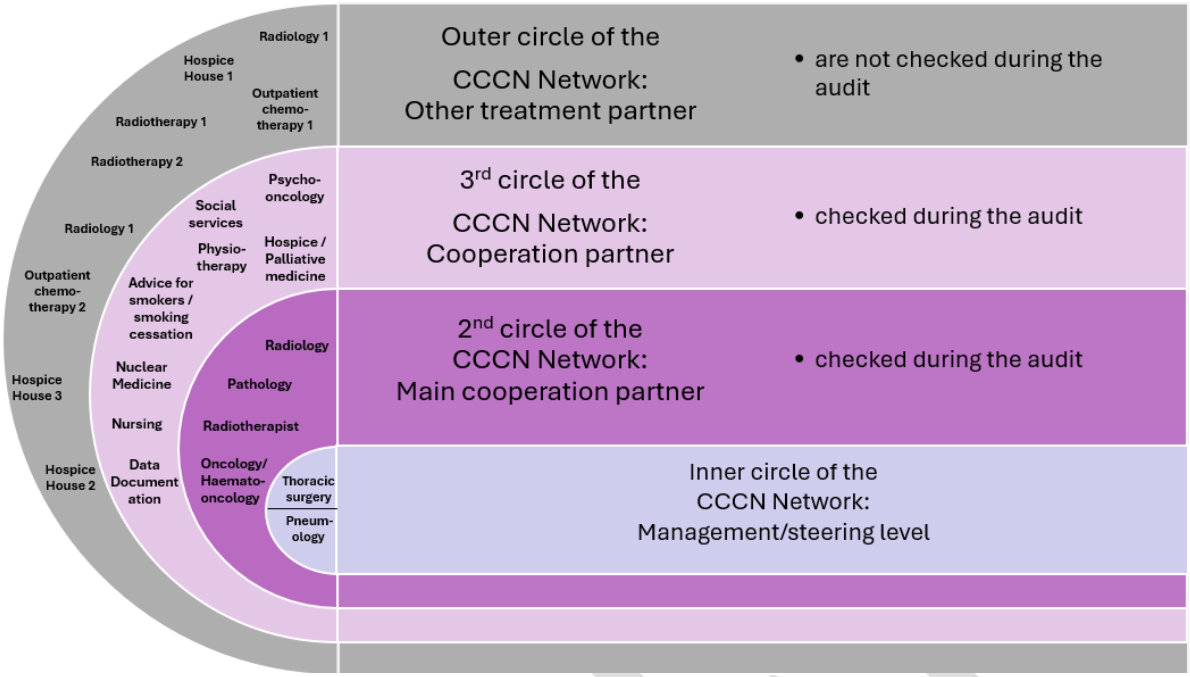


Figure 5: Representation of a CCCN Network structure on the example of a Lung Cancer CCCN

The involvement of the cooperation partners within a CCCN network can be divided into the following levels.

Management/steering level

- Lead, steer and coordinate the CCCN (i.e. CCCN director CCCN coordinator, Steering Committee)
- Often take on interdisciplinary tasks such as tumour documentation, further education events, public relations work

Main cooperation partners

- Take over essential parts of the care pathway
- Participate in tumour boards.
- Integration and cooperation within the CCCN is formalised in writing (i.e. cooperation agreements)
- Are audited and checked for compliance with the requirements in the Set of Standards as part of the certification process

Cooperation partners

- Integration and cooperation within the CCCN is formalised in writing (i.e. cooperation agreements)
- Participate in tumour boards (only main cooperation partners, see **Fehler! Verweisquelle konnte nicht gefunden werden.**)

- Take part in quality circles
- Participation in joint patient care
- Attend patient events, if applicable
- Are audited and checked for compliance with the requirements in the Set of Standards as part of the certification process
- Are audited and checked for compliance with the requirements in the Set of Standards as part of the certification process

Further Treatment partners

- No special integration into the network
- Cooperation is only considered in terms of patient-related care in the Audit
- These treatment partners do not have any special obligations within the framework of the CCCN.

5. How to select cooperation partners?

While there are many degrees of freedom and possibilities in the setting up of the CCCN network while keeping the qualification of the cooperation partners in mind, our two key recommendations are:

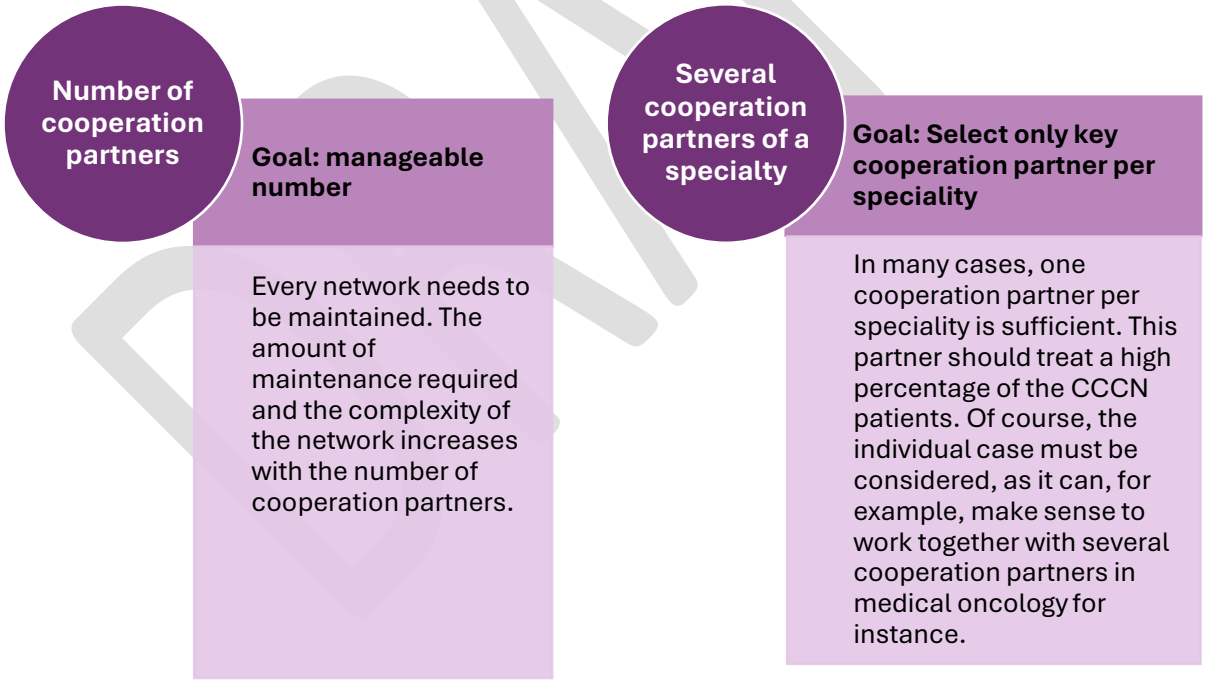


Figure 6: Principles of cooperation partners

6. Appointment of cooperation partners

The appointment and registration of cooperation partners within a CCCN follow clearly defined requirements:

- The obligatory members of the CCCN network according to the requirements in the SoS must be documented in the CCCN Partner Matrix.
- The cooperation partners can be changed or extended within the framework of the Surveillance Audits. Therefore an up-to-date version of the CCCN Partner Matrix has to be submitted on a yearly basis.
- Patients of the CCCN can also be cared for by treatment partners who do not have the status of a cooperation partner.
- For every tumour-specific CCCN there is a specific CCCN Partner Matrix available. The newest version of the CCCN Partner Matrix can be downloaded from the Document Collection Step1 [Hyperlink to Document Collection Step 1]

6.1 Example of multiple cooperation partners of same specialty

If multiple cooperation partners of the same specialty exist, a row for each must be added to the partner matrix and the details entered.

(Main) cooperation partners	Cooperation partners name (Department/Clinic)
Radiotherapy	Radiotherapy Novara
Radiotherapy	Radiotherapy Turin

Table 1: Multiple cooperation partners of the same kind

→ Submission of two separate SoS “Radiotherapy“ is necessary!

→ All listed cooperation partners “Radiotherapy“ are verified separately during the Audit!

When appointing cooperation partners, please note that recognition is only possible under the following conditions/checklist

Cooperation partner

The cooperation partner is actively involved in the further development of the CCCN and is committed to or participate in the CCCN activities (e.g. further education, patient information).

Set of Standard

The relevant requirements which are described in the Set of Standard for each cooperating partner are full-filled.

Written agreement

There is a written agreement between the CCCN and the cooperation partner.

Participation in the tumour board

If participation in the tumour board is required for a cooperation partner according to the Set of Standard (e.g. radiology, radiotherapist, pathologist), then their attendance at these meetings needs to be documented and proven

Figure 7: Checklist for cooperations partners

6.2 FAQ Structure of the Network

Are only registered cooperation partners allowed to treat patients of the CCCN?

- The execution of all therapy steps by the CCCNs cooperation partners at 100% is not feasible and is also not required.
- Every patient has the freedom to choose his or her treatment partners.
- Nevertheless, a large / main part of the therapies should also be carried out by the CCCN Network Partners
- Main part of therapy definition depends on tumour entity in general:
- Most of the treatment must take place within the CCCN structure or is controlled by the CCCN (tumour board or interdisciplinary treatment plan exists, main therapy, recording in the tumour documentation system, follow-up data are regularly determined etc.).

Can a cooperation partner work with several CCCNs?

- A cooperation partner can of course work with several CCCNs / clinics, regardless of whether they are certified or not.

- Example: Pathology A is a cooperation partner of a CCCN and regularly works with 2 other CCCNs, each with its own referral structures. Pathology A can also be listed as a cooperation partner in the Partner Matrix for the 2 other CCCNs.

Who cannot be a cooperation partner?

- Every cooperation partner must be actively participating in patient care together with the respective CCCN, otherwise an appointment as a cooperation partner is not possible ("paper cooperation").
- Facilities that only treat CCCN patients in rare cases (e.g., due to care close to home) and do not collaborate with the CCCN to a significant extent should not be listed as cooperation partners.
    - Example: Independent radiotherapy facility: A radiotherapy facility would like to be a cooperation partner of a Colorectal Cancer CCCN. However, the patients of the Colorectal Cancer CCCN are almost never treated with radiotherapy at the respective facility – then it cannot be a cooperating partner of this Colorectal Cancer CCCN.

Who must be a cooperation partner?

- If part of the therapy is regularly carried out by an external cooperation partner, integration into the CCCN is required in accordance with the SoS.
    - Example: External radiotherapy facility performs radiotherapy regularly on multiple patients at the Lung Cancer CCCN.

Document collection of Step 1 – CCCN Network

CCCN Partner Matrix

- *Colorectal Cancer CCCN*
- *Gynaecological Cancers CCCN*
- *Lung Cancer CCCN*
- *Pancreatic Cancer CCCN*
- *Pan-tumour CCCN*
- *Prostate Cancer CCCN*

Data Sheet

- *Colorectal Cancer CCCN*
- *Gynaecological Cancers CCCN*
- *Lung Cancer CCCN*
- *Pancreatic Cancer CCCN*
- *Prostate Cancer CCCN*

Set of Standards

- *Colorectal and Pancreatic Cancer CCCN*
- *Gynaecological Cancers CCCNs*
- *Lung Cancer CCCN*
- *Pan-tumour CCCN*
- *Prostate Cancer CCCN*
- *Prostate Cancer CCCN*
- *Pathology CCCN*
- *Radiotherapy CCCN*

Step 2. Preparation

In the second step of setting up a CCCN, it is important to analysis what is already in place, perform a gap analysis, identify missing standards/partners, identify challenges and to make an action plan. Further topics to be considered include deciding on a step wise approach towards certification and how patient pathways will be developed/implemented. Importantly, also data documentation needs to be addressed and assessed.

All documents relevant to Step 2 are provided in the Document Collection [*add hyperlink*].

1. Needs Analysis

As a first step it is recommended to create a priority task list. This list serves as a structured overview of essential tasks that must be addressed within the CCCN implementation and development process. It could address and include the following elements:

- Decide on the focus of the CCCN (Colorectal and Pancreatic Cancer CCCN, Lung Cancer CCCN etc.).
- Ensure support and encouragement from the management/leadership team.
- Designate a CCCN Director.
- Designate a CCCN Coordinator (see Step 1 for more information)
    - Ensure that the coordinator has sufficient time availability to perform the task.
    - Ensure that the coordinator has good standing / back up from leadership team in the CCCN.
- Setting up the Network (see Step 1 for more information [*add hyperlink*])
- Identify person(s) who might have knowledge / experience about certification processes.
- Assess SoS and DS.
    - Do a gap analysis & needs assessment (e.g. what is already in place, what has to be set-up, is additional staff necessary, financing available?).
    - Identify and designate responsible person per chapter/topic of Set of Standards and Data Sheet.

- Break down tasks into activities, allocated responsibilities and define the objectives and tasks that should be reached.
- Set up a timeline with milestones and submission deadlines (see Step 3 for more information) [*add hyperlink*]
- On-board IT-department, cancer registry/documentation department for data collection (see Step 1 for more information) [*add hyperlink*]
- Start holding regular meetings with aspiring CCCN team to align project goals, updating, and team spirit building.

Additional points to keep in mind are the following:

- Consider if it could be useful to commission a coaching/training to get extra external support with implementation.
- Conduct a (internal/external) Pre-Audit to get a trial run on the Audit and get a report with remarks/deviations.
- Consider taking a stepwise approach towards certification in order not to lose stamina along the way if, for instance, the gap analysis show that there are many topics to address (see "Stepwise approach towards certification" [*add hyperlink*]).

Helpful documents for download, such as a checklist with implementation examples and evidence for fulfilling the SoS, as well as the CCCN GANTT chart, are provided in Step 3. [*add hyperlink*]

2. Possible challenges within the CCCN implementation process

The implementation of the CCCN certification process can be accompanied by various organizational and operational changes that require careful planning and coordination. Overview of possible challenges identified during the research in the JA CraNE are listed below.

Change management

- The multi-stage certification process can be conflict-prone, time-consuming, and costly, involving potential changes to processes, IT solutions, and the creation of new positions or responsibilities.

Additional workload

- At the beginning certification means often more work for everybody involved (e.g. more documentation, different workflow, more meetings...).

Digitalization

- For documenting Data Sheets a functional IT-System as a foundation must be created, which can be challenging for some aspiring CCCNs

Staff resources and staff availability

- Due to the lack of uniformity in documentation systems and the high time expenditure required for implementation, it is essential to have a digital officer/ data manager who can provide significant assistance.
- CCCN coordinator needs to be able to dedicate significant time to certification project

Financing

- The biggest challenge for hospitals regarding certification is funding (i.e. (re)certification costs, IT system, additional human resources).

3. Stepwise approach towards certification

Full CCCN certification can be a complex and lengthy process especially if many changes need to be implemented in order to comply with the SoS (e.g. Data Documentation, specific training / further education not yet available, etc). The stepwise approach helps to not loose stamina along the way and allows a step-by-step implementation with feedback along the way. Moreover, the stepwise approach also supports the underlying key principle of the CCCN concept: continuous improvement along the demi-cycle (Plan-Do-Check-Act).

The three steps build on each other. Entry point can be at each steps. Figure 8 describes for each step the required mandatory chapters and facultative chapters of the SoS are depicted. Same applies for the Data Documentation in the DS.

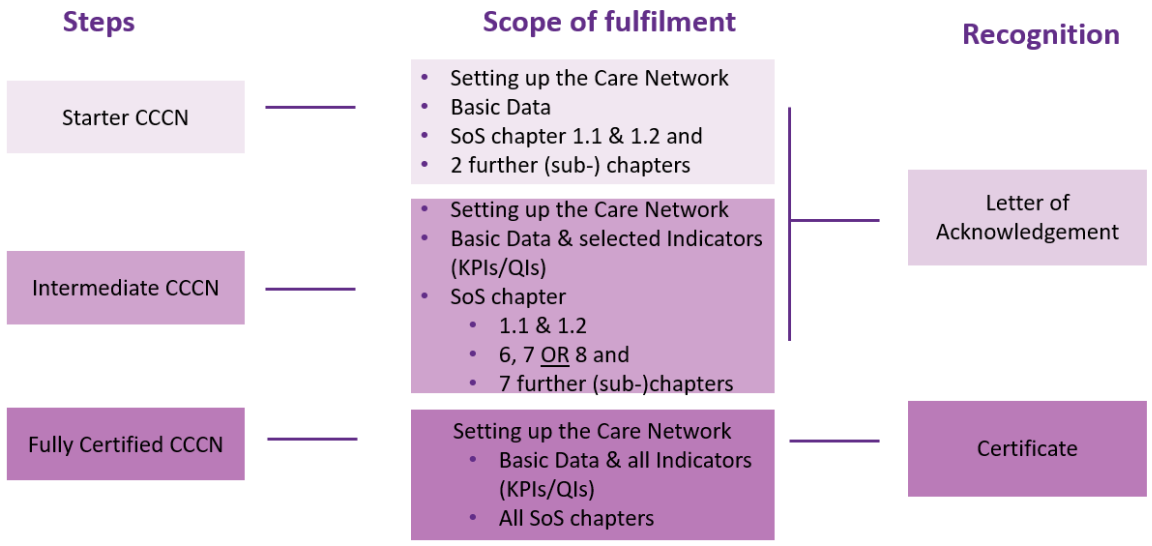


Figure 8: Stepwise Approach

The stepwise approach is valid for basic for a maximum of 3 years and for intermediate for a maximum of 2 x 3 years (6 years including a Re-Certification Audit) from the date of initial Audit. Within this period, the CCCN must extend its scope until all processes within the chosen module and the whole network must be fully included in the certification.

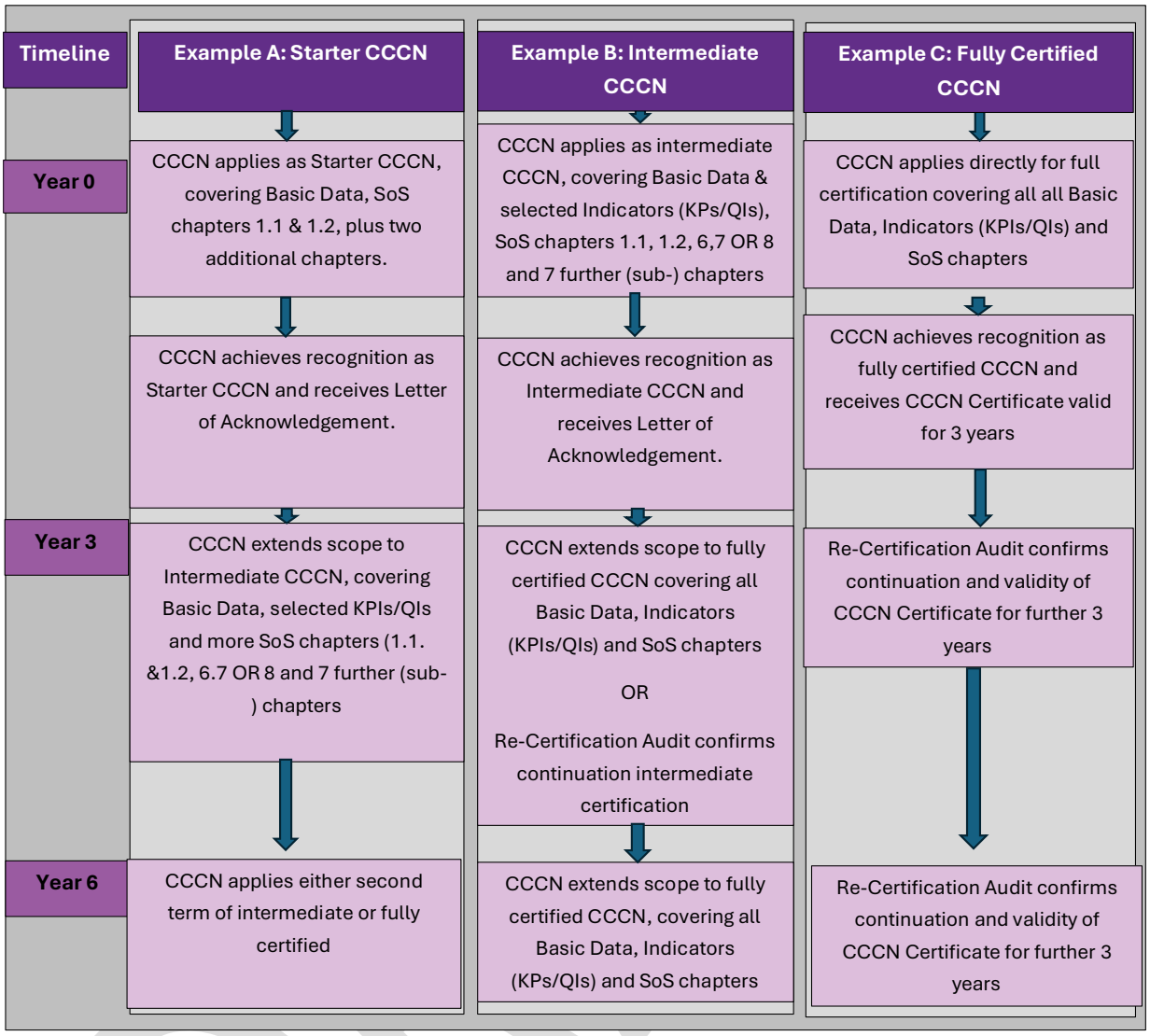


Figure 9: Examples of stepwise approaches in years

During the Audit, the starter and intermediate CCCN must present a clear plan for how it intends to reach full certification within the defined timeframe. This plan will be reviewed by the Certification Authority.

If the starter or intermediate CCCN is not able to mature into the next step within the defined timeframe a continuation of the CCCN process is not possible. As soon as significant steps towards the next steps are made (i.e. fulfilling further chapters of the Set of Standards), the aspiring CCCN can apply to re-join the process. Annual surveillance audits will take place in all 3 presented steps.

4. Patient Pathway

The Set of Standards describes that patient pathways should be developed and implemented within the CCCN Setting.

Standard	Requirements

1.1.10	• Overarching patient pathways are defined, reflecting the relevant national and international guidelines, and considering the interdisciplinary cooperation within the CCCN.
	• Patient pathways are defined for:
	  ○ Prevention
	  ○ Diagnostics
	  ○ Therapy
	  ○ Aftercare
	  ○ Rehabilitation
	  ○ Palliative care
	• Annual checks are made to ensure that the Patient pathways are up to date.
	• Patient pathways can be summarised in a QM manual, for example.

„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.” [4]

Optionally the patient pathway methodology developed during the Joint Action Innovative Partnership for Action Against Cancer (JA iPAAC) & JA CraNE can be used for this.

In the iPA²-Guide (Figure 11) a step-by-step method for development of patient pathways is described, providing concrete tool support for each phase of the development and implementation process.

Generic patient pathway templates act as blueprints for the development of patient pathways (Figure 11). They reflect the SoS and already include the necessary data collection points for relevant QIs. The patient pathway templates can be adapted to the national, regional or local conditions of a CCCN.

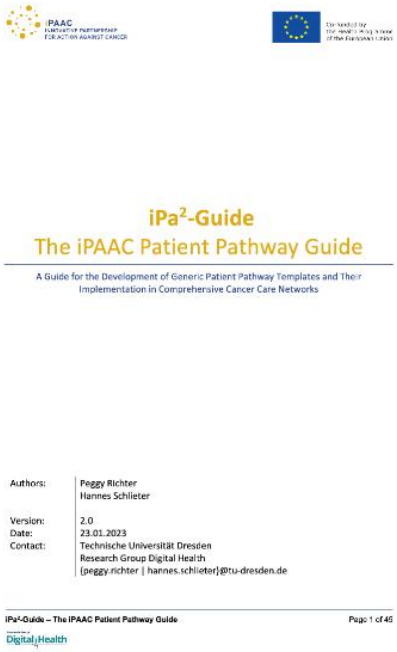


Figure 10: iPA2-Guide – A guide for the development of patient pathway templates and their implementation in CCCNs

CCCNs Templates for Patient Pathways

- Colorectal Cancer Patient Pathway Template for CCCNs [*add link*] (result from iPAAC)
- Pancreatic Cancer Patient Pathway Template for CCCNs [*add link*] (results from iPAAC)
- Lung Cancer Patient Pathway Template for CCCNs (results from CraNE) [*add link*]

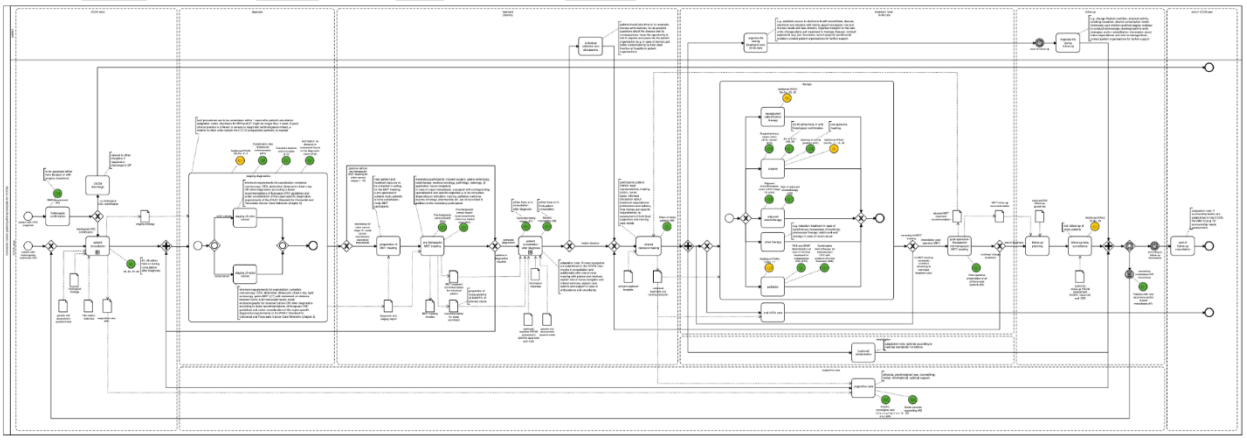


Figure 11: Example of Patient Pathway

For the development of patient pathways / the adaptation of patient pathway templates for CCCNs, there are online tools available. The XML files of the patient pathway templates developed can be provided for this purpose (Figure 12)

Tool support

- BPMN.io (free, to develop patient pathways as BPMN models, no pathway-specific elements available)
- Pathway modelling tool provided within the project context

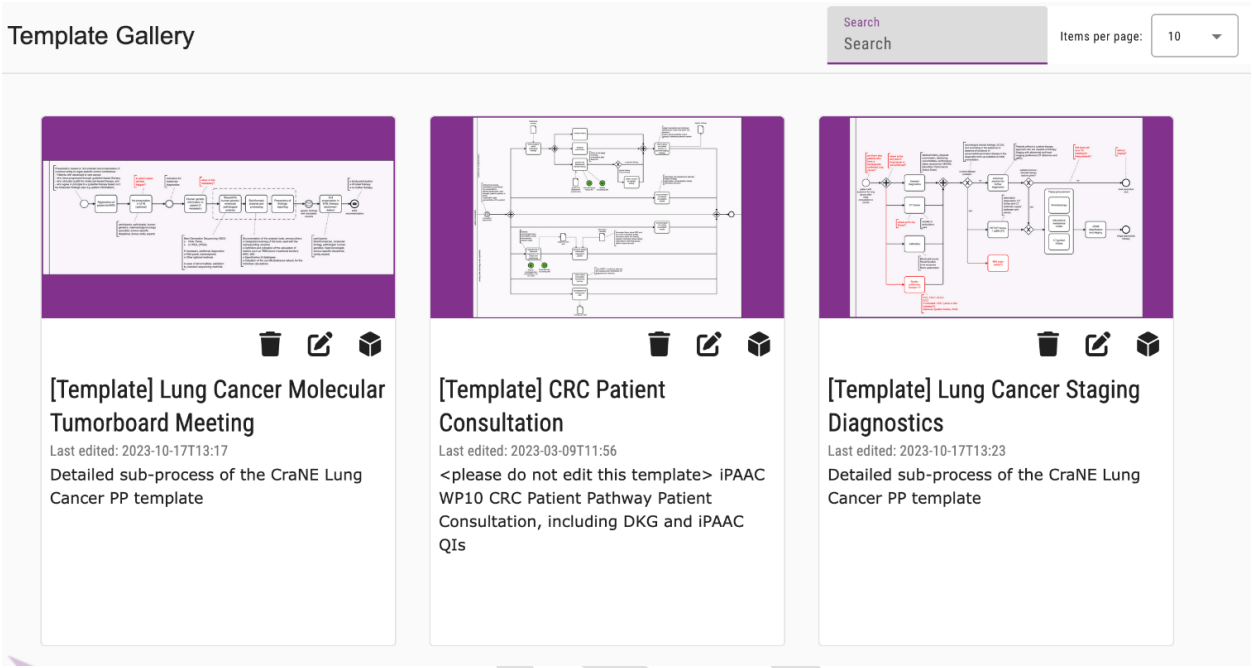


Figure 12: Template Gallery of Patient Pathways

Further information and guidance to develop and implement Patient Pathway can be found in the Document Collection of Step 2.

5. Data Documentation

The process of structured and uniform data documentation is challenging due to the fragmented nature of data, where information is often siloed across multiple databases and systems, leading to a situation where each parameter may be coded several times. This redundancy makes consistent and accurate data collection difficult.

The following Figure 14 and 15 illustrate this reality and highlights the interconnected relationship between strict medical and technical requirements (SoS) and robust tumour documentation (Data Sheet).

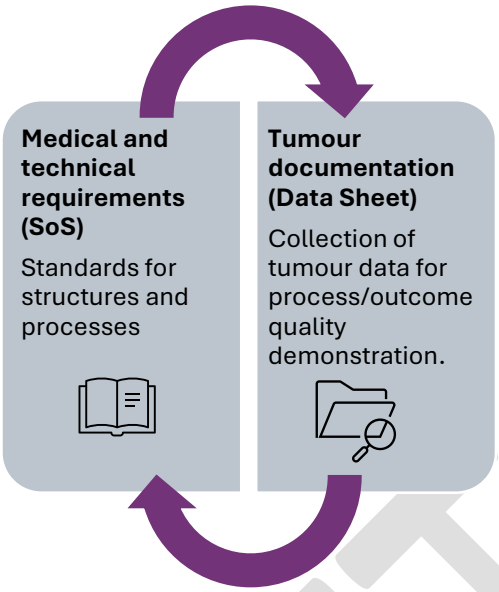


Figure 13: Requirements for Data Documentation

The goal is to provide a clear framework for ensuring the collection of accurate, well-organized data to meet the stringent timeframes and documentation standards required for the initial Audit.

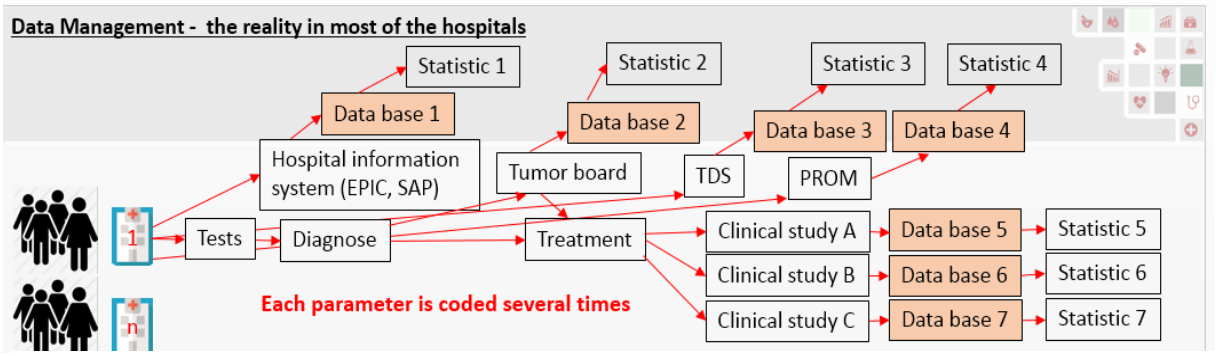


Figure 14: Overview of possible interconnections in data documentation

The qualitative requirements in the SoSs and the quantitative requirements in the DS are interdependent and therefore it is advisable to address the implementation and preparation of both topics simultaneously to ensure a successful certification

5.1 Basic Rules for Data Documentation

The process of data documentation is governed by basic rules designed to ensure accuracy and consistency.

- All reported figures must reflect actual measured values, with estimates explicitly excluded.
- Data entries are to be referenced to a full calendar year and must correspond precisely to the designated Audit year; the use of outdated data, such as figures from 2016 for a 2020 Audit, is not allowed.
- Moreover, when target values for specific Indicators are not achieved, a clear and case-specific explanation must be provided within the DS at the case level.

A definition of initial certification period can be downloaded in the document collection of Step 2 [*add hyperlink*].

These requirements form the basis for reliable, verifiable, and transparent documentation practices.

Here are some guiding questions on how to organize and structure the steps towards CCCN Data Documentation:

- Analysis of the Data Sheet: which information/data has to be documented in order to fill-out the basic data and indicator data?
- Gap analysis: which data is already routinely documented by the hospital, cancer registry, etc? What additional data needs to be collected.
- Data collection process: which data can be collected automatically? Which data has to be documented manually? Can additional data fields be added to the hospital information system (HIS)? If yes how expensive is this?
- Timeline: when do we have to start documenting which data in order to be able to submit everything for the Audit?

A detailed Training Course on data documentation specific for each tumour entity as well as Specification on all data fields that need to be documented to be able to calculate the Indicators can be found in the Document Collection of Step 2 [*add Hyperlink*].

To prevent challenges associated with processing Data Sheets, clear responsibilities and competencies are required for effective data management. The roles of various personnel, from clinic staff to doctors and coordinators, are important for ensuring the correct and complete collection, analysis and merging of data.

A guiding question for example on how to organize filling in the DS could be:

Who is responsible for the content and editorial?

Documentation Officer / Data Manager

Responsible for the correct and complete collection of data

Main cooperation partners

Responsible for the analysis of data and, if necessary, definition of actions to improve

CCCN Coordinator

Responsible for merging the data

CCCN Director /Management

Overall responsibility / contact person for the data

Cancer Registry

Might take over responsibility for delivering data, depending on the agreed form of cooperation

Figure 15: Example of distributing of responsibilities within Data Documentation

Keep in mind

- Every CCCN is different
- It depends on distribution of qualifications / personal characteristics
- It is important to decide the assignment individually
- Do cross checking of the SoS and DS by same people

Further explanations of KPIs are presented in various documents, including

- Directly in the DS
- In the SoS
- In the FAQs
- In the specification document

All above mentioned documents are provided in the Document Collection of Step 1 [*add Hyperlink*] and Step 2 [*add Hyperlink*] .

6. CCCN Data Documentation Officer / Data Manger

Within a CCCN, the Documentation Officer/ Data Manager holds a critical role as one of the key stakeholders responsible for ensuring the accuracy, consistency, and proper maintenance of data. This function is essential for supporting quality assurance, monitoring performance, and enabling evidence-based decision-making throughout the certification process.

Tasks of the Documentation Officer/ Data Manager at your CCCN

- The CCCN needs at least 1 documentation officer / data manager who is designated for the CCCN
- Dedicated tasks include:
    - Ensuring and monitoring the timely, full, complete and correct transfer and quality of the patient data that are relevant for certification by all cooperation partners to the cancer registry.
    - Motivation of trans-sectoral cooperation with participating specialty units in the cancer registry (pathology reports, radiotherapy and medicinal treatments).
    - Qualification and support for the staff involved in data collection
    - Regular analysis of evaluations particularly over the course of time.

Profile of Documentation Officer/ Data Manager could include the following points[1]

- Completed medical assistant training (e.g. background in medical technology and/or medical information management and/or nursing…).
- Completed additional training in tumour documentation.
- Content and technical proficiency in handling medical documentation (e.g., medical report, protocols).
- Knowledge of clinical classification systems (e.g. ICD, TNM).
- Proficiency in the use of IT applications (MS Office, hospital information systems).

[1] There may be differences regarding the profile and task depending on the Member Sates. The following list is intended to provide an insight into the profiles and tasks of data managers

7. Structure of the Data Sheet

The Data Sheets consists of several spreadsheets:

- Basic Data
- Key Performance Indicators
- Studies

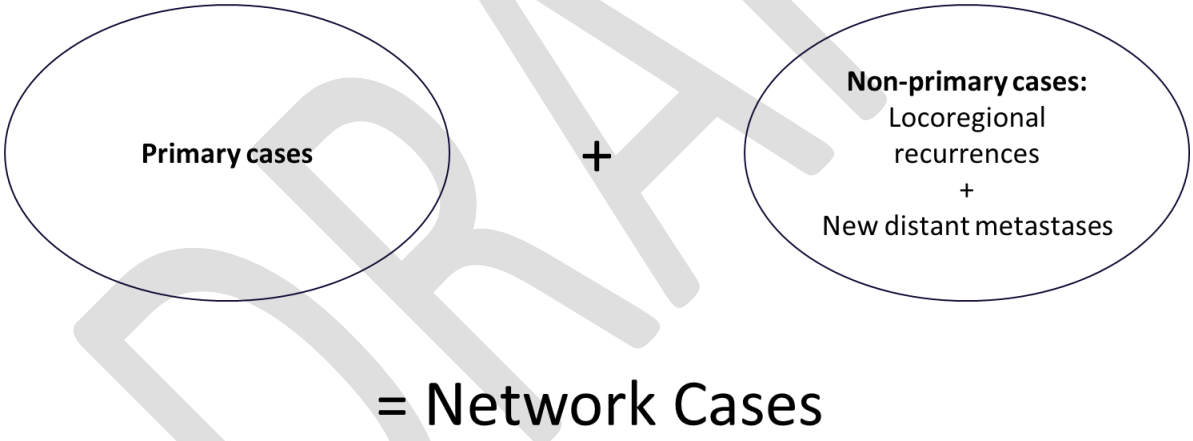
+ organ-specific spreadsheets, e.g.:

- Expertise for cooperating treatment unit
- Expertise for multi-site CCCNs

8. Important Information about the Data Sheet

8.1 Primary Case Concept

The most important concept for standardization is the concept of primary cases and network cases. For each tumour-entity primary cases are clearly defined and described in chapter 1.2.1 of the Set of Standards. Network cases are composed of Primary Cases and non-primary cases. For a more detailed explanation have a look at the data documentation trainings that can be downloaded from the Document Collection of Step 2 [*add Hyperlink*].



Read more about Primary Cases in the SOP “count of cases in the certification system” (see document collection Step 2) [*add Hyperlink*].

8.2 Interconnectivity and Automatization between Spreadsheets

A critical aspect of accurate documentation involves the relationship between the "Basic Data Sheet" and the "Indicator Sheet". It is a fundamental requirement that the "Basic Data Sheet" be completed in its entirety before any work begins on the "Indicator Sheet". This sequence ensures the basic data is in place, providing the necessary context for the Indicators. The methodology for populating the "Indicator Sheet" involves a clear process for inputting numerator and denominator values. While these values can be entered manually, a key feature is the ability to automate this process by

transferring data directly from the "Basic Data Sheet." This automation minimizes the risk of transcription errors and maintains data consistency

Once the data is entered, the system performs automated calculations, which result in one of several defined outcomes.

These outcomes are crucial for interpreting the quality and validity of the data:

- **OK:** Indicates a successful calculation where the value meets the defined target.
- **Plausible:** Suggests the calculated value is within an acceptable range, though further review may be necessary.
- **Plausibility Not Clear:** Signifies that the value is questionable and requires immediate investigation to determine its accuracy.
- **Target Value Not Met:** The calculated value does not meet the target, indicating a potential issue that needs to be addressed.
- **Erroneous:** Denotes a clear error in the data, calculation, or input, requiring correction.

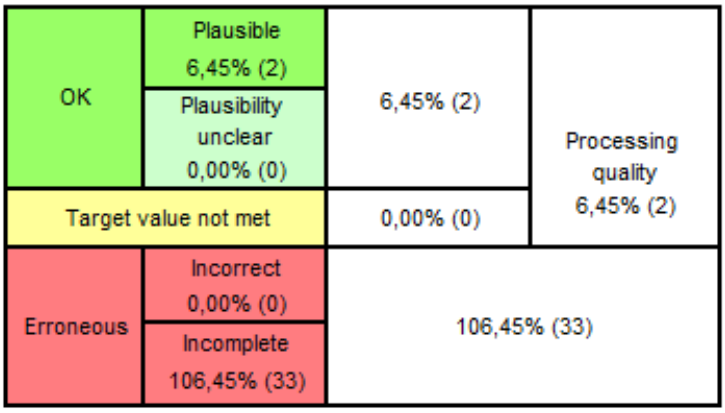


Figure 16: Data quality of the KPIs shown "at a glance" via traffic light

Understanding these outcomes empowers users to interpret data quality and take appropriate corrective actions, ensuring the integrity of the documentation.

8.3 Different types of Indicators

KPIS with a target value or plausibility corridor

- If target value or plausibility corridor is not met, CCCNs have to give an explanation and reason

KPIs without target value

- It is a new indicator for which there are no experienced values
- Definition of a target value without evidence base is not desired

Mandatory KPIs

- If not filled out → this represents a deviation

Optional KPIs

- New KPIS are optional in the first year, mandatory from the second year onward to allow time for the CCCN and the Data Documentation to prepare collection
- if optional KPIs are fill-in, the CCCN must explain any data deficits

More detailed information on how to fill in the Data Sheet and what mistakes to avoid can be found at the Document Collection of Step 2.

8.4 Supporting Documents on Data Sheet

- How to fill in the Data Sheet
- Definition on initial certification period
- Processing and Revision of Data Sheet

Document collection of Step 2. – Preparation

- Data Documentation Workshop on Colorectal and Pancreatic Cancer CCCN
- Data Documentation Workshop on Gynaecological Cancers CCCN
- Data Documentation Workshop on Lung Cancer CCCN
- Data Documentation Workshop on Prostate Cancer CCCN
- Supporting Document on Data Sheet
- Patient Pathway Workshop
- Stepwise Approach Details

Step 3. Action Plan

In the third step planning needs to be put into action. A collection of checklist, examples, good practices, FAQ, templates etc. that support the filling in and implementation of the Set of Standards and Data Sheet are included in this step. Within this step future CCCNs also start to initiate and prepare for the Audit.

A set of resources and useful documents is available to support the CCCN in getting into action. The set of resources includes the following documents types:

- Checklists
- Example / Good practice
- FAQs
- Guidance supporting document
- Information Resource
- Learning Material / Training Material
- Templates

All documents are provided in the Document Collection of Step 3 [*add hyperlink*].

1. Checklists

- Colorectal CCCN: Patient Questionnaire to identify the risk of a hereditary type of Colorectal Cancer
- Gynaecological Cancers CCCN: Checklist for hereditary predisposition

2. Example/ Good Practice

- Topic's for Quality Circle
- Tumour board minutes
- CCCN Partner Matrix
- Audit Agenda for Lung Cancer CCCN

3. FAQs

- Colorectal and Pancreatic Cancer CCCN

- Gynaecological Cancers CCCN
- Lung Cancer CCCN
- Prostate Cancer CCCN

4. Guidance supporting document

- SoS Guidance Document

5. Information Resource

- Supporting Document on Data Sheet
- Count of cases in the Certification System
- Overview of Stepwise Approach
- Audit Preparation Overview: List of Evidence
- Explanation for studies and treatment

6. Learning Material / Training Material

- Data Documentation Workshop on Colorectal and Pancreatic Cancer CCCN
- Data Documentation Workshop on Gynaecological Cancers CCCN
- Data Documentation Workshop on Lung Cancer CCCN
- Data Documentation Workshop on Prostate Cancer CCCN
- Patient Pathway Workshop

7. Templates

- Cooperation agreement
- CCCN Gantt Chart
- CCCN Implementation Plan
- Audit Agenda
- Audit Report
- CCCN Application and Inquiry Form
- Deviation Protocol
- Non-Disclosure Agreement
- Letter of Acknowledgement / Certificate Awarding Minutes

Self-Assessment Tool

Moreover a digital self assessment tool is available for CCCNs.
The Self-Assessment Tool was developed to help CCCNs to evaluate how well they meet the requirments in the Set of Standards and as such the certification standards.
The Self-assessment Tool depicts the complete SoS including all requirements. It guides the CCCN through each standard with space for explanatory remarks how the standards are implemented in the CCCN and optionally supporting documents that provide evidence for the fullfillment of the Standards can be uploaded. In a dashboard overview the CCCNs can see how many standards are fulfiled already and where further work is necessary. The

Set of Standard and explanatory remarks can be exported and be submit it as the filled-in SoS for the Audit. Long term perspective is that the certificatio process is fully digitalized.

Key benefits are:

- Prepare efficiently for certification
- Identify gaps and areas for improvement
- Plan strategic development and continuous improvements
- Gain a comprehensive overview of your current performance

Are you interested?

- User credentials can be requested at the following contact: wp9eunetccc@krebsgesellschaft.de.
- After you received your use credentials, get online and try it out: *[add hyperlink]*

Document collection of Step 3. – Action Plan

- Checklist: Colorectal CCCN: Patient Questionnaire to identify the risk of a hereditary type of Colorectal Cancer
- Checklist: Gynaecological Cancers CCCN: Checklist for hereditary predisposition
- Example / Good Practice: Topic's for Quality Circle
- Example / Good Practice: Tumour board minutes
- Example / Good Practice: CCCN Partner Matrix
- Example / Good Practice: Audit Agenda for Lung Cancer CCCN
- FAQs: Colorectal and Pancreatic Cancer CCCN
- FAQs: Gynaecological Cancers CCCN
- FAQs: Lung Cancer CCCN
- FAQs: Prostate Cancer CCCN
- Guidance supporting document: SoS Guidance Document
- Information Resource: Supporting Document on Data Sheet
- Information Resource: Count of cases in the Certification System
- Information Resource: Stepwise Approach Details
- Information Resource: Explanation for studies and treatment
- Learning Material / Training Material: Data Documentation Workshop on Colorectal and Pancreatic Cancer CCCN
- Learning Material / Training Material: Data Documentation Workshop on Gynaecological Cancers CCCN
- Learning Material / Training Material: Data Documentation Workshop on Lung Cancer CCCN
- Learning Material / Training Material: Data Documentation Workshop on Prostate Cancer CCCN
- Learning Material / Training Material: Patient Pathway Workshop
- Templates: Cooperation agreement
- Templates: CCCN Gantt Chart
- Templates: CCCN Implementation Plan
- Templates: Audit Agenda
- Templates: Audit Report
- Templates: CCCN Application and Inquiry Form
- Templates: Deviation Protocol
- Templates: Non-Disclosure Agreement
- Templates: Certificate Awarding Minutes

Step 4. Audit

The fourth step of setting up a CCCN includes all information about the certification framework, the certification process including timeline and the carrying out and follow up work of the on-site audit. Roles an responsibilities within the certification process are explained and some guiding recommendations on what should be prepared and presented are outlined

All documents relevant to Step 4 are provided in the Document Collection [*add Hyperlink*].

1. Certification Framework

1.1. Introduction

The trustworthiness and value of a certification system is reflected by the quality of the stated requirements and moreover by the underlying principles of the monitoring and evaluation processes that form the basis of the framework.

It must be ensured that each section of the framework works independent from another and that potential conflicts of interest are avoided.

The following sections of the framework should therefore be separated from each other:

- Definition of the SoS
- Review/Audit of the implementation of the SoS
- Awarding of the certificate

In the scope of the current certification framework the division of power is ensured as described below:

Definition of the Sets of Standards

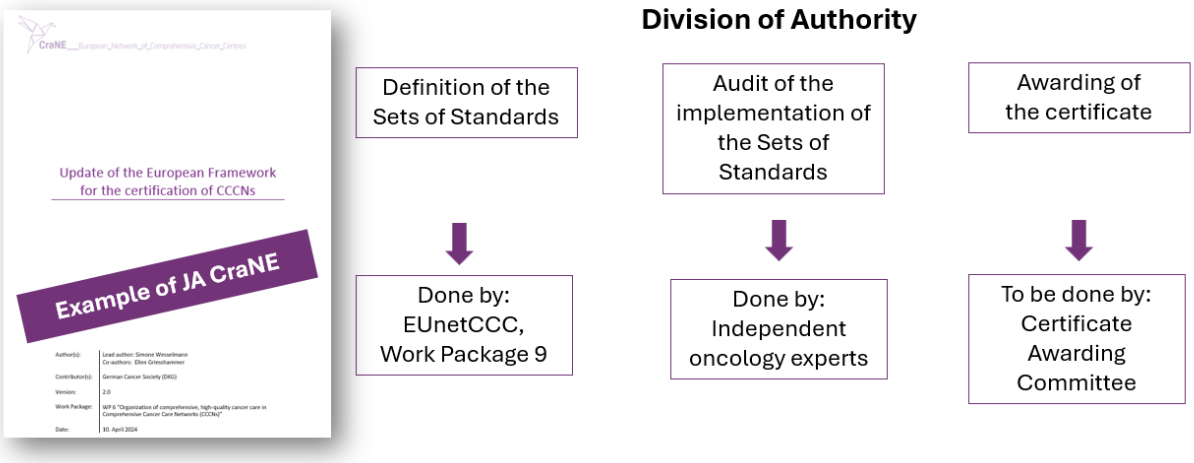
- Working group EUnetCCC WP9 defined the requirements for Comprehensive Cancer Care Networks (CCCNs). The requirements consist of a Set of Standards including Quality Indicators and Key Performance Indicators.

Review/Audit of the implementation of the set of standards

- Oncology experts who are not affiliated with the pilot centres will review the implementation of the Standards in the pilot CCCNs.

Awarding of Certificate

- On the basis of the results of the Audit the certificate is awarded on behalf of EUnetCCC. The awarding of the certificate will take place after agreement by a certificate awarding committee.



The certificate is valid for 3 years. If the improvement potential of the CCCN is very high the period of validity of the certificate can be reduced.

Annual surveillance audits will be conducted in year 1 and 2.

Continuation of the certificate beyond the defined term requires a Re-Certification Audit. During the validity of the certificate, the CCCN is allowed and encouraged to use the certificate for public communication (e.g., website, letter heads, etc.).

In case there have been significant changes to the SoS over the course of 3 years the Auditors should receive an update/refresher training

1.2. Roles and Responsibilities within the certification Framework

1.2.1 Auditors

The Auditors have the task of checking the degree of implementation of the SoS and identifying, if necessary, any need for quality improvements within the CCCN. In order to address these improvement opportunities and increase the quality of care, appropriate actions with the CCCNs have to be discussed and agreed upon by the time of the finalization of the Audit Report.

In order to fulfil the outlined tasks, the Auditors must be fully knowledgeable of the processes, procedures and day-to-day clinical practice in oncological care structures. In addition, the Auditor must be familiar with the current diagnostic and therapeutic concepts of the oncological disease which is being audited and be able to assess the effects and side effects of all treatment steps of an oncological therapy.

Only when the Auditors can fulfil the above described prerequisites, an assessment of the implementation of the requirements, and the detection of quality improvements required with simultaneous development of meaningful quality improvement measures, can be achieved.

It is highly desirable that at least one person of the Audit team is fluent in the language of the audited CCCN to ensure that all members of the reviewed network can benefit from the Audit and the discussions.

Guiding principles: at least two Auditors must meet the following requirement: Medical doctor with a board qualified specialist training; preferably in the relevant discipline of the tumour entity being audited.

It is suggested that the size of overall Audit team for each pilot CCCN be based on the size of the CCCN and the number of sites being visited, but be at least two persons.

Auditors should meet the following requirements:

- at least seven years of experience of working in the field of oncology (the experience cannot date back more than three years),
- a successful participation in the CCCN-Audit-Training Course[2],
- cannot be a member of the JA WP9, should declare the absence of potential conflict of interest to the centres being audited
- must sign a non-disclosure agreement (NDA) (see Document Collection Step 4 [*add hyperlink*]).

[2] To be developed

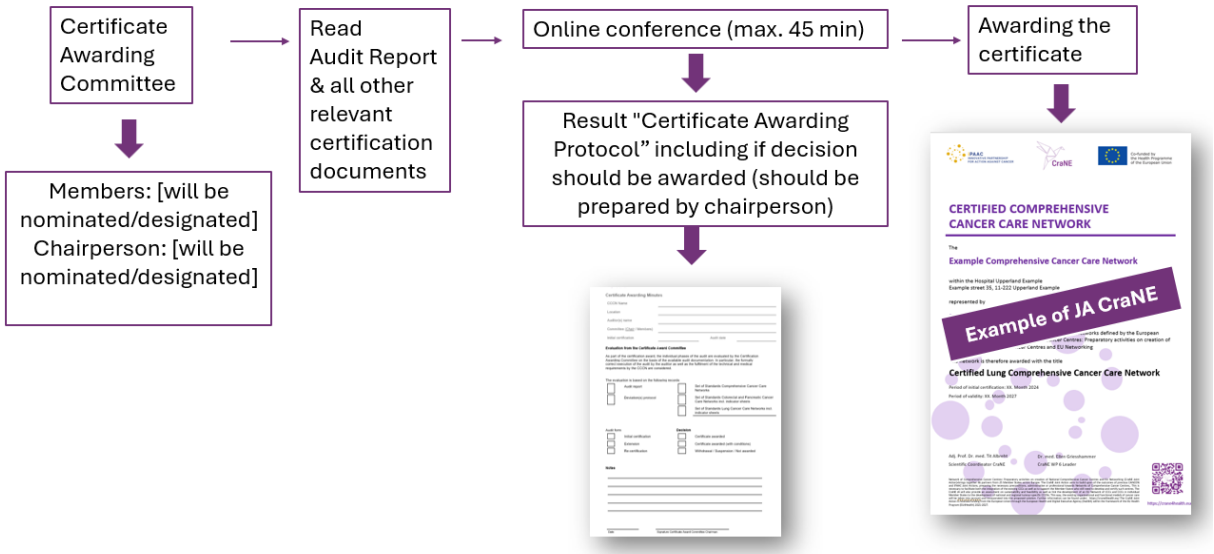
Within the certification process the Auditors have the following functions:

	Prior to the Audit	Audit Agenda Audit check done by the auditors
	During the Audit	Assessment of the medical and technical requirements of the SoS are fulfilled
	After the Audit	Audit Report Recommendation if certificate should be awarded Addressing any deviation(s)

Figure 17: Auditors function - 3-stage approach

1.2.2 Certificate Awarding Committee

The Certificate Awarding Committee undertakes a document review, examining the Audit Report along with all other submitted documents during the Audit. In an online meeting, limited to a maximum of 45 minutes, the members discuss the case. Following this discussion, the chairperson prepares the Certificate Awarding Protocol, which documents the committee's decision regarding the issuance of the certificate (see Document Collection Step 3 "Certificate Awarding Protocol". Upon approval, the certificate is formally awarded to the CCCN.



2. Certification Process

2.1 Steps towards CCCN certification

The overall CCCN certification process is structured into four phases, each comprising several essential steps. It begins with a self-assessment and an initial request, a (Pre-) Audit, which, if successful, leads to the award of certification. This is then followed by annual Surveillance Audits, and a Re-Certification Audit every three years.

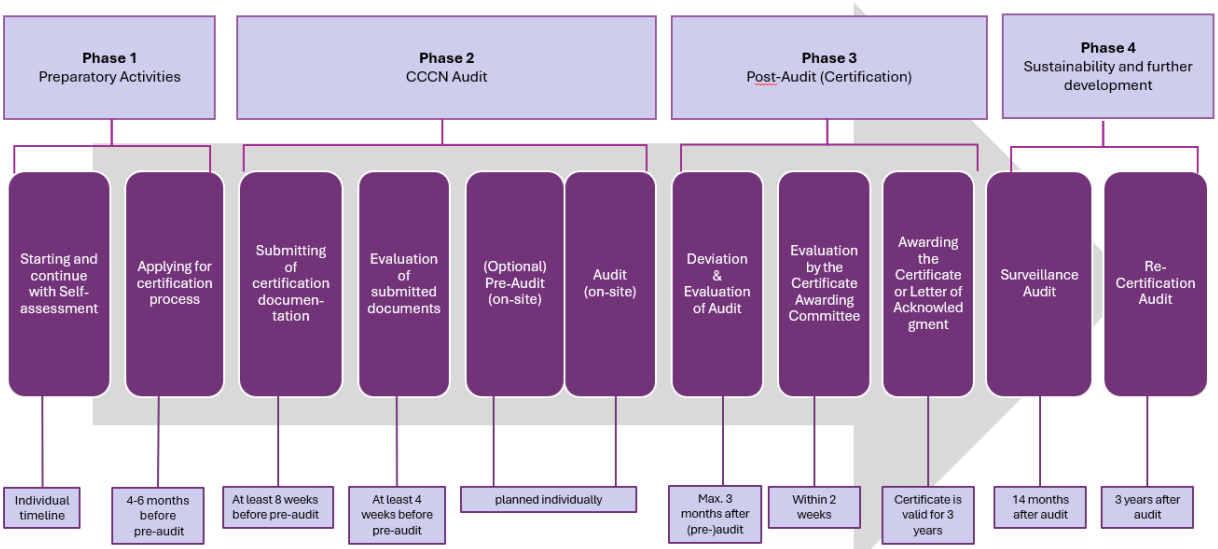


Figure 18: Timeline for CCCN certification process

Overview of steps

Phase 1 "Preparatory Activities"

Starting and continue with Self-Assessment

- This step focuses on conducting a initial gap analysis based on the selected Set of Standards, developing a priority list, and planning how to implement the missing structures and processes. For more information see Step1 and Step 2 *[add hyperlink]*

➔ ⏱ Timeline: to be scheduled individually by each CCCN

Applying for certification process

To formally commence the CCCN certification process, the following documentation must be submitted.

- **CCCN Application and Inquiry Form** (Word-Document): The certification process is officially initiated upon submission of the Application and Inquiry From.
- **Basic Data Sheet** (sheet 1 of Data Sheet): Supporting the application form the first spreadsheet of the Data Sheet, the Basic Data has to be submitted as well. The basic data indicated must reflect a complete calendar year, typically the year immediately preceding the scheduled Audit (the year before the Audit).
- **CCCN Partner Matrix**: The CCCN Partner Matrix, completed in full, must also be submitted for review.

The certification management team will examine the documents to verify the readiness of the aspiring CCCN to initiate the certification process.

All documents must be complete, accurate, and provided within the required submission timeframe (6 months before planned Audit), as they form the basis for the certification team's review and assessment. The process is only initiated when all documents on time are submitted to wp9eunetccc@krebsgesellschaft.de

➔ ⏱ Timeline: 6 months before planned Audit

All documents are provided in the Document Collection of Step 1 and Step 4 [*add hyperlink*] .

Phase 2 "CCCN Audit"

Submitting of certification documentation

- At least 8 weeks before the Audit all filled in certification documents have to be submitted to the certification management team:
    - CCCN Partner Matrix
    - Set of Standards
    - Data Sheet (including all spreadsheets)

➔ ⏱ Timeline: At least 12 weeks before Audit

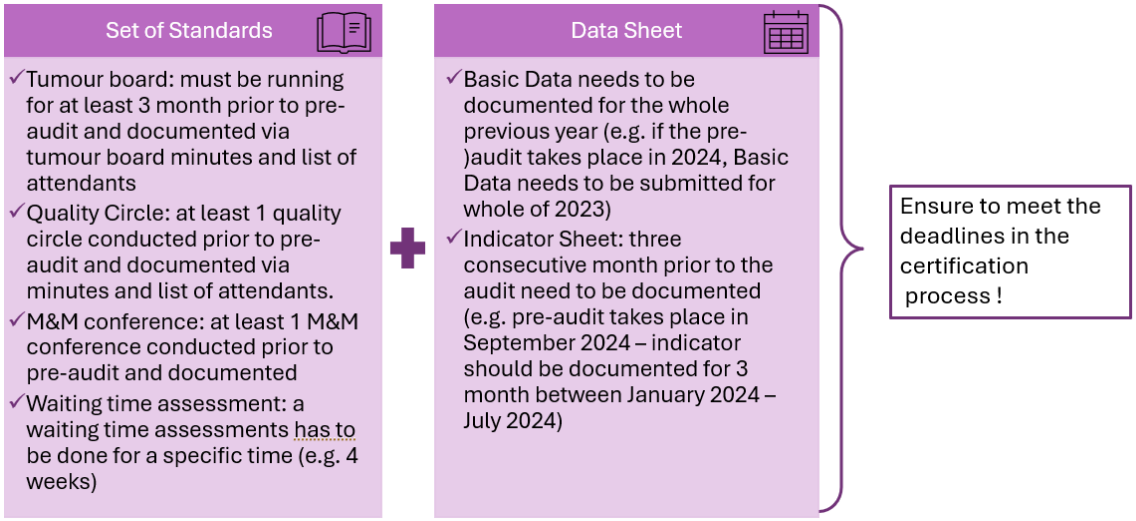
Evaluation of submitted documents

- At least 6 weeks before the Audit the Auditor and the certification management team reviews the submitted documents to determine whether the Audit can take place and/or if additional information is needed.

➔ ⏱ Timeline: At least 6 weeks before Audit

The following checklist helps to understand all the necessary processes and data that must be implemented and prepared prior to the Audit. The ultimate goal is to ensure that

all requirements and deadlines are met for a successful Audit.



Pre-Audit

- The Pre-Audit is optional and is planned individually between the CCCN, the certification management team and the Auditors. It serves as a trail run before the Audit and offers the opportunity to address any critical issues that could endanger a successful CCCN certification within the Audit. The organization and carrying out of the Pre-Audit—such as its duration, the Audit team, the Audit Agenda and Audit Report—follow the same procedure as for the Audit (the process is decribed in detail below).
- It is recommended to have at least 6 month between the Pre-Audit and the Audit to allow sufficient time to implement any remarks and recommendations from the Pre-Audit.

Audit

- At least 4 weeks prior to the Audit, the Audit Agenda and final selection of Auditors should be agreed in close cooperation with the CCCN.
- The duration of the Audit takes is normally 1-2 days onsite depending on the size of the CCCN and its network.
- Participants of the Audit are the Audit team (Lead Auditor, Co-Auditor, optionally guests/observer) and all members of the CCCN which mentioned in the SoS and Partner Matrix. The Audit follows three main pillars: it **opens** with participant introductions and an explanation of the Audit process, continues with the **execution** of the Audit focusing on inspection of the CCCN, selected departments and cooperation partners, and the review of Set of Standards through interviews, presentations and document checks, and **concludes** with feedback on results, recommendations if the certificate should be awarded and if necessary identification of deviations, and discussion of next steps or improvement measures.

Sidenote presentations during the audit:

In order to present the implementation of the requirements of the SoS and to give an overview of the CCCN and its cooperation partners short power point presentation from the CCCN partners should be prepared for each topic on the Audit Agenda. It is helpful to keep the presentation as informative and simple as possible in order to make sure that it is easy to follow. Below you find some hints and suggestions:

  - Stick to the allocated time in the agenda and allow enough room for Q&A from the Auditors
  - Slides should be in English – presentation can be in any language.

- Important during the Audit is that the Auditors understanding the network, where the patients enter the CCCN and how the patient pathway is organized as well as how the requirments of the SoS have been implemented and how interdisciplinary cooperation is organized
- If a pre-audit took place it is nice to include and overview of the changes/improements that took place since the pre-audit

-

➔ ⏱ Timeline of Agenda & Final Selection of Auditors: 4 weeks

➔ ⏱ Timeline of Audit: 1-2 days onsite

Phase 3 "Post-Audit (Certification)"

Audit Report

- 4 weeks after the Audit, the CCCN receives an Audit report. The audit reports summarizes the findings of the audit including any notes, remarks and if applicable any deviations that the auditors found. Most importantly the audit report includes the recommendations from the auditors if the certificated should be awarded. Key findings will be already shared with the CCCNs during the closing meeting of the audit.

Deviation:

- Deviations are identified non-conformities during the audit that relate to the SoS, Data Sheet and/or Partner Matrix and that address core requirments for CCCNs i.e. tumour board meetings are not according to SoS, main cooperation partners do not fulfill SoS etc. If a deviation is noted during the audit a deviation report will be issued. Deviations can lead to not awarding the certificate or recommendations for a shorter validity of the certificate. Deviation can be remidied by the CCCN if they can provide documentation/evidence within three month after the audit that corrective actions have been implemented. The submitted documentation/evidence will be reviewed by the Auditors.

➔ ⏱ Timeline of Audit Report: 4 weeks after Audit

➔ ⏱ Timeline: Addressing deviations and submitting evidence 3 months

Evaluation by the Certificate Awarding Committee and awarding of the Certificate / Letter of Acknowledgement

- At least 4 weeks after the Audit Report has been issued, the Certificate Awarding Committee should meet. The basis for this decision and discussion of the committee are the submitted certification documents, the audit report and the

recommendations of the auditors. The decision of the Certificate Awarding Committee will be noted in the minutes of the certificate awarding meeting.

- For more details see “Certification Framework” and “Certificate Awarding Committee” [*add hyperlink*]

➔ ⏱ Timeline: 4 weeks after submission of Audit Report

Phase 4 “Sustainability and further development”

Annual Surveillance Audit (on-site)

- The Surveillance Audit takes place yearly. Updated certification documents (SoS, DS, Partner Matrix) have to be submitted. Duration is 1 day
- The Surveillance Audit is shorter in time and scope than the initial Audit or the Re-Certification Audit. Not every part of the CCCN or every technical and medical requirement (SoS/DS) will be reviewed in detail. Instead, a sampling approach is applied based on the previous audit report. However the complete DS has to be submitted detaling updated Data for the audit year (deadline end of January)

➔ ⏱ Timeline: up to 14 months after initial Audit or Re-Certification Audit

Re-Certification Audit (on-site)

- The renewal of the certificate after its defined term requires a Re-Certification Audit.
- If the Re-Certification Audit is successful, the certificate is extended for another three years
- The same process as described for the initial Audit applies.

➔ ⏱ Timeline: 3 years +/- 2 month of the initial audit

For more details regarding “Surveillance Audit” and “Re-Certification” see Step 5 [*add hyperlink*]

3. Spotlight on important documents within the CCCN audit process

3.1. Audit Agenda

An Audit Agenda will be prepared for every (Pre-) Audit in advance and in cooperation with the CCCN. The contents of the Audit Agenda are based on the chapters of the Set of Standards. Basically, all specialist disciplines and cooperation partners of the CCCN are visited on site. The responsible clinical personnel of the respective area will present their work and will be available for the exchange/discussion with the Audit team. The overall structure of the CCCN including the relevant KPIs and quality of results are presented in the beginning with an introductory presentation by the Directors of the CCCN. The duration of the Audit is two full days on site.For your internal preparation, it is helpful to keep the following preparatory steps for the Audit Agenda in mind:

Content of an Audit Agenda

- An Audit Agenda contains the essential information on the time schedule of the Audit, the persons involved and the public.

Selection of the areas to be audited - initial Audit

- All areas of the CCCN the technical and medical requirements are to be evaluated.
- All remarks, unclear points and deviations in the assessment of the Set of Standard will be checked (the assessment of the Set of Standard can be used as a checklist in the Audit).

Selection of the areas to be audited - Mandatory content

- Correctness of structure of the network / cooperation partners
- Tumour board
- Guideline conformity/ patient files
- Indicators/ tumour documentation

All in all the Audit Agenda lists:

- Departments/Facilities to be visited on-site (e.g. operating room)
- Processes being discussed (e.g. preparation of chemotherapy protocols)
- People responsible for the individual areas / departments / processes within the CCCN
- Times and location
- List of documents that have to be available (in English language!)

The Audit Agenda is based on the SoS and thus has a standardized template, but will be individualised - depending on the CCCN's and the Auditor's preferences as well as the prior Audits.

The Template and example for the Audit Agenda can be found under Document collection of Step 4 [*add hyperlink*] .

3.2. Audit Report

The Audit Report acknowledges what has already been established in the CCCN. In addition, it highlights key findings and remarks for further development, as well as potential deviations that may arise.

After the Audit, the Auditors prepare an Audit Report with a summary of the actual situation within the CCCN for each chapter of the SoS. Guiding requirements for the Audit report are described below:

Content of the Audit Report

- Summary of the audit results.
- Serves as evidence document why the award of a certificate was or was not recommended.
- Most important source of information in case of change of auditors for re-certification.
- Description of the identified potential for improvement.
- Feedback for the CCCN and foundation for the preparation of the next audit.

General remarks

- For each sub-item in the audit report, a brief description of the results are provided (“observation", "recommendation" or "deviation").
- For reasons of data protection, personal details (of both patients and staff) should be avoided.

Deadlines

- The audit report should be submitted no later than 14 days after the audit to the certificaion authority.
- The report should be sent to the CCCN no later than 4 weeks after the audit.Timeline

Figure 19: Main points of Audit Report

In the Audit Report, the Auditors recommend if the certificate should be awarded.

3.3 Deviation Protocol

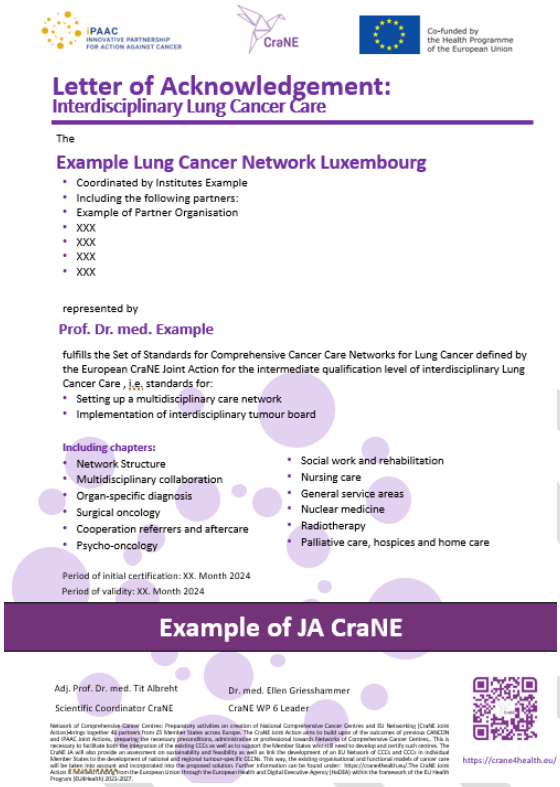
Deviations from the Set of Standards are bound to happen for a lot of aspiring and already certified CCCNs. In the spirit of continuous improvement, these Deviations have to be corrected for the certification status to be continued. The deviation protocol describes the non-conformity identified in the Audit in relation to the Set of Standards, Data Sheet and CCCN Partner Matrix. It must be written directly while the Audit is carried out on site and signed by a representative of the CCCN. A copy of the signed deviation remains at the CCCN. The wording of the deviation is to be transferred 1:1 into the Audit Report. The

CCCN has three month to correct the deviation and submit proof to the certification authority and Auditors.

After the deviation has been corrected, the Auditor records the new assessment result on the deviation protocol.

All documents relevant to Step 4 are provided in the Document Collection

3.4 Awarding of the Letter of Acknowledgement and Certificate


Letter of Acknowledgement:
Interdisciplinary Lung Cancer Care

The

Example Lung Cancer Network Luxembourg

- Coordinated by Institutes Example
- Including the following partners:
- Example of Partner Organisation
- XXX
- XXX
- XXX
- XXX

represented by

Prof. Dr. med. Example

fulfills the Set of Standards for Comprehensive Cancer Care Networks for Lung Cancer defined by the European CraNE Joint Action for the intermediate qualification level of interdisciplinary Lung Cancer Care , i.e. standards for:

- Setting up a multidisciplinary care network
- Implementation of interdisciplinary tumour board

Including chapters:

- Network Structure
- Multidisciplinary collaboration
- Organ-specific diagnosis
- Surgical oncology
- Cooperation referrers and aftercare
- Psycho-oncology
- Social work and rehabilitation
- Nursing care
- General service areas
- Nuclear medicine
- Radiotherapy
- Palliative care, hospices and home care

Period of initial certification: XX. Month 2024
Period of validity: XX. Month 2024

Example of JA CraNE

Adj. Prof. Dr. med. Tit Albreht
Scientific Coordinator CraNE

Dr. med. Ellen Griesshammer
CraNE WP 6 Leader

https://crane4health.eu/


CERTIFIED COMPREHENSIVE CANCER CARE NETWORK

The

Example Comprehensive Cancer Care Network

within the Hospital Upperland Example
Example street 35, 11-222 Upperland Example

represented by

Prof. Dr. med. M. Example

fulfills the Standards for Comprehensive Cancer Care Networks defined by the European Joint Action Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking

The network is therefore awarded with the title

Certified Lung Comprehensive Cancer Care Network

Period of initial certification: XX. Month 2024
Period of validity: XX. Month 2027

Example of JA CraNE

Adj. Prof. Dr. med. Tit Albreht
Scientific Coordinator CraNE

Dr. med. Ellen Griesshammer
CraNE WP 6 Leader

https://crane4health.eu

As detailed in the “Certification Framework” the Certificate Awarding Committee is the final decision body if the Letter of Acknowlegement/Certificate will be awarded. The decision is based on the Audit Report, submitted certificate documents. The Certificate Awarding Committee decision documented in the minutes of the meeting. The CCCNs receive a copy of the minutes.
The certificate and Letter of Acknowledgement are each valid for three years.

Document collection of Step 4. – Audit

- Example: Certificate Awarding Minutes
- Example: Audit Agenda for Lung Cancer CCCN
- Template: Non-Disclosure Agreement
- Template: Audit Agenda
- Template: Audit Report

- Template: Deviation Protocol
- Template: CCCN Application and Inquiry Form

Step 5. Sustainability

The fifth step of setting up a CCCN refers to sustainability. With the awarding of the certificate the journey does not finish, but it is rather the beginning of a continuous quality improvement process in a sense of a Plan-Do-Check-Act cycle with annual data reporting and regular surveillance audits and re-certification audits.

1. Maintaining CCCN Certification

For CCCNs, the letter of acknowledgement and the certificate are valid for a period of three years, provided that the network continues to comply with the requirements and conditions of the Certification Framework. To maintain certification, CCCNs must undergo annual Surveillance Audit and every three years a Re-Certification-Audit and demonstrate a continuous compliance with the Technical and Medical Requirements (SoS/DS).

Each CCCN should ensure that records of key personnel, workforce, services are kept up to date. These may include for example adjustments in the range of services offered, changes in key staff, workforce reductions or structural modification. Significant changes should be reported to the Certification Authority within four weeks. Keeping these records up-to-date not only supports compliance with the Certification Framework but also helps the CCCN itself to manage processes more effectively and maintain continuity in the delivery of high quality of care.

1.1. Surveillance Audit

As part of the annual Surveillance Audit, CCCNs are expected to provide information on further developments and updates in line with the SoS and submitted Data Sheet for the year that is being audited (previous year). The Surveillance Audit itself is conducted on site and takes place two times after each initial Audit and Re-Certification Audit.

Within the Surveillance Audit, and in preparation for the Audit it is helpful to keep the following points in mind:

- Not all areas of the CCCN and Technical and Medical Requirements (SoS) need to be audited (sampling is allowed by Auditors). Therefore, the areas to be

audited are selected on the basis of the results of the previous year's Audit Report to confirm ongoing compliance with the SoSs.

- The remarks and deviations contained in the previous year's Audit Report must be reviewed in detail during the Audit and recorded in the Audit Report.
- In addition a systematic review of the indicators submitted annually will be carried out

Figure 20: Process of Surveillance Audit

1.2. Re- Certification Audit

All requirements of the Set of Standards must be checked at least all three-year during a so-called Re- Certification Audit. Within the Re- Certification Audit all areas of the CCCN and the Technical and Medical Requirements (SoS/DS) are to be evaluated. All remarks, unclear points and agreed improvement measures in the assessment of the SoS will be checked.

After successful verification of compliance, a new certificate is issued for a another three years.

Figure 21: Process of Re-Certification Audit

1.3. Withdrawal of CCCN Certification

If a CCCN cannot demonstrate compliance within the required timeframe, or if sustained non-conformities are identified, the Certification Authority can withdraw the certificate. After withdrawal, the CCCN must stop using the certificate or the statement of conformity in promotional or communication materials. Withdrawal may also apply if misuse of certification is detected.

Withdrawal may also occur if a CCCN is found to be operating unlawfully or without integrity. In such cases, the CCCN must cease using all certification-related materials, return certification documents, and inform stakeholders of the withdrawal.

Concluding Remarks

[content will follow]

Annex

- CCCN Partner Matrix: Colorectal Cancer CCCN
- CCCN Partner Matrix: Gynaecological Cancers CCCN
- CCCN Partner Matrix: Lung Cancer CCCN
- CCCN Partner Matrix: Pancreatic Cancer CCCN
- CCCN Partner Matrix: Pan-tumour CCCN
- CCCN Partner Matrix: Prostate Cancer CCCN
- Checklist: Colorectal CCCN: Patient Questionnaire to identify the risk of a hereditary type of Colorectal Cancer
- Checklist: Gynaecological Cancers CCCN: Checklist for hereditary predisposition
- Data Documentation Workshop on Colorectal and Pancreatic Cancer CCCN
- Data Documentation Workshop on Gynaecological Cancers CCCN
- Data Documentation Workshop on Lung Cancer CCCN
- Data Documentation Workshop on Prostate Cancer CCCN
- Data Sheet: Colorectal Cancer CCCN
- Data Sheet: Gynaecological Cancers CCCN
- Data Sheet: Lung Cancer CCCN
- Data Sheet: Pancreatic Cancer CCCN
- Data Sheet: Prostate Cancer CCCN
- Example / Good Practice: Audit Agenda for Lung Cancer CCCN
- Example / Good Practice: CCCN Partner Matrix
- Example / Good Practice: Topic's for Quality Circle
- Example / Good Practice: Tumour board minutes
- Example: Audit Agenda for Lung Cancer CCCN
- Example: Certificate Awarding Minutes
- FAQs: Colorectal and Pancreatic Cancer CCCN
- FAQs: Gynaecological Cancers CCCN
- FAQs: Lung Cancer CCCN
- FAQs: Prostate Cancer CCCN
- Guidance supporting document: SoS Guidance Document
- Information Resource: Count of cases in the Certification System
- Information Resource: Explanation for studies and treatment
- Information Resource: Stepwise Approach Details
- Information Resource: Supporting Document on Data Sheet
- Learning Material / Training Material: Data Documentation Workshop on Colorectal and Pancreatic Cancer CCCN
- Learning Material / Training Material: Data Documentation Workshop on Gynaecological Cancers CCCN
- Learning Material / Training Material: Data Documentation Workshop on Lung Cancer CCCN

- Learning Material / Training Material: Data Documentation Workshop on Prostate Cancer CCCN
- Learning Material / Training Material: Patient Pathway Workshop
- Patient Pathway Workshop
- Set of Standards: Colorectal and Pancreatic Cancer CCCN
- Set of Standards: Gynaecological Cancers CCCNs
- Set of Standards: Lung Cancer CCCN
- Set of Standards: Pan-tumour CCCN
- Set of Standards: Pathology CCCN
- Set of Standards: Prostate Cancer CCCN
- Set of Standards: Prostate Cancer CCCN
- Set of Standards: Radiotherapy CCCN
- Stepwise Approach Details
- Supporting Document on Data Sheet
- Template: Audit Agenda
- Template: Audit Report
- Template: CCCN Application and Inquiry Form
- Template: Deviation Protocol
- Template: Non-Disclosure Agreement
- Templates: Audit Agenda
- Templates: Audit Report
- Templates: CCCN Application and Inquiry Form
- Templates: CCCN Gantt Chart
- Templates: CCCN Implementation Plan
- Templates: Certificate Awarding Minutes
- Templates: Cooperation agreement
- Templates: Deviation Protocol
- Templates: Non-Disclosure Agreement

Glossary

[add hyperlink]

List of tables

List of figures

References

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[3] JA CraNE; WP6, Task 6.21.: Baseline assessment. Online: https://crane4health.eu/wp-content/uploads/2024/06/CraNE_Sub-task-6.2.1-results-baseline-assessment.pdf

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