Updated European Framework for the certification of CCCNs

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Abbreviations and Acronyms

CCCN	Comprehensive Cancer Care Network
CraNE	Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking
CanCon	European Guide on Quality Improvement in Comprehensive Cancer Control
EC	European Commission
EU	European Union
iPACC	Innovative Partnership for Action Against Cancer
JA	Joint Action
SoS	Set of Standard
WP	Work Package

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1 Prologue

The goal of Work Package 6 in the Joint Action CraNE is to further develop practical instruments ensuring a standardised integrated and comprehensive oncological care in all European Member States that is tumour-specific and delivers all-encompassing high-quality care to all patients. Based on the results of the previous Joint Actions CanCon and iPAAC, WP 6 has defined Set of Standards (SoS) for Lung Cancer Comprehensive Cancer Care Networks and updated the two SoS for Comprehensive Cancer Care Networks (CCCNs) defined during JA iPAAC (SoS "Colorectal and Pancreatic Cancer" and SoS "Generic CCCN" which is non-tumour-specific for a basic and pan-cancer organisation of oncological care within a CCCN). The SoS include guideline-based requirements, structural requirements, e.g., staffing and technical infrastructure and key performance figures.

With the goal of setting up and rolling out CCCNs in the European MS the newly developed content of SoS for Lung Cancer CCCN will be implemented in two pilot centres (Lower Silesian Oncology, Pulmonology and Hematology Center, Wroclaw, Poland and Luxembourg Lung Cancer Network). The purpose of this document is to define the conditions necessary to verify the successful and sustainable implementation of the defined standards.

The implementation of CCCNs is an ongoing process that requires a continuous reflection and assessment of the treatment outcomes and of the underlying processes and structures. The prerequisites, which are defined in this framework are therefore an important element in order to monitor and evaluate the status quo of implementation and with this the overall quality of oncological care within CCCNs.

During JA iPAAC, as the CCCN concept was operationalized and implemented for the first time, an independent evaluation group assessed the process by conducting structured interviews with the pilot sites, the audit teams, and the certificate awarding committee. The evaluators produced a report about how effective the process in the pilots was and whether any modifications to the process are needed going forward. Moreover, a feedback assessment was conducted during JA CraNE with already certified CCCNs to gather information on the CCCN implementation and certification process including recommendations for further developments and updates. The feedback from the evaluators and CCCNs were taken into consideration in the update of the European Framework for the certification of CCCNs.

The described process and outlined standards in this document are only to be used in the context of the CraNE pilot CCCN certification. Any further use requires that the described criteria remain unchanged.

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2. Division of Authority

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:

1. Definition of the Sets of Standards

Working group iPAAC WP 10, task 5 defined the requirements for CCCNs and Colorectal and Pancreatic Cancer Care Networks. The Working Group of CraNE WP6, task 3 defined the requirements for CCCNs for Lung Cancer. The requirements consist of a set of standards including key performance indicators.

2. 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 two pilot CCCNs.

3. Awarding of the certificate

On the basis of the results of the audit the certificate is awarded on behalf of both Joint actions iPAAC WP10 and CraNE WP6. The awarding of the certificate will take place after agreement by a certificate awarding committee consisting of at least five oncology experts.

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3 Documents needed for certification

The following documents must be sent to the CCCN certification scheme coordinator in the European project (e.g. CraNE WP6 leader) in advance of the audit:

a. Master data sheet with overview of all partners of the CCCN
b. Generic Standard for Comprehensive Cancer Care Networks
c. Standard for Colorectal and/or Pancreatic and /or Lung Cancer Networks including Self-Assessment with scoring system

The Master data sheet (a) contains the information (discipline, name, department, address, mail, etc.) of all partners of the CCCN, the Colorectal and/or Pancreatic, and/or the Lung Cancer Network.

In the Sets of Standards (b) and (c), the pilot CCCNs describe their individual compliance with the Standards. The Set of Standards includes a Self-Assessment with a scoring system. The completed Set of Standards including the key performance indicators are the basis for the on-site audit.

The scoring system for the Self-Assessment lists one score for each chapter of the Set of Standards. The score is an indicator for the implementation degree of each chapter in the Set of Standards.

The completed Set of Standards will be assessed by the auditors prior to the audit. In the case of implausible or incomplete information, the CCCN will be consulted and may need to provide further information or explanations in preparation for the on-site audit. The auditors will provide a list with the names of documents which should be translated in English for the onsite audit.

4 Modular Approach

The Set of Standards include guideline-based requirements, structural requirements, e.g., staffing and technical infrastructure and key performance figures.

If necessary, the requirements of the Set of Standards can be implemented in a stepwise approach (starter, intermediate and fully certified). The three steps build on each other and support the setting up of CCCNs.

In the figures below the modular approach is depicted and procedures are explained.

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Figure 1: Overview of requirements/chapters to be fulfilled according to three modules

	Starter	Intermediate	Fully Certified CCCN
Requirements	Set of Standards – 4 chapters [1)]	Set of standards – 12 chapters [1)]	Set of Standards – 18 chapters (entirely)
Mandatory chapters	SoS 1.1.Structure of the network [2)] SoS 1.2. Interdisciplinary cooperation [3)] [2)] Cooperation agreements optional [3)] Focus on tumour boards	SoS 1.1. Structure of the network [4)] SoS 1.2. Interdisciplinary cooperation SoS 2 Organ-specific diagnostics SoS 5 Operative oncology [4)] Cooperation agreements should be available	
Supplementary chapters		1 Chapter from: SoS 6 Medical / internal oncology SoS 7 Radiation oncology SoS 8 Pathology	
	2 additional chapters are to be selected	In addition, 7 further chapters are to be selected (SoS 6, SoS 7, SoS 8 also possible)	
Data Sheet	(Determination of chapter left to the centre)		
	Basic data/Case list	Data Sheet with Basic Data and Indicators	

1) The CCCN is free to choose further chapters in addition to the 4 chapters for Starter or 12 chapters for Intermediate.

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Figure 2: Description of verification / certification process for modular approach

	Starter	Intermediate	Fully certified CCCN
Type of evaluation	On-site auditing	On-site auditing	On-site auditing
Type of credential	Letter of appreciation: Interdisciplinary care for CCCN Qualification level: Starter	Letter of appreciation: Interdisciplinary care for CCCN Qualification level: Intermediate	CCCN Certificate
Basis of evaluation (=required evidence)	Master Data Sheet	Master Data Sheet	Master Data Sheet
	Set of Standards (extract of relevant chapters)	Set of Standards (extract of relevant chapters)	Entire Set of Standards
	Tumour board Procedural instructions, minutes of the "tumour board" and lists of participants for 4 tumour boards held in the last 3 months.	Tumour board Procedural instructions, minutes of the "tumour board" and lists of participants for 8 tumour board held in the last 3 months.	All other documents are viewed during the on-site audit
	Basis Data, case list	Data Sheet with Basic Data and Indicators	
Scope of fulfilment requirements	A maximum of 1 individual requirements in the supplementary chapters is allowed to not to be met or undercut (for chapters 1.1. and 1.2. all requirements must be fulfilled); in the case of quantitative requirements (e.g. number of cases), evidence of at least 50% of the target must be provided.	A maximum of 5 individual requirements in the supplementary chapters is allowed to not to be met or undercut (for chapters 1.1. and 1.2. all requirements must be fulfilled); in the case of quantitative requirements (e.g. number of cases), evidence of at least 50% of the target must be provided.*	Full compliance with the requirements

*In the supplementary chapters, individual requirements may not be met or may be below the minimum requirements. However, the auditors have the freedom to decide to issue deviations if patient care is endangered by the non-fulfilment of the requirement. If individual requirements are not met. The CCCN must specify them in advance of the audit at the time of submission of the audit documents. The requirement must be fulfilled for the surveillance audit. If necessary, a country specific equivalence is defined until the next audit, whereby the requirement can be proven by the CCCN. Independent of these regulations, the auditors are free to define conditions that these requirements must be fulfilled of the follow-up audit.

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5 Auditors

The Set of Standards summarises the requirements that, when implemented in CCCN´s, should provide patients with comprehensive, high-quality care at all stages and in all areas of an oncological disease. The requirements are tumour specific and generic and pursue the goal of a continuous improvement process within the CCCN.

The auditors have the task of checking the degree of implementation of the Standards and identifying the need for quality improvements. 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 finalisation of the 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 auditor 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.

Further 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.

Based on these 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 the number of sites being visited and the selected module (starter, intermediate or fully certified).

For the fully certified CCCN the audit team should consists of up to 4 persons. These should include a senior oncology nurse, and an oncologist who has experience of conducting clinical trials.

For the intermediate CCCN the audit team should consists of at least 2 persons, for the starter CCCN at least 1 person.

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All members of the audit team should meet the following requirements:

- at least 7 years of experience in working in the field of oncology (the experience cannot date back more than 3 years)
- Successful participation in the CCCN-Audit-Training Course* (*to be developed)
- Cannot be a member of the iPAAC WP 10 and/or CraNE WP6
- should declare the absent of potential conflict of interest to the centres being audited
- must sign a non-disclosure statement

Guests and the extent of their involvement should be agreed by the audited CCCN. They can participate in the on-site audit but have no authority to independently assess or verify the implementation of the Set of Standards.

6 Audit

6.1. Audit Plan

An audit plan will be prepared for the audit.

The contents of the audit plan 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 key performance figures and quality of results are presented in the beginning with an introductory presentation by the Directors of the CCCN.

The audit plan is prepared by the CCCN certification scheme coordinator in the European project (e.g. CraNE WP6) in consultation and in co-ordination with the pilot sites.

The duration of the audit dependes on the selected module (starter, intermediate, fully certified).

For the fully certified CCCN the duration of the audit is two full days on site. For the intermediate CCCN 1.5 days on site and for starter 1 full day on site.

The audit plan 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

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6.2. On-site Audit

During the on-site audit, the CCCN substantiates the information provided in the SoS with the presentation of the accompanying documents (e.g.: SOPs, cooperation agreements, standard chemotherapy protocols, training calendars, etc.).

During the on-site audit, the auditors verify the compliance with the set of standards. They determine the degree of implementation of the CCCN and deduce an overall impression of the maturity stage of the CCCN. Areas with improvement potential will be identified and, together with the CCCN, improvement measures discussed and agreed upon. Through randomly selected patient records, the adherence of the guideline-based care of the patients and the implementation of the requirements laid out in the SoS will be verified and checked by the auditors.

6.3. Audit Report

The auditors have three options to evaluate the performance of the CCCN if the requirements are not fully implemented or if quality deficiencies are identified during the audit: (a) observations, (b) recommendations and/or (c) deviations. Through this, the CCCN receives a feedback and a reference point of the importance of the pointed-out short-comings which need to be addressed and remedied.

After the audit, the auditors prepare an Audit Report in which they either recommend or do not recommend that the certificate should be issued. In the report, the auditors write a summary of the actual situation for each chapter of the SoS and assess the chapters via the listed comment options. In addition, the auditors use the self-assessment tool to score each chapter/subchapters.

Comment options:

Observation(s)	Observations describe general impressions from the audit process that are neither recommendations nor deviations.
Recommendation(s)	Recommendations for the further development of the CCCN. If the “must” formulation has been used, failure to comply with the recommendation may lead to a deviation being formulated in the next re-audit.
Deviation(s)	Deviations document non-compliance with the technical and medical requirements. The deviations must be remedied within 3 months (Exceptions must be explained) by the Network and this must be proven to the working group of WP 10 within the period specified in the deviation report.

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7. Certificate

On the basis of the audit report, the scoring instrument and the documents provided by the CCCN (a-d), a committee (Certificate Awarding Committee) will issue the certificate on behalf of iPAAC, WP 10 and CraNE WP6.

The certificate awarding committee consists of at least five members of iPAAC Task 5, WP 10 or CraNE WP6 including the WP leader.

The certificate is valid for 5 years. If the improvement potential of the CCCN is very high the period of validity of the certificate can be reduced. In the years 1 and 3 after the initial audit, the CCCN must submit the annual results of the quality indicators and submit a written statement on the state of play in the areas where recommendations were made. The information will be evaluated by the audit team and the Certificate Awarding Committee will decide on the continuation of the certificate.

Continuation of the certificate beyond the defined term requires a re-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 Set of Standards over the course of 5 years the auditors should receive an update/refresher training

8. Example Set of Standards

Assumption:

The structures and processes summarized in the Set of Standards should be implemented and with this good oncological care is made possible. There are different ways in which the individual standards of a chapter can be implemented in a CCCN. However, it is crucial that the overall process is implemented. For the example of Chapter 1.8, this means that nursing care is fully integrated in a CCCN with the right qualified professionals and sufficient human resources and the described tasks in the sense of the CCCN and the patients are fulfilled. However, it is not sufficient to show only the current state of the CCCN. Recommendations for further development must be listed to enable continuous quality improvement within the CCCN.

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Example: Excerpt of the Set of standards provided by the CCCN before the audit:

(see Chapter 3 Documents needed for certification)

1.8 Nursing care

Chapter	Requirements	**Explanatory remarks of the CCCN**
1.8.1	The members of the Network who deliver clinical care to patients have written policies covering the number of specialist oncology nurses to deliver high quality care. Specialist oncology nurses (with the exception of paediatric oncological care). • At least 2 full-time active specialist oncology nurses must be employed on day duty in the CCCN to facilitate care coordination and provide specialized care. • Specialist oncology nurses are identified by name. • Active care by a specialist oncology nurse must be proven in the units in which patients receive inpatient oncology care. Pre-condition for the recognition as oncology nursing staff are • Further training as oncology nursing staff according to the country specific regulations • If there are no country specific regulations the CCCN must demonstrate how oncology nurses are educated (recommendation: European Oncology Nursing Society Educational Framework http://www.cancernurse.eu/education/cancernursingeducationframework.html)	***The CCCN describes here how it has implemented the standards described in the left column***
1.8.2	Responsibilities / tasks Patient related tasks include:	

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1.8 Nursing care

	• Specialist assessment of symptoms, side effects and stress/strain • Conduct and evaluation of nursing measures • Pain and symptom identification • Identification of individual patient-based counselling needs. • The specialist counselling needs are already to be defined in the nursing concept of the individual Tumour specific networks. • A specialised nurse should be present in the consultation hours where the diagnosis and further diagnostic/treatment steps are planned • Ongoing information and counselling of patients (and their family members) during the entire course of the disease • Conduct, coordination and documentation of structured counselling sessions and guidance of patients and family members. Depending on the concept this can also be done by specialist nurses with many years' experience and specialist expertise. • Participation in the tumour board is desirable. • Initiation of and participation in multi-professional case discussions/nursing visits; the aim is to find a solution in complex nursing situations.; Criteria for the selection of patients are to be laid down; per year and centre at least 12 case discussions/nursing visits are to be documented		
Self assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once.	Yes	
		Mostly	
		Partially	

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1.8 Nursing care

	• Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	No	
		Not Applicable	

9. Example Audit Report

(see Chapter 5c On-site-audit, comment options)

1.8 Nursing care	Observation(s)	***The audit team describes here how the standards of the chapter are implemented in the CCCN***	
	Recommendatiomns	***The audit team describes here recommendations and the agreed improvement measures for the further development of the integration of nursing care within the CCCN.*** ***For example: implementation of a further training programm, providing more full-time employees***	
	Deviation(s)	***The audit team describes here deviations (= non-compliance with the technical and medical requirements) which must be remedied***	
	Overall assessment Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. Partially – the chapter has been	Yes	***The audit team states the current state of play with the overall assessment***
		Mostly	
		Partially	
		No	
		Not Applicable	

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	only partly implemented, or only recently introduced and not evaluated. No – the chapter has not been implemented Not Applicable (rare).		

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