CraNE

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Comprehensive Cancer Care Networks (CCCN´s)

Set of Standard for Pathology

Included are Requirements/Standards:

- Joint Action innovative Partnership Action against Cancer (iPAAC), WP 10 Governance of Integrated and Comprehensive Cancer Care (https://www.ipaac.eu/en/work-packages/wp10/)
- European Cancer Centre Certification Programme
    - Catalogue of Requirements Lung Cancer Centres (cr_lcc-l1_ENG_220831) (https://ecc-cert.org/wp-content/uploads/2023/01/cr_lcc-l1_220831-fin.docx)
    - Catalogue of Requirements Radio-Oncology (cr_radio-K1_ENG_220928) (http://dev.ecc-cert.org/wp-content/uploads/2023/01/cr_radio-K1_ENG_220928_fin.docx)
    - Catalogue of Requirements Pathology (cr_pat-L1_ENG_220928) (http://dev.ecc-cert.org/wp-content/uploads/2023/01/cr_pat-L1_ENG_220928_fin.docx)
- European Cancer Organisation Essential Requirements for Quality Cancer Care (ERQCC): Lung Cancer (2020) (https://www.sciencedirect.com/science/article/abs/pii/S0169500220305912)
- OECI Accreditation and Designation Programme European Quality Standards for Cancer Networks Doc00_OECIUserManual_2_0.pdf (https://www.oeci.eu/accreditation/Attachments/Doc00_OECIUserManual_2_0.pdf)
- European Respiratory Society Guideline on various aspects of quality in lung cancer Care (2022) (https://erj.ersjournals.com/content/early/2022/10/13/13993003.03201-2021)

Developed in the context of CraNE from the working group of Work Package 6, based on the previous work done by the Joint Action iPAAC*

***https://www.ipaac.eu/roadmap/detail/112**

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Prologue

This standard sets out the requirements to be met by Comprehensive Cancer Care Networks for Lung Cancer (CCCN Lung Cancer).
This Set of Standards will be piloted in the scope of the Joint Action "Creation of National Comprehensive Cancer and EU-Networking" (CraNE)" and based on the results of Joint Action "Innovative Partnership Action Against Cancer" both financed by the European Commission.

The document is to be used in conjunction with:

- SoS for CCCN (https://www.ipaac.eu/res/file/outputs/wp10/cccn-standard.pdf)
- "Supporting Document Standard for CCCN" (https://www.ipaac.eu/res/file/outputs/wp10/cccn-standard-supporting-document.pdf)
- SoS Radio-oncology
- SoS Pathology

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Members of the working group on Implementation of CCCN (Task 6.3), (in alphabetical order) are:

Miguel	Areia	Directorate - General of Health (DGS)
Olga	Balaoura	Athens General Oncology Hospital (Agios Savvas)
Anastasia	Balasopoulou	1st Regional Health Authority of Attica (1st YPE ATTICA)
Harriët	Blaauwgeers	Organisation of European Cancer Institutes (OECI)
Beate	Brenner	Technical University of Dresden (TUD)
Karen	Budewig	Federal Ministry of Health (BMG)
Maja	Čemažar	Institute of Oncology Ljubljana (OI)
M. Rudy	Chouvel	Fédération Hospitalière de France, commission cancer (FHF Cancer)
F.	Costa	Directorate - General of Health (DGS)
Ineta	Derjabo	Riga East University Hospital (REUH)
Anne	Drochon	Institut National du Cancer (INC)
Dorota	Dudek-Godeau	National Institute of Public Health - National Institute of Hygiene (NIZP PZH-PIB)
Markus	Follmann	German Cancer Society (DKG)
Arne	Fosseng	Oslo University Hospital (OUS)
George	Georgiou	Athens General Oncology Hospital (Agios Savvas)

Vasiliki	Gkioka	Athens General Oncology Hospital (Agios Savvas)
Nikolai	Goncharenko	Institut National du Cancer (INC)
Nele	Grapentin	German Cancer Society (DKG)
Ellen	Griesshammer	German Cancer Society (DKG)
Ingrid	Guldvik	Oslo University Hospital (OUS)
Jenny		
Rui	Henrique	Directorate - General of Health (DGS)
Lidia	Janicka	National Institute of Public Health - National Institute of Hygiene (NIPH-NIH)
Kathy	Jaworski	Institut National du Cancer (INC)
Uroš	Kuhar	Institute of Oncology Ljubljana (OI)
Thomas	Langer	German Cancer Society (DKG)
Claudio	Lombard	Organisation of European Cancer Institutes (OECI)
Per	Magnus	Oslo University Hospital (OUS)
Delia	Nicoara	The Oncology Institute ”Prof. Dr. Ion Chiricuta”, Cluj-Napoca (ICON)
Simon	Oberst	Organisation of European Cancer Institutes (OECI)
Alain	Ravaud	Fédération Hospitalière de France, commission cancer (FHF Cancer)
Peggy	Richter	Technical University of Dresden (TUD)
Hannes	Schlieter	Technical University of Dresden (TUD)
Sigbjørn	Smeland	Oslo University Hospital (OUS)
Kim	Tiede	German Cancer Aid (DKH)
Sonja	Tomšič	Institute of Oncology Ljubljana (OI)
Xavier	Troussard	Fédération Hospitalière de France, commission cancer (FHF Cancer)
Heidi	van Doorne	Organisation of European Cancer Institutes (OECI)
Simone	Wesselmann	German Cancer Society (DKG)

Valid from 01 January 2023

This Set of Standards (SoS) is binding for all peer reviews from 1 January 2023. All changes to the previously applicable versions of this Set of Standards are marked in yellow.

Tumour-specific requirements are marked as follows:
Colorectal Cancer = violet
Lung Cancer = green
Pancreatic Cancer = red

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Set of Standard Pathology

This "Set of Standard (SoS) Pathology" sets out the requirements which must be met by the cooperation partner pathology in Comprehensive Cancer Care Networks (CCCNs). The Set of Standard Pathology is, therefore, an annex to the Set of Standard CCCNs and tumour-specific Set of Standards.

Name of the Institute [1) 2)]	
Head of the Institute	
Contact certification	
Address	
Tel.	
Email	

1) Definition clinical site: The clinical site is determined by the address. 1 clinical site is 1 cooperation partner of the Centre, irrespective of any existing different organisational/legal forms (private practice, part of the clinic, medical care centres…). In the registration as a cooperation partner only 1 name may be used.
2) Details of any additional existing frozen section laboratories are to be given on the next page.

Please indicate for which CCCN the pathology is a cooperation partner:

_____

_____

_____

_____

_____

_____

Scope of pathology

☐ CrC ☐ Panc ☐ LC

Preparation / Updating of the Set of Standard Pathology

Valid from 01 January 2023

Structural data on the clinical site

Scope of the Set of Standard / Participation tumour board

CCCN	Tumour entities)	Time point / Cycle Tumour board	Attendance Tumour bord in %

Frozen section laboratories

No.	Frozen section laboratories [8)]	Address (street, postal code and city)
1		
2		
3		
4		

[8)] related to the one clinical site of the Pathology Institute to which this Set of Standard refers; hence, any other frozen section laboratories do not have to be mentioned here

Molecular pathology

Molecular pathology on site ☐ yes ☐ no

If molecular pathology is performed in cooperation, the cooperation partners for molecular pathology are to be listed below (multiple entries possible).

No.	Molecular pathology	Address (house number, street, postal code and place)
1		
2		
3		
4		

8.1 Interdisciplinarity

Section	Requirements	Explanatory remarks Pathology	
8.1.1	Cooperation agreement When the cooperation partners of a CCCN work under a funding body or at a clinical site, no written agreements are needed (nonetheless the implementation of the following points must be ensured). The following points are to be dealt with: • Description of the treatment processes of relevance for the CCCN bearing in mind the interfaces • Obligation to implement indicated guidelines • Description of cooperation on tumour documentation • Declaration of willingness to cooperate on internal/external audits • Undertaking to comply with the relevant CCCN Set of Standards and the annual submission of the relevant data • Upholding of medical confidentiality • Participation in continuing education/specialty training schemes and public relations work • Declaration of consent to be publicly identified as part of the CCCN (e.g. homepage)		
8.1.2	Tumour board • Binding participation Pathology • Ensuring availability on specialist level		
	Demonstration visual material Patient-related images (e.g. pathology, radiology) must be available at the tumour board and suitable technical equipment must be provided for the presentation of this visual material. A computer-aided presentation is sufficient.		

8.2 Case numbers per Pathology Institute

Section	Requirements	Explanatory remarks Pathology	
	Case numbers Pathology Institute At least 10,000 histologies/year (case numbers, documentation via journal no.)		
	Tumour-specific characteristics		
colorectal	• Ever year at least 50 histologies of colon/rectum biopsies • Ever year at least 50 histologies of colon/rectum specimens		
pancreatic	Every year at least 12 pancreatic surgery histologies		

8.3 Specialists - Number / Qualifications

Section	Requirements	Explanatory remarks Pathology	
	Head • Pathology specialist (Board pathologist) Requirements (desirable) Authorisation for specialty training in the field of pathology.		
	CCCN • At least 2 qualified pathology specialists • The specialists are to be designated by name		

Specialists pathology institute

Name, first name	Title	Specialist qualitification	Full-time or part-time as %	Additional qualification / tumour-specific focus [9)]

[9)] The requirement of medical and technical competence for the corresponding tumour entity is described below.

8.4 Specialists - Competence

Section	Requirements	Explanatory remarks Pathology	
lung	Each named specialist must assess 100 malignant lung tumours a year.		

8.5 Medical technical assistans(MTAs)

Section	Requirements	Explanatory remarks Pathology	
	A sufficient number of qualified MTAs / technical assistants must be available.		

8.6 Procedures that must be available

Section	Requirements	Explanatory remarks Pathology	
	Procedure to be followed - Immunohistochemical analysis - In-situ hybridisation - Molecular pathology These special services may only be commissioned to pathology institutes, which must be named upon presentation of a cooperation agreement. The institutes should have a recognized QM system or a valid accreditation or prove successful participation in in round robin tests..		

8.7 Autopsies

Section	Requirements	Explanatory remarks Pathology	
	Within the CCCN the unlimited carrying out of autopsies must be possible. An autopsy room must be documented (possibly in cooperation).		

8.8 Frozen sections

Section	Requirements	Explanatory remarks Pathology	
	• The technical and organisational preconditions for frozen sections must be in place for each surgical clinical site. • The readiness for operation of the cryostat must be ensured.		
	Parameters for frozen sections Time required and time measured from arrival in pathology (in min.) to announcing the result (benchmark max. 30 minutes) Evaluation of time needed: min./max./range figure		

8.9 Time to histological result

Section	Requirements	Explanatory remarks Pathology	
colorectal	Time to reception of pathology reports • Biopsies / polyps maximum 3 working days • Surgical specimens maximum 5 working days		
lung	Time to the first pathology report (primary diagnosis) – requirement ≤ 3 working days.		

8.10 Storage times

Section	Requirements	Explanatory remarks Pathology	
	• Archiving paraffin blocks ≥ 10 years • Storage fresh material ≥ 4 weeks after reception • Cryopreservation should be possible.		
lung	Preservation of tumour-free lung tissue, e.g. for dust analysis, with corresponding clinical indications.		

8.11 Pathology reports

Section	Requirements	Explanatory remarks Pathology	
	Pathology reports must contain, for macroscopic and microscopic assessment, 100% of the information stipulated in the Guidelines (In particular: histological type according to the current WHO classification, grade, TNM stage (), R classification).		
	Tumour-specific characteristics		
colorectal	• Pathology reports for the macroscopic report and the microscopic examination must contain 100% of the information required by the guideline. The following information is required: • Site • Tumour type acc. to WHO classification • Tumour invasion depth (pT classification) • Status of the regional lymph nodes (pN classification) • Number of lymph nodes analysed • Number of lymph nodes affected • Grading • The pathologist must always indicate the resection edges and the minimum safety distance (quality indicator derived from the guideline); (deviations must be explained). • R classification • Lymph/blood-vessel invasion • TME quality (quality indicator derived from the guideline)/CRM quality		

8.11 Pathology reports

Section	Requirements	Explanatory remarks Pathology	
	• Degree of tumour regression in the case of neoadjuvant therapy (optional).		
pancreatic	Mandatory information pathology report • Status of the resection area with regard to the remaining part of the pancreas and the circumferential resection margins (marked in India ink) • R0 narrow/wide • Lymph vessel invasion • Vein invasion • Perineural invasion		
lung	Mandatory information pathology report • Determination of regression grading or complete pathological regression in the case of patients with neoadjuvant treatment. • Description of tumour localisation		

8.12 Lymph nodes (LN)

Section	Requirements	Explanatory remarks Pathology	
	• All lymph nodes in the surgical specimen are to be examined macroscopically and microscopically. • Deviations from the minimum numbers in the Guidelines are to be discussed on an interdisciplinary level. • The lymph nodes must be examined in line with the Guidelines. • The localisation of the lymph node (at least regional versus distance from the tumour) is to be indicated.		
	Tumour-specific characteristics		
Colorectal	At least 12 lymph nodes in the surgical specimen are to be examined.		
pancreatic	At least 12 regional lymph nodes in the surgical specimen are to be examined.		
Lung	• The localisation of the LN (IASLC Classification) is to be indicated. • Guidance value: At least 6 lymph nodes are to be examined in the surgical specimen.		

8.13 Distance to resection margin /safety margin

Section	Requirements	Explanatory remarks Pathology	
	Pathologist must always give details of the resection margins (deviations are to be justified).		

8.14 External quality assurance

Section	Requirements	Explanatory remarks Pathology	
	Regular successful participation in external quality assurance measures (example benchmarking, external quality circles) particularly in interlaboratory experiments every 2 years.		
	Consultative second opinion Facilitation of consultative second opinion when asked by clinic or patient or when definitive assessment is not possible.		
	Tumour-specific characteristics		
colorectal	The procedure for an external second diagnosis is to be outlined.		
lung	For EGFR testing it should be documented whether this is an Exon 21, Exon 19 mutation or an uncommon mutation.		

8.15 Quality circles

Section	Requirements	Explanatory remarks Pathology	
	• Quality circles, in which oncological aspects are addressed, are to be conducted at least 3 times per year. • Scheduling, e.g. in training plan • Minutes of quality circles are to be taken. Participation is to be proven in total and not for each individual tumour entity; quality circles can be interdisciplinary, for a specific tumour-entity and/or trans-organ in nature (see SoS CCCN 1.1.16).		

8.16 Continuing education/specialty training

Section	Requirements	Explanatory remarks Pathology	
	• A training plan for medical and non-medical staff listing the training sessions planned for the period of one year is to be submitted • At least 1 dedicated continuing education/specialty training session for each staff member who carries out quality-relevant activities for the CCCN.		

8.17 Other tumour-specific requirements

Section	Requirements	Explanatory remarks Pathology	
colorectal	Microsatellite instability If no examination is done directly at the pathologist's then a cooperation agreement is to be entered into.		
Colorectal	Diagnostics MSI testing should be carried out - in the case of a positive patient questionnaire with suspected hereditary colorectal carcinoma - in patients between the 50th and 60th year of life with MSI-suspicious histology - in mCRC optional for determining the therapy strategy - before adjuvant chemotherapy in stage II if indicated		

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. • 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).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	