CCI4EU

Comprehensive Cancer Infrastructures 4 Europe

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Abbrevations and acronyms

CBI	Capacity Building Interventions
CCC	Comprehensive Cancer Centre
CCI	Comprehensive Cancer Infrastructure
CraNE	Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking Joint Action
CSA	Coordination and Support Action
EC	European Commission
EU	European Union
HaDEA	European Health and Digital Executive Agency
iPAACC	Innovative Partnership for Action Against Cancer
JA	Joint Action
JANE	Joint Action on Networks of Expertise
MM	Maturity Model
MMWG	Maturity Model Working Group
MS(s)	Member State(s)
MTB	Molecular Tumour Board
NCP	National Cancer Plan
NCCPs	National Cancer Control Plans
PBCR	Population-Based Cancer Registry
PP	Patient Pathway
PREMS	Patient Reported Experience Measures
PROs	Patient Reported Outcomes
QI	Quality Indicators
WG	Working Group

Summary

The CCI4EU project is commissioned and financed by the European Commission as a Coordination and Support Action (CSA). The Grant agreement was concluded with HADEA, the project was launched on the 23rd of May 2023 in Milan. There are 27 Member States (MSs) participating alongside 5 associated countries (Albania, Georgia, Moldova, Norway, Romania, Ukraine).

The work package (WP) 2 of the CCI4EU project aims to develop a joint understanding and scope of Comprehensive Cancer Infrastructures (CCIs), along with a set of criteria to assess and improve CCIs in all European Member States (EU MSs). The defined Quality Criteria (QI) will be embedded in a Maturity Model (MM), which will be the contextual backdrop to assess CCI maturity and develop tailored interventions to increase the individual CCIs maturity level.

The report is divided into four chapters starting with an introduction, followed by the description of the CCI criteria and QI development process and methodology.

Chapter 3 provides an overview of the agreed eight themes with corresponding criteria, target stages and proof of achievements for the potential CCIs.

Chapter 4 outlines the agreed Quality Indicators.

The annex includes the final maturity model, as well as the data overview document for collection of quantitative data/ QI documentation.

1. Introduction

The objective of Work Package (WP2) of the CCI4EU project is to develop a joint understanding, definition, and scope of Comprehensive Cancer Infrastructures (CCIs) along with a defined set of criteria to assess and improve CCIs in all Member States (MS). Moreover to embed the defined quality criteria in a maturity model (MM) assessing the (potential) CCI maturity and to develop tailored interventions, which aims to increase the individual CCIs maturity level.

The Mission Board of the EU Mission on Cancer has defined CCIs as: "national or regional infrastructures that provide resources and services to support, improve, and integrate cancer care, research, training of care professionals and education for cancer patients, survivors, and families/carers. Different formats of CCIs are possible including existing Comprehensive Cancer Centres or Care Networks"[1]. The mission aims to achieve the target of ensuring that 90% of eligible cancer patients have access to CCIs by 2030 [2].

Based on this definition, a total of eight themes (see table 1) have been identified which depict the key elements of a CCI and are to be used to (further) develop (potential) CCIs with the support of tailored interventions of the Capacity Building Interventions (CBI). The eight themes will be used as a golden thread throughout all further WPs during the CSA.

	Themes:	
1		Structure of the Comprehensive Cancer Infrastructure (CCI)
2		Comprehensive Cancer Centres (CCC)
3		Interfaces & Quality Indicators
4		Discovery and Translational Research
5		Clinical Research
6		Outcomes Research
7		Screening and Early Detection
8		Patient Pathway

Table 1: Overview of eight themes

For each theme, WP2 developed criteria, target states and proof of achievements, as well as a set of quality indicators (QI).

[1] European Commission, Directorate-General for Research and Innovation, Pita Barros, P., Beets-Tan, R., Chomienne, C., et al., *Conquering cancer: mission possible*, Publications Office, 2020, https://data.europa.eu/doi/10.2777/045403

[2] Horizon Europe –Work Programme 2021-2022 Missions https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-12-missions_horizon-2021-2022_en.pdf

The work of WP2 is closely aligned with the Network of Comprehensive Cancer Centres: Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking Joint Action (JA CraNE), and Joint Action on Networks of Expertise (JA JANE). In addition, the results of the Innovative Partnership for Action Against Cancer Joint Action (JA iPAAC) were included in the work process.

Both developed qualitative and quantitative parameters (criteria and QI) are there to ensure sufficient flexibility in assessing the various CCI structures and at the same time, allow a measurable comparison of the CCIs.

Moreover, to address the heterogeneity of CCIs in the MSs, a MM was also developed using the developed criteria. The aim is to be able to assess the different CCI maturity levels by breaking down the developed criteria and agreed target states into levels.

The MM approach was used to define criteria for the CCI in a differentiated way and to create a transparent overview of the maturity of CCI structures in the MSs. Based on the themes and criteria in the MM, differentiated tailored interventions for capacity building can be defined: themes/ criteria with potential for improvement are quickly identified. The effects of the capacity building interventions are visible afterwards upon a following MM assessment.

As depicted in figure 1 MMs are used as tools to break down complex problems into individual fields of action (= themes) and define a target state of the subject under study and detail the path to the target state into manageable steps. MMs are typically characterized by a series of maturity levels (figure 1).

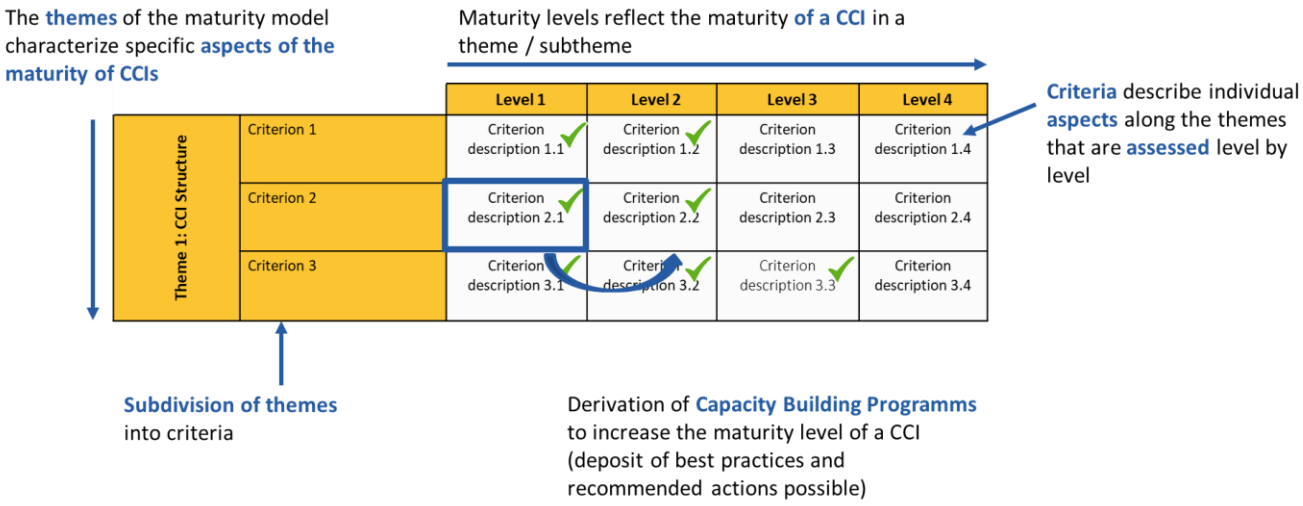

Figure 1: CCI Maturity Model theoretical framework

2. Methodology

For the development of the criteria and corresponding target states per theme, as well as the levelling for the maturity models, the members of the CCI4EU consortium were asked to nominate subject-experts/ theme. For each theme, a working group was established and developed jointly the corresponding criteria, target states and MM levels. Figure 2 illustrates the process. The same process was applied for developing the set of criteria, quality indicators and levelling for the maturity model.

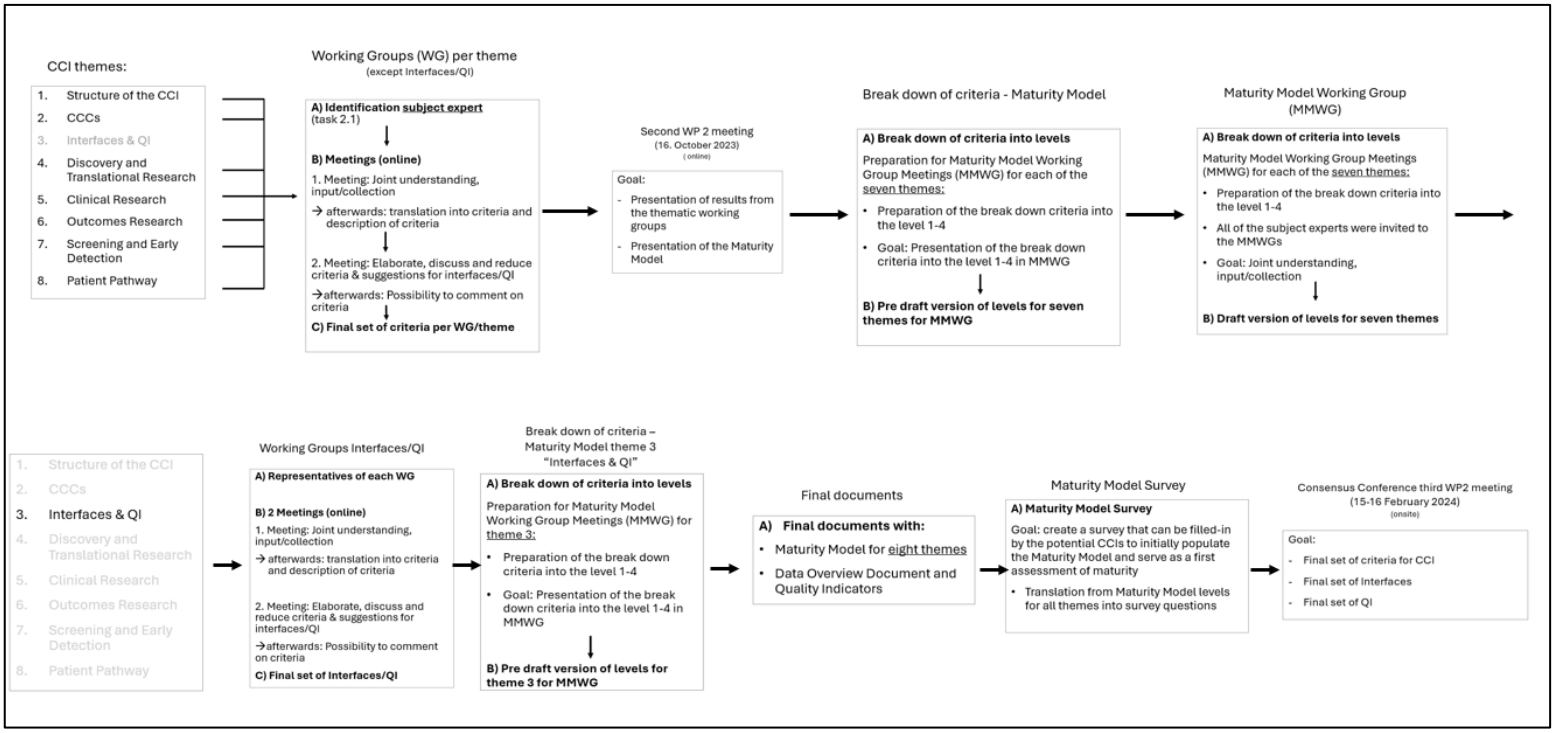

Figure 2: Overview of how criteria were defined

For the identification of subject experts, the following selection criteria were agreed with WP2 members:

- Consortium members of CCI4EU can nominate subject experts for all seven themes[3]. However, only 1 person per Working Group (WG) per member organization had the possibility to vote (1 person = 1 vote).
- The nominated subject expert should have substantial expertise in the WG theme.
- If a subject expert cannot attend a WG meeting, a substitute can be nominated.
- Observers from other WPs were welcome to join.

An overview per theme can be found in table 2

	Themes	Number of subject experts	Obsever
1	Structure of the Comprehensive Cancer Infrastructure (CCI)	26	1
2	Comprehensive Cancer Centres (CCC)	26	1
3	Interfaces & Quality Indicators	12	2
4	Discovery and Translational Research	31	1
5	Clinical Research	22	1
6	Outcomes Research	21	1
7	Screening and Early Detection	24	1
8	Patient Pathway	29	2

Table 2: Overview subject experts per theme

Two WG meetings per theme were conducted. The goal of the first WG meeting was to develop a joint understanding of each theme and identify objectives and target states. Based on the discussions, the collected input was translated into criteria, target states and proofs of achievements. At the second WG meeting, subject experts had the chance to elaborate, discuss and reduce criteria. At the second WG meeting the WG could also make a first suggestion of criteria suitable for interfaces/ QI.

Theme 3 "Interfaces and Quality Indicators" followed the same process but was performed after all other WG meetings were concluded. Along with criteria and target stages, a set of QI were defined.

Target states were further broken down into four levels. This allows CCI´s to develop progressively towards the highest level. The compiled first results of all themes/ WG meetings were presented, discussed, and agreed upon at the second WP2 meeting, October 16, 2024.

Comments from the second WP2 meeting were further processed by WP2 and subject experts in correspondence. The final MM levels per theme were presented, discussed and (Annex 5.1. Maturity Model), agreed on at the WP2 Consensus Conference (15-16 February 2024). As a last step, the final

[3] The subject experts for theme 3 "Interfaces and Quality Indicators" were identified out of the thematic working groups.

MM levels' descriptions were translated into questions for the CCI4EU survey, developed by WP3. The Goal of the CCI4EU Survey is to initially populate the MM and serve as a first assessment of maturity of (potential) CCIs.

The final set of criteria, target stages and proof of achievements for all eight themes are listed in chapter 3.

3. Set of criteria

For each theme, a definition was jointly developed and agreed by the subject experts of the theme. The set of criteria are divided into eight themes.

The set of criteria and target states describe a fully developed CCI (= highest level). Together they reflect a goal that is aimed to be achieved prospectively.

The column "Proof of achievement of target" describes what the "Target states" should or must contain to be considered fulfilled.

The column "Proof of achievement of target" often gives examples of how the achievement of the target can be demonstrated. This does not preclude CCIs from using other means/ forms for implementation (example: Target state: "A coordination board is appointed -> If necessary, other stakeholders can be included (e.g. associated partners (criterion 2))").

When the phrase "among other things" is used, it means that at least the items mentioned are addressed. Of course, additional topics can be included (example: Target state: "An agenda for the further development of the CCI is available -The following points, among others, are to be addressed with the definition of milestones").

3.1. Theme 1: Structure of the Comprehensive Cancer Infrastructure (CCI)

Definition: Structure of the CCI: Regional, national, or cross-border CCIs should ideally bring together all oncological prevention, screening, care, and research structures (such as universities, hospitals, research institutes, and screening facilities) within their scope. These structures interface with one another, and the foundation of the CCI should be based on the needs of patients and citizens. A coordination board should represent all CCI participating entities, as well as public authorities and/or agencies.

Comprehensiveness: In addition to researchers, the CCI should include interdisciplinary and/or interprofessional disciplines along the patient pathway (both in hospitals and primary care). It is vital to integrate patient representatives and other stakeholders within the CCI framework.

Structure: The CCI comprises various collaborative structures tailored to specific tasks, such as network(s) for clinical research and network(s) for tumour-specific care. Each of these networks requires its own coordinating structure. There can be overlaps among the different layers of networked collaborative structures, as individuals and institutions may serve multiple roles. The scope of a CCI can be adapted based on country-specific characteristics. The term “CCI” refers to cooperation of institutions within the scope of the CCI. The CCI is not necessarily meant as an official institution or an organizational structure with command and control mechanisms.

Criterion	Target state	Proof of achievement of target
1. Scope of the CCI	The defined scope of the CCI is fully comprehensive (regarding topics and treated entities/cases)	• The scope of the CCI is to be presented and the participating independent institutions and their functions are to be named (e.g. via organisation chart; min. number of members: minimum of 3 institutions with different functions or scope in cancer care, research and education). The representativeness of the participating institutions in relation to the region/MS and the catchment area characteristics should be described (e.g. why is the described scope selected; taking into account population density and linguistic characteristics). If representativeness is not sufficient, measures should be described on how it could be improved (e.g. cross-border collaboration). • The defined scope covers the topics of the other themes (CCC, discovery and translational research, clinical research, outcome research, screening and early detection and patient pathway). • The CCI can offer research and quality-assured care for a significant number of tumour diseases. The goal is that 90% of the oncological diseases and 90% of the incident cases in the region/catchment area can be treated along the entire patient pathway (PP) within the CCI structures, as evidenced e.g. by the organigram of the networks (see also Theme 8).
2. Structure of the CCI	Participating entities of the CCI are named	• Participating entities of the CCI can be not only institutions but also e.g. departments within institutions. Responsible persons have to be named. • Participating entities of the CCI are be selected in such a way that they together can fulfil the comprehensive mission of the CCI. This includes (among other points): ◦ They represent all the main infrastructural elements to make a

		cancer infrastructure comprehensive ◦ They represent and/or fulfil the topics of the other themes (CCC, discovery and translational research, clinical research, outcome research, screening and early detection and patient pathway). ◦ The CCI can offer research and quality-assured care for a significant number of tumour diseases (as in 1 above), with a possible focus on rare cancers. ◦ (Newly) named participating entities of the CCI fulfil the CCI-criteria relevant to their function ◦ In addition to the researchers, the interdisciplinary/ interprofessional disciplines along the patient pathway (in hospitals and primary care) and patient representatives, other stakeholders should be included in the CCI-structure (as e.g. associated partners): e.g. representatives of the ministries of health and research, health insurance companies, health economists and legal experts for data access/GDPR, public, national cancer societies, public health institutes, health technology assessment offices. The collaboration and interactions should be described.
	Written cooperation agreements between the participating entities are signed	• Cooperation agreements define the tasks and competences of the individual members within the CCI (e.g. participation in coordination board and other meeting formats, definition of interfaces to other members). The cooperation agreements are updated regularly.
	The structure, objectives, and scope of the CCI are publicly available	• The Participating entities of the CCI of the CCI are listed on a website. Responsible persons and contact details are named. The tasks, objectives and competencies of the CCI and its individual members are presented to the public and other stakeholders.

3. Operational structure of the CCI	The CCI has rules of procedure	• The rules of procedure describe the objectives, tasks, working methods (e.g. election of chairpersons, voting, how to become a member of the CCI etc.) and meeting formats (e.g. coordination board, topic-specific working groups, etc.) of the CCI including the coordination point/function.
	An annual budget and financing plan for the CCI is in place	• A financing plan describes ways of financially supporting the CCI (e.g. membership contributions, government, third-party funds (e.g. EU tenders & funding programme, European Innovation Council Accelerator, health insurance, etc.). If its not feasible an explanation should be provided.
	A coordination point/function is set up	• A head for the coordination point/function is to be appointed. The tasks of the coordination point/function are described in the rules of procedure and include e.g. organising the coordination Board and other working groups, supporting the development and extension of the CCI and financial accountability. The coordination point/function is the contact point for external requests, maintaining the website, and supervising CCI projects.
	A chairperson and deputy chairperson for the CCI are appointed by the coordination point/function	• The spokespersons represent the CCI to the public
	A coordination board is appointed	• Representatives from all members of the CCI are actively involved in the coordination board. If necessary, other stakeholders can be included (e.g. associated partners (criterion 2). The coordination board has rules of procedure that describe among other things the objectives, tasks (see criterion 4), working methods (e.g. election of chairpersons CCI and/or coordination board, voting, etc.) and meeting formats.

		• The initiation of further boards should be reviewed in the coordination board.
For the following points, the <u>realization and implementation</u> should be described, responsible persons should be named (e.g. initiation of topic-specific working groups) and the results should be available (e.g. minutes of coordination board meetings with results and measures derived from them):		
4. Tasks of the CCI	Evaluation of the performance of the CCI	• This could be done by using the Maturity Model (including monitoring and benchmarking). • The evaluation must at least contain (table is attached at the end of the list of criteria): Number of third-party funded projects carried out, number of patients treated in the CCI per year in relation to the number of new cases in the region; number of tumour-specific patient pathways in use. • See also: Theme 8 “Patient Pathway”, criterion 5 “Evaluation”
	The CCI has an overall research plan	• The plan should be developed in a bottom-up process including all relevant partners from research and care and should include mapping and discussion of the research in the CCI as a whole.
	The CCI has a plan how the Patient Pathways used in the CCI are developed	• The realization of the PP used in the CCI can be done e.g. via the coordination board. The coordination board can entrust other working groups or partners of the CCI with the tasks. • The development must also include the implementation, updating and evaluation of the overall Patient Pathways process within the CCI.
	The CCI has a continuous educational and training agenda for different disciplines and professional groups within the CCI	• In coordination with national/regional programs. • The professional groups that are active in the tumour-specific patient pathways should be addressed in particular.
	The CCI has a strategic plan for the further development of the CCI	The following points, among others, are to be addressed with the definition of milestones:

		• How to foster cooperation between the CCI-partners as well as regional, national and cross-border and EU-wide other CCIs/stakeholders/projects/partners (e.g. Cancer Mission Hubs (ECHOS), Networks of Expertise etc.)
		• The CCI will identify and address inter-organizational collaboration needs and potential inter-organizational synergies and organize the necessary activities to make the infrastructure fit to handle these problems and leverage the synergies
		• How to ensure that the available resources are leveraged if needed (i.e. identification of synergies and optimal use of resources (i.e. molecular pathology, genomics, etc.))
		• Ensuring better access for the patients to the CCI (equity of access, minimising social disparities)
		• How can the costs of care and research be evaluated and the results used for further development?
		• Developing a data infrastructure in the CCI, that enable
		  • Documentation/data sharing (→ see also theme: “CCI interfaces” and “patient pathway”)
		  • The implementation of a clinical cancer registry for the patients treated by partners within the CCI (in coordination with national/European cancer registries)
		Responsible persons/working groups for the implementation according to the plan are named.

Theme 2: Comprehensive Cancer Centres (CCCs)

Definition: Comprehensive Cancer Infrastructures (CCIs) are built around Comprehensive Cancer Centres (CCCs) in each Member State. The CCC is the hub in the CCI, however respecting/taking into account cancer care in cancer centres/tumour-specific centres (i.e. treatment close to home). The term CCC refers to the CCC structures that are certified in accordance with the criteria for CCC developed in the JA CraNE, which presently recognize only OECI and DKH as CCC certification schemes.

Criterion	Target state	Proof of achievement of target
1. CCC	A CCC is certified based on the pan-European consensus criteria/standards being developed in JA CraNE	The following points will be deleted, if they are addressed by the CCC-criteria defined in JA CraNE Irrespective of the type of certification, the (to be formed) CCCs shall present: • How the results of other Joint Actions (e.g. Jane and the networks of expertise for palliative care; paediatric, poor prognosis cancer, etc.) are taken into account to fill the potential gaps of the resp. CCC and to ensure/help to connect/encourage dialogue/exchange on national and international level • How training for clinicians/other professional groups outside of the CCC is provided. • Provide an overview for patients and public what will/can be delivered in the resp CCC (e.g. which research foci are pursued, which tumour entities are treated in the CCC, which treatment for specific cancers is available, if molecular pathology is available etc.)

3.2. Theme 3: Interfaces

Definition: An interface is defined as a point of connection between partners of the CCI. Interfaces between themes are the areas in which themes affect each other, have links with each other and where there is a need for an overarching coordination within a CCI. The interfaces are being worked on in the Interface Working Group (IF-WG). Representatives of all participating entities of a CCI and all themes should be represented in the IF-WG. Other stakeholders can also be included.

Criterion	Target state	Proof of achievement of target
1. Interface Platform	An Interface Working Group (IF-WG) is established	• The IF-WG should address all identified interface topics listed below • The IF-WG includes representatives of Themes 1-2 and 4-8 (could be e.g. the person/s filling in the MM; an interprofessional and interdisciplinary member recruitment should be realised and, if appropriate, other CCI stakeholders (regional, national, cross border, EU-wide, international) • The IF-WG meets on a regular basis (e.g. at least 1x/y) for among others updating of the different topics • Minutes of the meetings with results and measures derived from them are available
2. Interface Topics	There is a common data infrastructure in the CCI (see theme 1 "Structure of the CCI")	• An IF-WG "Data Infrastructure" has been implemented in coordination with the coordination board (theme 1). • Departments/institutions and persons responsible for the (further) development of the data infrastructure (including legal/ethical aspects) have been appointed. • The data utilization concept includes, among other things, coordinated specifications for data definition, collection, storage and analysis, as well as patient consent (e.g. broad consent). Duplicate documentation must be avoided. The data utilization concept is harmonized between different CCIs (national/EU-wide).

		• The data infrastructure is GDPR compliant, and a Quality Management System is in use. • Sufficient personnel resources are available for the documentation of the data in the networks, study units and CCI's own hospital-based cancer registries. • Within the CCI, data is collected on the basis of a common, standardized data set • This data set corresponds to the national/European/international standards/classifications (e.g. ICD-10, ICD-O, WHO, DICOM) • The data infrastructure has interfaces and/or reports data to the population based national cancer registries (if available) or regional cancer registries or screening cancer registries • Data can be exchanged/linked between the CCI networks/institutions (e.g. interfaces, web platforms, etc.) and, if possible, with partners/other registries outside the CCI (cross-border, international). Study data and data from the biobanks are, if possible, integrated into the data infrastructure • Results provided by other European projects (for example: BBMRI, ECRIN, European Health Data Space etc) should be taken into account.
	The CCI has an overall research strategy	• The research strategy of the CCI is agreed in the IF-WG with regard to its topics • The representatives from themes 1-2, 4-8 contribute their existing research strategies (if applicable) • The research strategy (taking into account the respective healthcare system and the CCI structure (e.g. existing expertise of the members)) includes, among other things: ◦ A broad spectrum of research areas and questions (e.g.

		personalized medicine, early detection, nursing research, ...) ◦ Mapping of the research in the CCI as a whole ◦ Topics from the theme's discovery & translation, clinical and outcome research ◦ Integration of research and care (among other things: improving patients' access to clinical studies, standardized procedure for screening patients for study participation; increasing the number of studies available within the CCI...) ◦ A comprehensive research infrastructure (e.g. ECTU, Biobank, CTU,…) ◦ Continuous evaluation of the strategy (min . 1x/year) ◦ the CCI being part of national, international, EU-wide research networks (e.g. ERN)
	The CCI has a strategy for patient involvement and participation	• The concept is developed with national/regional patient advocacy groups • The representatives from themes 1-2, 4-8 contribute their existing concepts (bottom-up process) • The concept addresses, among other things: ◦ how patients are involved in research planning, implementation and evaluation ◦ how the CCI provides continuous education for patients; including among others topics addressed in themes 1-2 & 4-8 ◦ how patients are involved in the development and application of the PP ◦ how research and care topics are prepared and presented for oncological patients (e.g. organization of events for patients; PPs that can be used by patients) aiming for a partnership between patients and health care professionals

	The CCI has a continuous educational and training agenda for different disciplines and professional groups within the CCI (see theme 1 "Structure of the CCI")	• The educational and training agenda of the CCI is coordinated with all participants of the IF-WG • The agenda is in coordination with national/regional programmes. • The representatives from themes 1-2, 4-8 contribute their existing education & training agendas (bottom-up process) and responsible institutions/persons are appointed • The agenda should take into account: ◦ all relevant stakeholder groups (researchers and professional groups that are active in the tumour-specific patient pathways etc) ◦ the different areas within the CCI (research, care, different professional groups) • The agenda, the trainings included in the agenda, the professional groups addressed, and the participants can be presented
	A working group for quality management within the CCI exists	• The quality management systems required for the individual areas and processes within the CCI are defined, harmonised and mapped • The quality management contact point supports the members or representatives from the themes 1-2 & 4-8 in the implementation and update process of a quality management system. E.g. by organising internal audits or training courses on quality management-relevant topics.
	The CCI promotes the inclusion of outcomes research in the National Cancer Plan (NCP)	• In the NCP outcome research is described, including: allocation of resources for outcome research and using results from outcome research for further development of the NCP

3.3. Theme 4: Discovery and Translational Research

Definition: Frameworks and quality standards that are needed to support the development of basic, pre-clinical, and clinical research including innovation and real-world data, to translate the knowledge/discovery into the clinical environment for the benefit of the patients.

Criterion	Target state	Proof of achievement of target
1. Organisation of core research capacity	Established state-of-the-art research platforms are available and reachable for the whole research community	• Available national requirements for platforms in each member state. • Available organizational platforms such as data management, ethical agreements, approval of trials. • Available technical platforms and facilities for scientific measurements ◦ preparative platforms (sampling and prep for analysis) ◦ analytical platforms (analyse samples acquired) ◦ omics, imaging, … • Number of platforms open and reachable for the research community • Successful integration and utilization of omics, imaging. etc, technologies in research initiatives. • Defined throughput time of the platforms (How many samples the platform can process). • Quality assurance programs ◦ Type and quality of equipment (age, maintenance, handling timeframes...) ◦ Latest updates on data collection ◦ Compliance of platforms to IVDR (as a measurement)
	Biobanks are established and accessible to the entire research community within the CCI	• There are established agreements with biobanks for productive research collaborations. • Biobanks covering all major tumour types. • Biobanks are linked to clinical data. • Data of analysis is available in the biobank.

		• Data available on type of tissue, collection method, when it was collected
	Early phase Clinical Trial Units (CTU) are available and accessible within the CCI	• Collaboration agreement with research platforms • Define minimal required data for clinical trial unit (early phase) • Numbers/Percentage of patients included in early phase studies (Phase I) • Number of studies available • First in human facility • Dedicated personnel, researchers for phase I studies • Harmonise different regional criteria for definition of phase I units. Set a minimum criterion to interact with the platform. • Capability to have pharma funded and self-funded phase I studies. • Define and harmonise certification and accreditation processes. • Definition, collaboration and bridging between basic, translational, and clinical research. • Structures needed for the early phase trials (pharma, diagnostic, MTB)
2. Framework for conducting translational research	There is a robust support framework enabling translational research and implementation of results	Ethical & Regulatory framework ◦ GCP – medical ethics or Implementation of Good Clinical Practice (GCP) principles in line with medical ethics. ◦ Consent form / General Data Protection Regulation (GDPR) expertise Funding strategies ◦ There is a grant support office. ◦ Utilization of quantitative measures: funding in terms of % of centres GDP (due to MS different size)
	Support for Innovations is available for the entire research community	◦ Operation of a Technology Transfer Office (TTO) to facilitate the transfer of research advancements into practical applications. ◦ Facilitation of industry collaborations and agreements to foster innovation.

		◦ Formalization of interactions among Academia, Industry, and Health Organizations to enhance cross-sector collaboration. ◦ Number of patents (DOFIs). ◦ Standardized process for integration of new innovations, technology, progress etc
3. Collaborations & Networks	Existing partnerships and networks including academia, research institutions, healthcare organisations, industry, and patient advocacy groups	• Documentation of formal agreements and MoU between academic institutions, research organizations, healthcare providers, industry partners, and patient advocacy groups. • Evidence of joint funding applications and secured grants for interdisciplinary research endeavours. • Records of workshops, conferences, seminars, and symposiums organized with participation from academia, industry, healthcare, and advocacy groups. • List of research papers, publications, patents, and innovative solutions resulting from collaborations across sectors. • Co-authored publications involving researchers, clinicians, industry experts, and patient advocates. • Expansion of the networks
4. Education & Training	There is a comprehensive program of education and training for all translational researchers	• Training modules catering to researchers, clinicians, professionals, and patients covering various aspects of discovery and translational research. • Demographic information to showcase the diversity of participants. • Educational programs tailored for patients, caregivers, and advocacy groups to understand and engage in translational research.

3.4. Theme 5: Clinical Research

Definition: Infrastructures that are needed to support planning and execution of comprehensive Clinical Research including all research fields in oncology.

Criterion	Target state	Proof of achievement of target
1. Capability Platforms*	Established state-of-the-art capability platforms are available and reachable for the whole research community to support clinical research.	• Comprehensive state-of-the-art platforms are accessible and in use for all researchers in the CCI (level 4. (Examples: Diagnostic platforms, Drugs and technology, Reporting of toxicity and adverse events and health related quality of life, High Tech Platforms – to support adaptive trials, OMICS, AI, innovative medicine, radiotherapy, surgery, novel drugs screening, etc.) • There is an integration process of novel capabilities (novel techniques, therapies, innovations etc) (level 3) • Cooperation with primary care (level 4)
2. Clinical Trial Office (CTO)	Equal accessibility to CTO (clinical trial office)	• Phase II/III/IV (indicator: # active trial/year, % pat. enrolled) (level 4) • Comprehensive Management in place (i.e. administration, internal quality control (including case report form (CRF)) and guiding of funding applications. (level 4) • Connection to Biobanking facilities (level 2) • Do the CCI have an accessible Data base to clinical trial/research. (level 3) • Established uniform protocols and guidelines for monitoring clinical trials. • Support available for the different aspects of clinical trial monitoring (Clinical Trial Office (CTO)) (level 3) • Quality and Assurance Control
	Continuous education for all clinical staff members in clinical research	• Educational training and support on various aspects in connections to clinical research.

		• Management and education on side effects from treatments, expert support and sharing of information. • Palliative care management, alleviating the symptoms while in the structure of a clinical trial
3. Collaboration in national and international Clinical Research Networks	Broad access to clinical research in other CCIs	• Clinical trial Unit networks or CCC-networks facilitating activities, on National and European level. • Number of patients included in clinical trials in other MS. • Participation in multicentre trials, international working groups. (percentage of patients included in multicentre trials) • Written agreements in place
	Active participation in high expert networks aiming to improve clinical research	• Connection to networks (ERN) (Examples: professionals, disciplines, management, nuclear medicine, PET, pathologist, High-Tec medical resource network, precision medicine, industry, etc.) • Participating in Networks of Molecular Tumour Boards (MTB) • Numbers of publications from networks • Participation in Clinical trial Unit networks or CCC-networks facilitating activities, on National and European level.
4. Patient Involvement	Active patient involvement in all clinical research phases	• Patient involvement in formulating the research question, taking part of the study design. • Co-creation in clinical research • Give possibility to patient and patient organisation to disseminate the results of clinical trials. • Structured/ standardised evaluation by the patient about clinical efficacy/interest of clinical intervention.

3.5. Theme 6: Outcomes Research

Definition: Outcomes research generates knowledge to improve clinical decision-making and sustainable health care delivery to optimize patient outcomes. Outcomes research studies the performance of the structure and processes of health care systems in terms of the health and well-being of patients and populations. It takes into account a wide range of parameters such as mortality, morbidity, quality of life, symptoms, quality of care, risk factors, health economic measures and patients' experiences, preferences, and values.

Criterion	Target state	Proof of achievement of target
1. Engagement and commitment of stakeholders	High awareness among patients and patient organisations to enable discussions with patients about outcomes and outcomes research	• Continuous education and training of professionals and patients. • Patient engagement, cancer society, patient organisation, including people with low health literacy. • Involvement of patients/patient organisations as co-researchers. (level 4) • Patients and public representatives are part of ethical committees in the institutions. (level 4) • Patient empowerment and shared decision-making: Discussions with patients/next of kin on the outcomes (level 4)
2. Standardized collection of outcomes data	Collection and analysis of outcomes data is used to improve and ensure equal access to cancer care, research, and education within the CCI.	• Hospital Cancer Registry is in operation and used for outcome research and for reporting to the population-based cancer registry (PBCR) • Data is collected using validated methods and tools (level 2 or 3) Example on data and collection methods: ◦ Patient reported measurements: • PROMS • PREMS • Socioeconomic level and financial situation • Quality of life • Relevant questionnaires and documents are available in all languages spoken by the population in the CCI.

		◦ Process outcomes: • Mortality • Health economics (costs) • Data from research and Real-world data • Timelines (from symptom-diagnosis – treatment) are known and followed according to regional / national guidelines. • Data set for reporting to the PBCR defined and variables reported in a structured format • Collected data is analyzed and used. (level 4) Examples: ◦ Use of the PDSA cycle as a decision tool as quality of care improvement ◦ Outcome data is used as a decision tool when forming and developing regional, national, and pan-European guidelines. ◦ Collected outcome data is used for research.
3. National cancer registry	Data for outcomes research are integrated/linked into the national/regional cancer registry	• Access to patients' follow-up information from PBCR National Cancer Registries, for the whole CCI (level 3) • Outcome research data is linked to national or regional cancer registry. (level 4) • Merging of Outcome data sources is performed automatically on a regular basis (level 4) • Legal framework and data sharing agreement in place
4. Data / ICT	Accessible standardised data and databases for internal and external partners	• Data bases, infrastructure for harnessing data. (Including Administrative databases, Clinical databases, Disease Registers, Clinical Trial Databases, Datasets, Biobanks and their level of interface and interoperability.) • Electronic tools for data collection and presentation • Established protocols and management for data extraction • GDPR regulations / privacy issues • Harmonisation between the different MS • Standardized use of the data

		• Standardized communication/ sending of data. • The level of digitalization of data (not only data collection but also the extent of use of software's, electronic tools to share information, discuss cases, communication with patients, telemedicine, clinical practice, coordination)

3.6. Theme 7: Screening and Early Detection

Definition: Screening and Early Detection Infrastructures for screening and early detection aim to create systems that facilitate and ensure equal access to screening, interventions, and research, particularly targeting high-risk groups. These infrastructures also include initiatives for raising awareness about the importance of early detection and diagnostics.

Criterion	Target state	• Proof of achievement of target
1. Organization and structure	The CCI promotes that data from Screening and Early Detection is linked to the national / regional cancer screening registry	• Harmonization of data collection and regular reporting on a regional, national and pan European level.
	Governance of screening and early detection	• Well-defined role as a key stakeholder to the authority responsible for organisation of screening and prevention within a CCI • Provide expertise to development of national/regional guidelines (aligned with EU guidelines?) (level 2) • Provide data for auditing (Level 4) • Use of standardised screening methods within a CCI (level 4) • Implementation of novel methods (e.g., AI, deep tech, etc) (level 4) • Existing protocols to systematically review the entire CCI terms of: (Example: Overall screening performance, Patient involvement, Compliance to clinical pathways) (level 4) • Are there defined timelines from screening to intervention
	Participation and collaborations in national and/or international networks	• Active participation in screening and early detection expert networks (Existing agreements, protocols) • Examples of sharing good models, cooperation, research and good practices and outcomes.

2. Research in Screening and Early Detection	There is ongoing research on screening and early detection and implementation of new discoveries within the CCI	• Existing funding mechanisms for screening and early detection in cancer research • Availability of different screening modalities • Adoption of new technologies (AI, digital pathology, development of biomarkers, spectroscopic techniques) • Evaluation of new techniques, can they be developed and implemented in every CCC within the CCI) • Health economics analysis
3. Screening Programs, Protocols, and Guidelines	Identification of Screening Population	• A well-defined role of the CCI in the referral pathway • Role of service providers in screening programs is defined (recommending and delivering cancer screenings) • Opportunistic screening (level 1) • Population screening à Age range based (level 2) • Targeted screening à High risk group screening (level 3) • Subpopulation identification and screening (level 4) • Taken in consideration the following: Socio-economic status, educational level, Health literacy, Multicultural societies, Geographical situation. • Percentage of population reached (>85%?) (level 4) • Identification of the non-attending/adhering population
	Continuous education and training in screening and early detection of professionals, patients, and citizens	• Education for primary health care personnel, GPs in early detection to catch the early signs and patients at early stages using risk models. • Training/capacity building for healthcare providers involved in delivery of health services in the screening program • Information on training of professionals on risk stratified cancer screening.

3.7. Theme 8: Patient Pathway

Definition: Patient pathways should cover the entire pathway from diagnosis to palliative care/long-term survival/survivorship. Based on national health system structures, the tumour-specific patient pathway should be comprehensive and guideline based. They should be assessed e.g. with the help of Quality Indicators (QIs) and Patient Reported Outcomes (PROs). A patient pathway should help to deliver high-quality care and foster improved access to research by bringing researchers and care providers together. Patient Pathway should improve cooperation and coordination between partners within the tumour-specific networks including the transversal aspects of the tumour-based pathways in the CCI.

According to the JA iPAAC, "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."

The patient pathways are intended to achieve that:

1. quality of care and

2. predictability of the process for patients and caregivers are improved,

3. cost control and

4. patient experiences and engagement are taken into account.

Criterion	Target state	Proof of achievement of target
1. Patient Pathway in Use	For all tumour entities a patient pathway is in use	• Tumour -specific patient pathways that meet the criteria of theme 8 shall be presented. (For MM-WG: for example -> Level 4 = 20 PPs?!)
2. Development, Application and Technical Implementation of Patient Pathways	There is an implemented agenda how the used patient pathways in the CCI are developed and updated	• In cooperation with the CCI coordination point/function (see theme 1), a process is in place in which the PP development and updating process (among others in coherence with the guideline) within the CCI is described. Responsible persons and institutions are named (these could be for example representatives from the participating CCCNs). • An overview of the available PPs must be readily available to all partners within the CCI to guarantee a low-threshold access to the PP (e.g. via the CCI website). • A patient version of the PP should be made available for the patient. Including information about who is responsible for coordinating their pathway (in a medical and logistical sense; named by persons and organizational unit)
	Data collection points should be indicated in the patient pathways	• A description of the data fields to be collected along the PP is to be provided (see also Theme 1, Criterion 4). These should include the data needed for the QI and needed by the cancer registries and, if possible, study data.
	Patient pathways are embedded in the technical infrastructure of the CCI (MM-WG: = Level 4)	• There is a (step-by-step) concept of how the PP can be used by the CCI partners (e.g. first paper-based, then technically integrated). • The concept must describe how the timely generation of quality assurance and research data along the PP is to be made possible via integration into the technical infrastructure. If possible, including remote monitoring system based on the digital technology (e.g. telehealth).

3. Structure of the Patient Pathway	Patient pathways are comprehensive (scope of the patient pathway)	• All PPs should cover the entire pathway from diagnosis to palliative care/long-term survival/survivorship • The tumour-specific multi-professional team (MDT) must be addressed in the PP and related documentation (e.g. MDT protocols): ◦ Diagnostic specialist disciplines: pathology, radiology, nuclear medicine, and molecular diagnostics (including bioinformatics) ◦ Therapeutic specialist disciplines: surgery, endoscopic therapy, radiotherapy, interventional radiology, systemic therapies (including personalized therapy) ◦ Patient-centred care: palliative and supportive care including psycho-oncology, social service, rehabilitation/sports and physical activity counselling, nursing, nutritional counselling, pain management, patient engagement initiatives, patient organisations and support groups • Together with MDT meetings where, among others, the treatment plan (including screening for study participation) for the patients is prepared • The different institutions along a PP are to be made visible with a focus on the interfaces in their cooperation. It should be realised that (tumour-specific) highly specialised services (e.g. breast reconstruction) are offered centrally in a CCI, while standard oncological care (e.g. breast conservation therapy) is provided in several tumour-specific networks. • Referral from screening/prevention/survivorship to hospitals/networks and referral back to primary care/ambulatory care/local hospitals and social services should be addressed. • Interfaces to non-clinical institutions, like cancer registries, biobanks, research centres/departments must be implemented and described in the PP and associated documentation.

		• If needed: cooperation with other (inter)national/cross border groups/networks for patients/clinicians should be integrated (for example: rare tumour, paediatric oncology)
4. Requirements for Patient Pathways	Patient pathways include tumour-specific characteristics	The following points should be addressed in the PP (and if needed be elaborated in associated documents): • A reference to the underlying evidence-based guidelines (name, version, recommendation) must be made in the tumour-specific PPs. • The PP must contain an algorithm for the identification of hereditary tumour diseases including, if necessary, human genetic examination and counselling. At least for the entities: Breast, ovarian, colorectal, renal and paediatric tumour. • Tumour -specific environmental and lifestyle risks (e.g. asbestos, smoking, obesity) should be included in the PP and addressed in the communication/therapy (e.g. smoking cessation, vaccination). • To prevent long term effects: specialised disciplines or questions that are very tumour/therapy-specific should be addressed in the PP (i.e. cardiologists for Herceptin-therapy, or information about and application of fertility-preserving measures)
	Patient pathways support the enrolment of patients in studies and encourage the conduct of studies	• The PP includes screening and obtaining informed consent for possible study inclusion along the entire PP. Studies in this context are among others: translational, clinical interventional and diagnostic studies, organisational, outcome research studies • See also: criterion 2
	Patient pathways include the patient perspective	• The patient perspective must be included in the PP. This comprises, for example, the collection and use of PROs, the involvement of patient representatives, the concepts of patient-centred care, shared decision making and care-customization.

	Patient pathways include minimum technical, personnel and structural resources	• The PP includes requirements for: 1/ sufficient staff, 2/ skills maintenance/continuous education, 3/ adequate equipment, 4/ quality and safety management, 5/ patient involvement. • The tumour-specific requirements can be proven e.g. via the certification criteria from the Joint Actions iPAAC and CraNE, ECIBC, Essential Requirements ECO, ECC and other national guidelines (if available).
5. Evaluation	A regular evaluation of the patient pathways takes place	• The evaluation (e.g. through interviews/questionnaires with the partners of the tumour-specific network or discussion in the coordination board meetings (Theme 1) should at least contain the following information: ◦ Have there been changes in national guidelines that implying that adjustments in the PP should done? Do our practical experiences or accessible experiences from others imply that current PP do not express best practice? Do we need to develop additional PPs? Does the PP update processes work? Are all partners along the PP informed about the contents of the PP? How are the PPs used (e.g. in tumour boards / MDT meeting? For how many patients within the network are the PPs used? By how many partners?)? What impact do PPs have on the quality and cost of care and PROs? • Quality indicators should be used for the evaluation. E.g. the quality indicators of the European initiatives: iPAAC, CraNE, ECIBC, Essential Requirements ECO, ECC, OECI...

4. Quality Indicators for CCI

Within this chapter, the set of QI along the eight themes are presented.

The QIs, serve the purpose of gathering additional quantitative data from each potential CCI. This could be for example number of tumour entities treated and/or number of clinical trials. With the help of the defined QIs, comparison between the potential CCIs could be possible.

In total N=8 QIs are defined. QIs were identified for theme 1 „Structure of the Comprehensive Cancer Infrastructure (CCI) “, theme 4 „Discovery and Translational Research“, theme 5 „Clinical Research“, theme 6 “Outcomes Research” and theme 8 „Patient Pathway“. For theme 3 “Interfaces” and theme 7 “screening and early detection” it was concluded in the Working Group that no sensible QI could be derived.

Table 3 presents the overview of the agreed QIs per theme including definition and objective of the QI, numerator, denominator, target, and example/explanations.

Themes	Indictaor	Quality Indictaor / Definition and objective	Numerator	Denominator	Target	Example/Explanation
Theme 1 "Structure of the Comprehensive Cancer Infrastructure (CCI)"	1	As many incident cases as possible in the region are treated within the CCI	Incident cases of the denominator that are treated in the CCI	Number of incident cases in the region covered by the CCI (data provided by the official clinical cancer registry)	90%	The region has an incidence of 3,000 new cases per year (according to the cancer registry). Within the CCI, 1000 new cases are treated (= 33%). Incident cases CCI = First diagnosis of the respective (resp) tumour (including M1 at first diagnosis), pt. counted only once within the CCI and once in the resp year
	2	As many tumour entities as possible are treated within the CCI	Tumour entities (not cases!) of the denominator that are treated in the CCI	Number of tumour entities (not cases!) recorded in the regional cancer registry of the Member State	90%	Denominator: A list of tumour entities that are recorded in the regional clinical cancer registry of the Member State with at least 1 incident case in the year under consideration. Numerator: treated in the CCI = at least 1 case of the resp

						tumour entity is documented in the HIS
	3	Adequate number of institutions involved in the CCI	Number of independent participating entities of the denominator included in the scope of the CCI (see criterion "Scope of the CCI")	Number of independent entities in research, education, care in the catchment area of the CCI	Min 3	
Theme 4 "Discovery and Translational Research"	4	As many patients as possible are screened for an early phase/phase I clinical trial	Incident cases of the denominator who have been screened for an early phase/phase I clinical trial	Number of incident cases that are treated in the CCI	No target value	
Theme 5 "Clinical Research"	5	As many as possible Phase I clinical trials within the CCI	Number of Phase I clinical trials - ongoing & recruiting	Total number of ongoing clinical trials* within the CCI (see example)	No target value	*Clinical trials, Phase I - ongoing & recruiting Clinical trials, Phase II/III - ongoing & recruiting Clinical trials, Phase IV - ongoing & recruiting - "ongoing" = still recruiting Pt

	6	As many patients as possible are enrolled in clinical trials	Incident cases of the denominator enrolled in clinical trials	Number of incident cases that are treated in the CCI	≥10%	
Theme 6 "Outcomes Research"	7	Clinical trials/studies within a CCI which address patient reported outcome measures	Clinical trials of the denominator which adresses PRO/PREMS	Total number of ongoing clinical trials* within the CCI	No target value	*Clinical trials, Phase I - ongoing & recruiting Clinical trials, Phase II/III - ongoing & recruiting Clinical trials, Phase IV - ongoing & recruiting - "ongoing" = still recruiting Pt Definition "clinical trial" = Actively recruiting trials of Phase 1- Phase IV
Theme 8 "Patient Pathway"	8	A patient pathway is in use for as many tumour entities as possible that are treated at the CCI	Tumour entities of the denominator with implemented PP	Number of treated tumour entities in the CCI (= Numerator QI 2)	No target value	PP = according to the definition in Theme 8 "Patient Pathway"

Table 3: Overview of 8 Quality Indicators

All of the N=8 QIs are integrated in the so called “Data Overview Document”. The Data Overview Document serves the purpose of gathering quantitative data from each potential Comprehensive Cancer Infrastructure (CCIs).

Reasons for the need of this document and for collecting the outlined information are twofold:

Assessing the scope and comprehensiveness of potential CCIs requires both qualitative and quantitative data related to cancer care and research.

Comparing potential CCIs requires standardized information and data collection. The indicated figures in the Data Overview Document will also be used to calculate the proposed Quality Indicators (QIs) for the respective themes.

The Data Overview Document comprises four Excel tabs: 1) the “Overview CCI total” tab provides an overview of participating institutions and tumour entities, 2) the "Cancer Research" tab provides an overview of tumour entities, infrastructure, and related processes for cancer care, 3) the "Cancer Care“ tab provides an overview of tumour entities, infrastructure, and processes relevant to cancer research, 4) the “Quality Indicators” tab provides an overview of eight Quality Indicators (QIs).The document can be found as a download at the end MM Survey of theme 1 “Structure of the CCI”.

5. Annex

5.1. CCI Maturity Model

See attached PDF document “Annex 5.1._CCI4EU MM-Themes 1-8”

5.2. Data Overview Document

See attached PDF document “Annex 5.2._Data Overview Document”

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Annex 5.1._CCI4EU MM-Themes 1-8

CCI4EU MM-Theme 01: Structure of the CCI

Definition:

Structure of the CCI: Regional, national, or cross-border CCIs should ideally bring together all oncological prevention, screening, care, and research structures (such as universities, hospitals, research institutes, and screening facilities) within their scope. These structures interface with one another, and the foundation of the CCI should be based on the needs of patients and citizens. A coordination board should represent all CCI participating entities, as well as public authorities and/or agencies.

Comprehensiveness: In addition to researchers, the CCI should include interdisciplinary and/or interprofessional disciplines along the patient pathway (both in hospitals and primary care). It is vital to integrate patient representatives and other stakeholders within the CCI framework.

Structure: The CCI comprises various collaborative structures tailored to specific tasks, such as network(s) for clinical research and network(s) for tumour-specific care. Each of these networks requires its own coordinating structure. There can be overlaps among the different layers of networked collaborative structures, as individuals and institutions may serve multiple roles. The scope of a CCI can be adapted based on country-specific characteristics.The term “CCI” refers to cooperation of institutions within the scope of the CCI. The CCI is not necessarily meant as an official institution or an organizational structure with command and control mechanisms.

		Level 1	Level 2	Level 3	Level 4
Scope of the CCI	The defined scope of the CCI is fully comprehensive (regarding topics and treated entities/cases)	C111 A first meeting to define the scope of the Comprehensive Cancer Infrastrucutre (*CCI*) has taken place.	C121 The scope of the *CCI* is presented and the participating independent institutions and their functions are named. C122 The defined scope of the *CCI* covers a minimum of 3 institutions with different functions or scope in cancer care, research and education.	C131 The defined scope of the *CCI* is nearly comprehensive and the *CCI* meets one of the following conditions: 1. 70% or more of the oncological diseases and 70% or more of the incident cases in the region can be treated along the entire patient pathway within the *CCI* structures. 2. The scope covers at least 6 of the 8 themes (including at least 2 themes from the themes 4-6). C132 The representativeness of the participating institutions is described in relation to the region/MS and the catchment area characteristics (e.g., why is the described scope selected; taking into account population density and linguistic characteristics).	C141 If representativeness is not sufficient, measures are described on how it could be improved (e.g., cross-border collaboration).
		Level 1	**Level 2**	**Level 3**	**Level 4**
Structure of the CCI	Participating entities of the CCI are named	C211 An initial list of potential participating entities of the CCI that reflects the *themes of the MM* has been compiled.	C221 *Participating Entities of the CCI* are selected and responsible persons are named. C222 The *participating entities* are selected in such a way that they together can fulfil the *comprehensive mission of the CCI.*		C241 The collaboration and interaction with the *other stakeholders* is implemented.
	Written cooperation agreements between the participating entities are signed	C212 Initial discussions regarding *cooperation agreements* have taken place.	C223 *Cooperation agreements* have been drafted.	C231 Written *cooperation agreements* between the participating entities of the CCI are signed and in effect.	C242 *Cooperation agreements* are regularly reviewed and updated.
	The structure, objectives, and scope of the CCI are publicly available	C213 Initial discussions have taken place regarding the possibility of making the CCI's structure, objectives, and scope publicly accessible.	C224 The *participating entities of the CCI* are listed on a website. Responsible persons and contact details are named.	C232 The contributions/scope, objectives and competencies of the CCI and its individual *participating entities* are presented to the public and other stakeholders.	
		Level 1	**Level 2**	**Level 3**	**Level 4**
	The CCI has *rules of procedure*	C311 Initial discussions have taken place regarding the establishment of *rules of procedure* for the CCI. C312 A first meeting of the *Interface* Working Group (IF-WG) has taken place.	C321 *Rules of procedure* for the CCI are drafted.	C331 The CCI has established and finalised the *rules of procedure* , which are operational.	C341 The *rules of procedure* are regularly reviewed and updated.
	An annual budget and financing plan for the CCI is in place	C313 Initial discussions have taken place regarding the establishment of an annual budget and financing plan for the CCI.	C322 An annual budget and *financing plan* for the CCI is drafted OR if funding sources are not feasible an explanation is provided.	C332 The annual budget and *financing plan* for the CCI is in place OR if funding sources are not feasible an explanation is provided.	

CCI: Regional, national or cross-border CCIs should ideally bring together all oncological prevention, screening and care and research structures (universities, hospital, research institutes, screening facilities etc.) within their scope. These structures are interfacing and the foundation of the CCI should be the patient and citizen’s needs. A coordination board should represent all CCI members and public authorities/agency.

Comprehensiveness: In addition to the researchers, the interdisciplinary/ interprofessional disciplines along the patient pathway (in hospitals and primary care) and patient representatives, other stakeholders should be included in the CCI.

Structure: According to different tasks the CCI consists of different collaborative structures (e.g. network(s) of clinical research, network (s) of tumour-specific care) that need their specific coordinating structure. The different layers of collaborative structures can overlap as people and institutions are fulfilling multiple functions.
The scope of a CCI can be adopted according to country-specific characteristics.

The term "CCI" refers to cooperation of institutions within the scope of the CCI. The CCI is not necessarily meant as an official institution or an organizational structure with command-and-control mechanisms.
With the term CCI is meant “Participating independent institutions of the CCI".

Themes of the MM: Structure of the CCI, CCC, Discovery and translational reserach, clinical research, outcome research, screening and early detection and patient pathway

Participating entities of the CCI: These can be institutions as well as departments of Institutions.

Comprehensive Mission of the CCI: This mission includes among others points that the participating entities represent and/or fulfil the topics of the other themes (CCC, Discovery and translational reserach, clinical research, outcome research, screening and early detection and patient pathway) and that the CCI can offer research and quality-assured care for a significant number of tumour diseases as specified in C131 and 141 with a possible focus on rare cancers.

Other stakeholder: These stakeholders can include representatives from government ministries, health insurance companies, health economists, legal experts for data access and GDPR compliance, national cancer societies, public health institutes, and health technology assessment offices.

Cooperation agreements: These agreements outline the basic tasks and competences of the participating entities of the CCI, including participation in coordination boards and other meeting formats.

Rules of procedure: These rules describe the objectives, tasks, working methods (e.g., election of chairpersons, voting procedures, membership criteria) and meeting formats (e.g., coordination board, topic-specific working groups, etc.) of the CCI, including the coordination office.

Interface: An interface is defined as a point of connect between partners of the CCI. Interface between themes are the areas in which themes affect each other, have links with each other and there is a need for an overarching coordination within a CCI.

The financing plan: describes ways of financially supporting the CCI, such as membership contributions, government funding, and third-party funds (e.g., EU tenders and funding programs, European Innovation Council Accelerator, health insurance, etc.)

Operational structure of the CCI	A coordination point/function is set up	C314 Initial discussions have taken place regarding the establishment of a coordination point/function within the CCI and the appointment of a head for the coordination point/function.	C323 A coordination point/function is set up and a head for the coordination point/function is appointed.	C333 The *tasks of the coordination point/function* are written in the CCI's rules of procedure and they are operational.	
	A chairperson and deputy chairperson for the CCI are appointed by the coordination point/function	C315 Initial discussions haven taken place regarding the appointment of a Chairperson and Deputy Chairperson for the CCI.	C324 A chairperson and deputy chairperson are appointed by the coordination point/function.		
	A coordination board is appointed	C316 Initial discussions have taken place concerning the involvement of representatives from CCI members in a coordination board.	C325 A coordination board is appointed with representatives from all members of the CCI being actively involved.	C334 The initiation of further boards should be reviewed in the coordination board and the rules of procedure are regularly reviewed and updated.	
		Level 1	**Level 2**	**Level 3**	**Level 4**
		For the following points, the realization and implementation should be described*, responsible persons should be named (e.g. initiation of topic-specific working groups)** and the results should be available (e.g. minutes of coordination board meetings with results and measures derived from them)***:			
Tasks of the CCI	Evaluation of the performance of the CCI	C411 Initial discussions have taken place regarding the evaluation of the CCI performance, e.g., by using the Maturity Model.	C421 The CCI has established an initial framework for evaluating its performance. This could be done by adapting the Maturity Model (including monitoring and benchmarking).	C431 The Evaluation contains at least: Number of third-party funded projects carried out, number of patients treated in the CCI per year in relation to the number of new cases in the region; number of tumour specific patient pathways in use. Please also see criterion Evaluation in the Theme Patient Pathway.*,**	
	The CCI has an overall research plan	C412 Initial discussions have taken place in the Interface Working Group (IF-WG) regarding the development of an overall research plan within the CCI (see theme 03 "Interfaces").			
	The CCI has a plan how the Patient Pathways used in the CCI are developed	C413 Initial discussions have taken place, e.g., via the coordination board on how the Patient Pathways used in the CCI are developed. The coordination board can entrust other working groups or partners of the CCI with the task.	C422 An initial plan is drafted. This draft includes the implementation and evaluation of the overall Patient Pathways process within the CCI. See also Theme Patient Pathway and its supplementary documents on how to define a Patient Pathway.	C432 The plan on how the Patient Pathways used in the CCI are developed is finalised.*,**	C441 The plan is reviewed and updated and the fulfillment of previous objectives is documented.***
	The CCI has a continuous educational and training agenda for different disciplines and professional groups within the CCI	C414 Initial discussions have taken place regarding the development of a continuous educational and training agenda for different disciplines and professional groups within the CCI.	C423 A draft of the education and training agenda is formulated, which takes into account the different disciplines and professional groups. The professional groups that are active in the tumour-specific patient patways should be addressed in particular.	C433 The CCI has implemented a continuous educational and training agenda, coordinated with national/regional programs.*,**	C442 The continuous educational and training agenda is reviewed and updated and the fulfilment of previous objectives is documented.***
	The CCI has a strategic plan for the further development of the CCI	C415 The CCI has initiated the development of a strategic plan for the further development of the CCI.	C424 The strategic plan for further development of the CCI addresses at least two of the key points and defines milestones for this point.	C434 The strategic plan for the further development of the CCI is finalized and adresses at least four of the key points and defines milestones for these points.*,**	C443 The CCI has finalized the strategic plan for further development of the CCI, which adresses all of the key points and defines milestones for these points. In case individual key points could not be addressed an explanation is provided.***

The tasks of the Coordination point/function: include e.g., organizing the coordination board and other working groups, supporting CCI development and expansion, and ensuring financial accountability.

Key points:
1. How to foster cooperation between the CCI-partners as well as regional, national and cross-border CCIs/stakeholders
2. How to address inter-organisational collaboration needs and leverage the synergies
3. How to ensure that the available resources are leveraged if needed (i.e. molecular pathology, genomics, etc.)
4. How to ensure better access for patients to the CCI (equity of access)
5. How the costs and value of care and research be evaluated and the results used for further development?
6. How to develop a data infrastructure in the CCI, that enable documentation/data sharing

CCI4EU MM-Theme 02: Comprehensive Cancer Center (CCC)

Definition:

Comprehensive Cancer Infrastructures (CCIs) are built around Comprehensive Cancer Centres (CCCs) in each Member State. The CCC is the hub in the CCI, however respecting/taking into account cancer care in cancer centres/tumour-specific centres (i.e. treatment close to home). The term CCC refers to the CCC structures that are certified in accordance with the criteria for CCC developed in the JA CraNE, which presently recognize only OECI and DKH as CCC certification schemes.

		Level 1	Level 2	Level 3	Level 4
CCC	A CCC is certified based on the pan-European consensus criteria/standards being developed in JA CraNE	CC111 Initial discussions have taken place to define the *CCC structure.*	CC121 An overview of the CCC structure to be set up is available, the potential partners have been identified and a first meeting of the responsible persons has taken place.	CC131 There are formally established (but yet not certified) *CCC structures,* formally constituted under a CCC Board. CC132 The structures/institutions/networks of the future-certified CCC are part of the scope of the CCI (see theme "Structure of the CCI").	CC141 The CCC is certified by existing certification schemes (OECI and DKH) or future "EU Certification Scheme" recognized within CraNE/EUnetCCC.

CCC structures: The following areas are adressed :
-Education and training
-Research
-Integration Research and care
-Innovation
-Governance
-Prevention
-Care

CCI4EU MM-Theme 03: Interfaces

Definition:

An interface is defined as a point of connection between partners of the CCI. Interfaces between themes are the areas in which themes affect each other, have links with each other and where there is a need for an overarching coordination within a CCI. The interfaces are being worked on in the Interface Working Group (IF-WG). Representatives of all participating entities of a CCI and all themes should be represented in the IF-WG. Other stakeholders can also be included.

		Level 1	Level 2	Level 3	Level 4
Interface Platform	An Interface *Working Group (IF-WG*) is established	IF111 A first meeting of the *Interface Working Group (IF-WG)* has taken place. IF112 Minutes of the meetings with results and measures derived from them are available.	IF121 The *Interface Working Group (IF-WG)* addresses some of the interface topics as listed in this theme. IF122 The *Interface Working Group (IF-WG)* includes representatives of at least two themes.	IF131 The *Interface Working Group (IF-WG)* addresses most of the interface topics as listed in this theme. IF132 The *Interface Working Group (IF-WG)* includes representatives of at least four themes. IF133 The *Interface Working Group (IF-WG)* meets on a regular basis (e.g. at least twice a year for among others updating of the different topics).	IF141 The *Interface Working Group (IF-WG)* addresses all identified interface topics as listed in this theme. IF142 The *Interface Working Group (IF-WG)* includes representatives of themes 1-2 and 4-8.

An Interface Working Group (IF-WG): is defined as a point of contact between partners of the CCI.

		Level 1	Level 2	Level 3	Level 4
Interface Topics	There is a common data infrastructure in the CCI (see theme 1 "Structure of the CCI")	IF211 Initial discussions have taken place in the Interface Working Group (IF-WG) regarding the common *data infrastructure* . IF212 Initial discussions have taken place regarding the definition of a *data utilisation concept.* IF213 Initial discussions have taken place regarding the implementation of standardised data set for data collection within the CCI.	IF221 An Interface Working Group (IF-WG) "*Data Infrastructure*" has been implemented. IF222 The *data utilisation concept* is drafted. The draft includes, among other things, coordinated specifications for data definition, collection, storage and analysis, as well as patient consent (e.g. broad consent). IF223 The data infrastructure is GDPR compliant, and a Quality Management System is in use. IF224 Sufficient personnel resources are available for the documentation of the data in the networks, study units and CCI's own hospital based cancer registries. IF225 In some parts of the CCI/for some tumour entities, data are collected on the basis of common, standardised data set. IF226 The data set correspond to the national/European/international standards/classifications (e.g. ICD-10, ICD-O, WHO, DICOM).	IF231 Departments/institutions and persons responsible for the (further) development of the *data infrastructure* (including legal/ethical aspects) have been appointed. IF232 The *data utilisation concept* is in place. IF233 Data can be exchanged/linked between the CCI networks/institutions (e.g., interfaces, web platforms, etc.) and, if possible, with partners/other registries outside the CCI (cross-border, international). IF234 Within the CCI, data are collected on the basis of common, standardised data set.	IF241 The *data utilisation concept* is harmonised between different CCIs (national/EU-wide). IF242 The data infrastructure has interfaces and/or reports data to the population based national cancer registries (if available) or regional cancer registries or screening cancer registries (if participating in screening programmes). IF243 Study data and data from the biobanks are, if possible, integrated into the data infrastructure.
	The CCI has an overall research strategy	IF214 Initial discussions have taken place to define the overall research strategy of the CCI, taking into account the existing research strategies that representatives from the themes Structure of the CCI, Comprehensive Cancer Centres (CCCs), Discovery and Translational Research, Clinical Research, Outcomes Research, Screening and Early Detection, and Patient Pathways contributed (if applicable).	IF227 An overall research strategy of the CCI is defined and agreed on in the IF-WG.	IF235 The overall research strategy includes all *relevant research strategy topics.*	IF244 The overall strategy of the CCI is continuously reviewed and updated with national/regional patient advocacy groups.
	The CCI has a strategy for patient involvement and participation	IF215 Initial discussions have taken place to define a *strategy for patient involvement and participation* taking into account the existing concepts that representatives from the theme Structure of the CCI, Comprehensive Cancer Centres (CCCs), Discovery and Translational Research, Clinical Research, Outcomes Research, Screening and Early Detection, and Patient Pathways contributed (if applicable).	IF228 A *strategy for patient involvement and participation* within the CCI is drafted with national/regional patient advocacy groups.	IF236 A strategy for patient involvement and participation within the CCI is developed with national/regional patient advocacy groups. This strategy includes all relevant topics.	IF245 The research strategy for patient involvement and participation is continuously reviewed and updated with national/regional patient advocacy groups.

Data infrastructure: data infrastructure refers to the various components including hardware, software, networks, services, policies, etc. that enable the use, storage and sharing of data within a CCI.

A data utilisation concept: includes, among other things, coordinated specifications for data definition, collection, storage and analysis, as well as patient consent (e.g. broad consent). Duplicate documentation must be avoided.

Relevant research strategy topics:
- A broad spectrum of research areas and questions (e.g. personalized medicine, early detection, nursing research, ...)
- Mapping of the research in the CCI as a whole
- Topics from the theme's discovery & translation, clinical and outcome research
- Integration of research and care (among other things: improving patients' access to clinical studies, standardized procedure for screening patients for study participation; increasing the number of studies available within the CCI...)
- A comprehensive research infrastructure (e.g. ECTU, Biobank, CTU,...)
- Continuous evaluation of the strategy (min . 1x/year)
- the CCI being part of national, international, EU-wide research networks (e.g. ERN)

Relevant topics for the strategy for patient involvement and participation (among other things):
- how patients are involved in research planning, implementation and evaluation
- how the CCI provides continuous education for patients; including among others topics addressed in themes 1-2 & 4-8
- how patients are involved in the development and application of the PP
- how research and care topics are prepared and presented for oncological patients (e.g. organization of events for patients; PPs that can be used by patients) aiming for a partnership between patients and health care professionals

	The CCI has a continuous educational and training agenda for different disciplines and professional groups within the CCI (see theme 1 "Structure of the CCI")	IF216 Initial discussions have taken place to define a continuous educational and training agenda for different disciplines and professional groups within the CCI taking into account the existing education & training agendas. IF217 There are plans for a programme of seminars, lectures and colloquia between clinicians and researchers.	IF229 A continuous educational and training agenda for different disciplines and professional groups within the CCI is drafted, in coordination with national/regional programmes. IF2210 The agenda takes into account the different areas (research, care, different professional groups) within the CCI and the relevant stakeholder groups (researchers and professional groups that are active in the tumour-specific patient pathways etc.). IF2211 There is an annual programme of seminars, lectures and colloquia for clinicians and researchers.	IF237 A continuous educational and training agenda for different disciplines and professional groups within the CCI is developed, in coordination with national/regional programmes. IF238 The annual programme of seminars, lectures and colloquia involve clinicians and researchers from inside and outside the CCI.	IF246 A continuous educational and training agenda for different disciplines and professional groups within the CCI is developed, in coordination with national/regional programmes, and is continuously reviewed and updated. IF247 The annual programme of seminars, lectures and colloquia involves conferences with international representation of both clinicians and researchers.
	A working group for quality management within the CCI exists	IF218 Initial discussions have taken place to define, harmonise and map the QM systems required for the individual areas and processes within the CCI.	IF2212 The QM systems required for the individual areas and processes within the CCI are defined, harmonised and mapped. IF2213 A QM working group within the CCI exists.	IF239 The QM working group supports the members or representatives from the themes 1-2 & 4-8 in the implementation and update process of a QM system. E.g., by organising internal audits or training courses on QM-relevant topics.	IF248 The QM systems are continuously reviewed and updated.
	The CCI promotes the inclusion of outcomes research in the National Cancer Plan (NCP)			IF2310 Initial discussions have taken place on how discovery and translational research, clinical research, outcomes research, and screening and early detection can be integrated in the NCP.	IF249 The CCI supports the NCP development to well describe discovery and translational research, clinical research, outcomes research, and screening and early detection, including allocation of resources for these research areas and using results from these research areas for further development of the NCP.

CCI4EU MM-Theme 04: Discovery & Translational Research

Definition:

Frameworks and quality standards that are needed to support the development of basic, pre-clinical, and clinical research including innovation and real world data, to translate the knowledge/discovery into the clinical environment for the benefit of the patients.

		Level 1	Level 2	Level 3	Level 4
Organisation of core research capacity	Established state-of-the-art research platforms are available and reachable for the whole research community.	DT111 *State-of-the-art research/technical platforms* are planned and concrete initiatives are in the process of implementation. DT112 *Organisational support* is planned and concrete initiatives are in the process of implementation.	DT121 *State-of-the-art research/technical platforms* are available and in use in parts of the CCI. DT122 *Organisational support* is available and in use in parts of the CCI.	DT131 *State-of-the-art research/technical platforms* are available and in use in the whole CCI. DT132 *Organisational support* is available and in use for the whole CCI. DT133 Data on usage of platforms is collected systematically.	DT141 *Quality assurance programs* are in place. DT142 There is an increase in the usage of platforms in a period of 5 years.
	Biobanks are established and accessible to the entire research community within the CCI.	DT113 Initial discussions with potential biobanks for research collaborations in the CCI have taken place.	DT123 Agreements with biobanks for research collaborations are established and accessible within parts of the CCI.	DT134 Biobanks cover most *major tumour types*.	DT143 Biobanks are linked to clinical data. DT144 There are written agreements that biobanks are accessible within the whole CCI. DT145 Biobanks cover all major tumour types.
	Early phase Clinical Trial Units (CTU) are available and accessible within the CCI.	DT114 The minimal required data for early phase clinical trial units is defined.	DT124 The *neccesssary structures* needed for early phase clinical trials are available. DT125 A *first in-human-facility* is planned and concrete initiatives are in the process of implementation.	DT135 Early phase clinical trial studies are open and available within the CCI. DT136 Data on the number of patients included in early phase clinical trial studies is collected systematically. DT137 A *first in-human-facility* is available within parts of the CCI.	DT146 A *first in-human-facility* is available for the whole CCI.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Framework for conducting translational research	There is a robust support framework enabling translational research and implementation of results.	DT211 SOPs for Good Clinical Practice (GCP) are defined. DT212 A *unit or team* is designated as a contact point for general data protection regulations. DT213 Grant support offices are planned and concrete initiatives are in the process of implementation.	DT221 SOPs for Good Clinical Practice (GCP) are implemented in parts of the CCI. DT222 A *unit or team* designated as a contact point for general data protection regulations is available in parts of the CCI. DT223 Grant support offices are available for parts of the CCI.	DT231 SOPs for Good Clinical Practice (GCP) are implemented in the whole CCI. DT232 A *unit or team* designated as a contact point for general data protection regulations is available in the whole CCI. DT233 Grant support offices are available for the whole CCI.	DT241 The *support framework* enabling translational research and implementation of results is regularly reviewed and updated.
	Support for Innovations is available for the entire research community	DT214 Initial discussions and explorations regarding technology transfer in the CCI have taken place.	DT224 A standardised process for the integration of new innovations and technology is established. DT225 Collaborations and agreements of interactions with industry partners are established.	DT234 An operational *Technology Transfer Office (TTO)* is established. DT235 Collaborations and agreements of interactions among academia, industry, and health organisations are established.	DT242 Data on number of patents/*DOFIs* is collected systematically. (If yes then: Indicate the number of patents) DT243 Data on the number of spinoffs/startups is collected systematically.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Collaborations & Networks	Existing partnerships and networks including academia, research institutions, healthcare organisations, industry, and patient advocacy groups.	DT311 Initial networking and communication efforts with academia, industry, healthcare, and advocacy groups have taken place.	DT321 Workshops, conferences, seminars, or symposiums organised with participation from academia, industry, healthcare, and advocacy groups have taken place. DT322 Co-authored publications involving researchers, clinicians, industry experts, or patient advocates have been published.	DT331 Research papers, publications, patents/ DOFIs, and innovative solutions resulting from collaborations across sectors are systematically recorded. DT332 Joint funding applications and grants for interdisciplinary research between different partners are applied for within the CCI.	DT341 There are joint funding applications and secured grants for interdisciplinary research within the CCI.
		Level 1	**Level 2**	**Level 3**	**Level 4**

State-of-the-art research/technical platforms: Available technical platforms and facilities such as omics, imaging, etc.

Organisational support: Available organizational resources (financial and human resources) such as data management, ethical agreements, approval of trials.

Quality assurance programs: The comprehensive system of plans, procedures, instructions, and documentation describing the measures necessary to ensure that quality is planned and obtained.

Major tumour types: Eg. Breast, prostate, lung, and colorectal cancers

Necesssary structures: Clinical facilities, laboratories, pharmacy, clinical trial office, regulatory and ethical framwork including safety, adverse event procedures.

First in-human facility: Could be more than one first in-human facility.

Unit or team: Could be more than one unit or team.

Support framework: Grant office, Ethical & Regulatory framework, patent committee.

Technology Transfer Office (TTO): Unit to manage intellectual property (IP) assets and the transfer of knowledge and technology to industry.

DOFIs: Disclosure of Invention

Education and Training	There is a comprehensive programme of education and training for all translational researchers	DT411 Initial discussions have taken place to define an educational and training programme for researchers within the CCI. DT412 There is an annual programme of seminars, lectures and colloquia for researchers.	DT421 An educational and training programme for researchers is established including the appointment and funding of PhD students. DT422 The annual programme of seminars, lectures and colloquia involve researchers from inside and outside the CCI.	DT431 The education and training agenda for researchers is in operation continuously evaluated and feedback obtained. DT432 There is a system of mentoring for PhD students within the CCI. DT433 The annual programme of seminars, lectures and colloquia involves conferences with international representation.	DT441 The number of PhD students in the CCI has grown over the last 5 years. DT442 The annual programme of seminars, lectures and colloquia involves international representation and is evaluated regularly.

CCI4EU MM-Theme 05: Clinical Research

Definition:

Infrastructures that are needed to support planning and execution of comprehensive Clinical Research including all research fields in oncology.

		Key point	Level 1	Level 2	Level 3	Level 4
Capability platforms	Established state-of-the-art *capability platforms* are available and reachable for the whole research community to support clinical research.	State-of-the-art technical platforms	CR111 State-of-the-art *technical platforms* are planned and concrete initiatives are in the process of implementation.	CR121 State-of-the-art *technical platforms* are available and in use in parts of the CCI. CR122 A quality assurance program for state-of-the-art *technical platforms* is in place in parts of the CCI, ensuring that all processes are consistently reviewed, updated and improved.	CR131 State-of-the-art *technical platforms* are available and in use in the whole CCI. CR132 Data on the usage of platforms is collected systematically.	CR141 State-of-the-art *technical platforms* are available and in use in the whole CCI, including the systematic integration of *novel capabilities* . CR142 A quality assurance program for state-of-the-art *technical platforms* is in place in the whole CCI, ensuring that all processes are consistently reviewed, updated and improved. CR143 There is an increase in the usage of platforms in a period of 5 years.
		Organisational support	CR112 *Organisational support* is planned and concrete initiatives are in the process of implementation.	CR123 *Organisational support* is available and in use within parts of the CCI.	CR133 *Organisational support* is available and in use for the whole CCI.	CR144 A quality framework for organisational support is in place, ensuring that all processes are consistently reviewed, updated and improved.
		Cooperation with primary care			CR134 Cooperation with primary care is planned and concrete initiatives are in the process of implementation.	CR145 Cooperation with primary care is established.
			Level 1	**Level 2**	**Level 3**	**Level 4**
Clinical Trial Office (CTO)	Equal accessibility to CTO (clinical trial office)	Presence of a Clinical Trial Office (CTO)	CR211 A *CTO* is planned and concrete initiatives are in the process of implementation.	CR221 A *CTO* for clinical research is available in parts of the CCI.	CR231 A *CTO* for clinical research is available in the whole CCI. CR232 A comprehensive *quality assurance framework* for clinical trial offices is in place in parts of the CCI, ensuring that all processes are consistently reviewed, updated and improved.	CR241 A comprehensive *quality assurance framework* for CTOs is in place in the whole CCI, ensuring that all processes are consistently reviewed, updated and improved.
		Institutional Review Board			CR233 There is an Institutional Review Board which reviews all proposals to open a new trial within the CCI.	
		Collecting and analysing data		CR222 Data on number and type of clinical trials is accessible to parts of the CCI.	CR234 Data on number and type of clinical trials is accessible to the whole CCI. CR235 *Data on* phase II, III, IV *clinical trials* is collected systematically.	
		Connection to biobanks				CR242 Processes or procedures are in place indicating that biobanks are linked to clinical data.
		Industry and academic clinical trials		CR223 Industry-sponsored clinical trials are available in parts of the CCI.	CR236 Industry-sponsored clinical trials are available in the whole CCI. CR237 Academic-sponsored trials are available in parts of the CCI.	CR243 Academic-sponsored trials are available in the whole CCI.
		Research nurses and dedicated clinical research time	CR212 The CCI has research nurses available but not on a systematic basis.	CR224 The CCI has research nurses available who are trained in clinical research.	CR238There are mechanisms for releasing clinicians' time to conduct clinical trials. CR239 The CCI has research nurses available who are trained in clinical research and who are a team with defined leadership	CR244 Within the CCI there are mechanisms for protected time for clinicians to run clinical trials. CR245 The trained research nurses within the team has increased over the last 5 years.
		% cancer patients enrolled in clinical trials			CR240 At least 5% of cancer patients within the CCI are enrolled in *interventional clinical trials.*	CR246 At least 10% of the cancer patients are enrolled in *interventional clinical trials.*
	Continuous education for all clinical staff members in clinical research	Education for all clinical staff members	CR213 Initial discussions have taken place to establish an educational and training programme for clinical staff members within the CCI.	CR225 Education and training including regulatory aspects of clinical research for all *clinical staff members* is established in parts of the CCI.	CR241 Education and training including regulatory aspects of clinical research for all *clinical staff members* is established in the whole CCI.	CR247 Education and training including regulatory aspects of clinical research for all *clinical staff members* is established and performed regularly in the whole CCI.
			Level 1	**Level 2**	**Level 3**	**Level 4**
Collaboration in national and international Clinical Research Networks	Broad access to clinical research in other CCIs	Collaboration	CR311 Initial discussions have taken place regarding collaboration between CTOs in different CCIs.	CR321 Written agreements on collaboration between CTOs in different CCIs are established.		CR341 Patients have access to clinical trials outside of their CCI.
		% cancer patients enrolled in multicentre trials				
	Active participation in high expert networks aiming to improve clinical research	Establishment of networks	CR312 Initial discussions on organising working groups have taken place.	CR322 Co-authored publications involving different professionals in different parts of a CCI and/or across CCIs have been published. CR323 *Working groups* have been organised on a CCI level.	CR332 Data on the number and impact factor of publications originating from networking activities are collected systematically. CR333 *Working groups* have been organised across different CCIs. CR334 Workshops, conferences, seminars, or symposiums on clinical research have been organised.	CR342 The number of publications from networking activities has increased in a period of 5 years. CR343 *Working groups* have been organised across different European countries.
		Networks of MTB			CR335 An initial knowledge and experience exchange between different molecular tumour boards (MTB) has been performed.	CR344 A network of molecular tumour boards between CCIs and/or across CCIs is established.
			Level 1	**Level 2**	**Level 3**	**Level 4**

Capability platforms: The concept of a capability platform includes elements such as technology, process, people and governance issues and includes enabling core capabilities such as collaboration and leadership.

Technical platforms: Available technical platforms and facilities such equipment for sample preparation, equipment for sample analysis, omics, imaging, AI, drug testing , reporting adverste events and toxicity, etc.

Novel capabilities: Examples of novel capabilities include new techniques, therapies, innovations etc.

Organisational support: Available organizational resources (financial and human resources) such as data management, ethical agreements, approval of trials.

Quality assurance framework: Quality assurance programmes include e.g. quality standards, policies, standard operating procedures (SOPs), quality control measures, roles and responsibilities, continuous improvement strategies, documentation and records, compliance, monitoring, evaluation, management of: data, risk, integrity, facility, training, adverse event reporting, quality assurance audits...

Data on clinical trials: For instance data on the number of active trials/ year, % patients enrolled in clinical studies.

Interventional clinical trials: This can be both academic and industrial trials. Phase I-IV

Clinical staff members: All clinical staff also includes supportive staff/study nurses.

Clinical Trial Office (CTO): The CTO is a central resource for principal investigators, study staff and units to support in developing, implementing, and reporting on all cancer clinical research studies. It could be more than one CTO.

Working groups: Different professionals (e.g. pathologists, radiologists, nursing, ..etc.) and/or management teams

Patient Involvement	Active patient involvement in all clinical research phases	**Training and education**	CR411 Specialised training programs for clinicians and patient representatives are planned.	CR421 Specialised training programs for clinicians and patient representatives are available and in use within parts of the CCI.	CR431 Specialised training programs for clinicians and patient representatives are available and in use within the whole CCI.	
		Advisory board/ active involvement of patient representatives	CR412 A *patient advisory board* is concretely planned.	CR422 A *patient advisory board* is established.	CR432 There is an *active inclusion* of patient representatives in every step of the research planning-, design- and decision-making process for academic studies in parts of the CCI.	CR441 There is an *active inclusion* of patient representatives in every step of the research planning-, design- and decision-making process for academic studies in the whole CCI.

Patient advisory board: patient advisory board could be more than one advisory board, it can also be represetntatives of patient organisations.

Active inclusion: Including dissemination of clinical trial results

CCI4EU MM-Theme 06: Outcomes Research

Definition:

Outcomes research generates knowledge to improve clinical decision-making and sustainable health care delivery to optimize patient outcomes. Outcomes research studies the performance of the structure and processes of health care systems in terms of the health and well-being of patients and populations. It takes into account a wide range of parameters such as mortality, morbidity, quality of life, symptoms, quality of care, risk factors, health economic measures and patients' experiences, preferences, and values.

		Level 1	Level 2	Level 3	Level 4
Engagement and commitment of stakeholders	High awareness among patients and patient organisations to enable discussions with patients about outcomes and outcomes research.	OR111 Initial discussions have taken place on how *patients* and patient organisations can be integrated in outcomes research activities. OR112 Continuous education and training of *professionals* about outcomes research is not yet established in parts of the CCI.	OR121 *Patients* and patient organisations are actively involved in discussions and decision-making processes in outcomes research activities in parts of the CCI. OR122 Continuous education and training of *patients* and patient organisations about outcomes research is established in parts of the CCI. OR123 Continuous education and training of *professionals* about outcomes research is established in parts of the CCI.	OR131 *Patients* and patient organisations are involved in discussions and decision-making processes in outcomes research activities in the whole CCI. OR132 Continuous education and training of *patients* and patient organisations about outcomes research is established in the whole CCI. OR133 Continuous education and training of *professionals* about outcomes research is established in the whole CCI.	OR141 *Patients* and patient organisations actively participate as co-researchers in outcomes research.

Patients: also include vulnerable populations (e.g., low literacy, adolescents, young patients, and the elderly).

Professionals: Healthcare professionals and researchers.

		Level 1	Level 2	Level 3	Level 4
Standardised collection of outcomes data	Collection and analysis of outcomes data is used to improve and ensure equal access to cancer care, research, and education within the CCI.	OR211 Initial discussion on the *collection of outcomes data* for research have taken place.	OR221 Outcomes data is collected and analysed in part of the CCI. OR222 The CCI collects data on mortality. OR223 Initial discussions have taken place on the standardised collection of return to work, sick leave and social participation.	OR231 Outcomes data is collected and analysed in the whole CCI. OR232 The CCI collects data on mortality and PROMS or PREMs. OR233 A standardised collection of return to work, sick leave and social participation is done in parts of the CCI. OR234 Questionnaires and documents are available in the main languages, including the major minorities within a CCI, if applicable.	OR241 The CCI collects data on mortality, PROMs and PREMs. OR242 A standardised collection of return to work, sick leave and social participation is done in the whole CCI. And the collected data is analysed and used for development of care.

Collection of Outcome Data: includes at least Patient reported outcome measures (PROM), Patient reported experience measure (PREM), mortality, health economics, risk factors, and timelines (from symptom-diagnosis-treatments).

		Level 1	Level 2	Level 3	Level 4
National cancer registry	Data for outcomes research are integrated/linked into the national/regional cancer registry	OR311 Initial discussions have taken place on how outcomes research data can be linked to the national/regional cancer registry.	OR321 Outcomes research data is linked to the national/regional cancer registry for mortality.	OR331 Outcomes research data is linked to the national/regional cancer registry for mortality and PROMS or PREMS.	OR341 Outcomes research data is linked to the national/regional cancer registry for mortality and PROMS and PREMS. OR342 Outcomes data is fed into a national/regional cancer registry at least once a year.

Outcomes research data: Patient Reported Outcome Measures (PROMs), Patient Reported Experience Measure (PREMs), mortality, morbidity, health economics, risk factors, and timelines (from symptom-diagnosis-treatments).

		Level 1	Level 2	Level 3	Level 4
Data / ICT	Accessible standardised data and databases for internal and external partners	OR411 First discussions have taken place on the [level of] *digitalisation of outcomes research data.*	OR421 Databases and infrastructure are used for harnessing outcomes research data. This includes, e.g., administrative datatbases, biobanks and their level of interface and interoperability.	OR431 The usage and distribution of outcomes research data is standardised within a CCI. This includes for example using established protocols and management for data extraction.	OR441 The usage and distribution of outcomes research data is harmonised between the different CCIs.

The digitalisation of outcome research data: includes not only data collection but also the extent of use of software, electronic tools to share information, discuss cases, communication with patients, telemedicine, clinical practice and coordination.

CCI4EU MM-Theme 07: Screening and Early Detection

Definition:

Screening and Early Detection Infrastructures for screening and early detection aim to create systems that facilitate and ensure equal access to screening, interventions, and research, particularly targeting high-risk groups. These infrastructures also include initiatives for raising awareness about the importance of early detection and diagnostics.

		Level 1	Level 2	Level 3	Level 4
Organization and Structure	The CCI promotes that data from Screening and Early Detection is linked to the national / regional cancer screening registry	SE111 Initial discussions have taken place for the development of a national/regional cancer screening registry. SE112 Initial discussions have taken place on how screening and early detection data can be linked to the national/regional cancer screening registry.	SE121 The first version of a national/regional cancer screening registry is operational, and the collection of screening and early detection research data has begun. SE122 Screening and early detection data are linked to the national/regional cancer screening registry in parts of the CCI.	SE131 Quality assurance is in place for reporting screening and early detection research data into the national/regional cancer screening registry, ensuring regular data reporting, compliance and evaluation. SE132 Screening and early detection data are linked to the national/regional cancer screening registry in the whole CCI.	SE141 Data from national/regional cancer screening registry is used in screening and early detection research.
	Governance of screening and early detection	SE113 There are national/regional guidelines for screening available. SE114 Initial discussions to identify the unit/team responsible for coordinating *early detection* efforts within the CCI have taken place.	SE123 Defined timelines are in place to ensure actions from screening to intervention. SE124 The unit/team responsible for coordinating *early detection* efforts within the CCI has been identified.	SE133 There are national/regional guidelines for *early detection* available. SE134 The targeted groups of screening programs are invited to participate in screening.	SE142 The responsible unit/team is actively involved in governing and coordinating early detection efforts within the CCI. Its role and responsibilities are periodically reviewed and optimized. SE143 A program for the detection and monitoring of individuals with increased risk of cancer established. SE144 Early detection practices within the CCI are implemented according to the national/regional guidelines, striving to align with EU guidelines.
	Participation and collaborations in national and/or international networks	SE115 Initial discussions to participate in screening and early detection expert networks, have taken place.	SE125 There are agreements and protocols for participation in screening and early detection expert networks in parts of the CCI.	SE135 There are agreements and protocols for participation in screening and early detection expert networks in the whole CCI.	SE145 The CCI is actively shaping and guiding expert network activities, supports involvement in clinical trials, resulting in continuous innovation, driving the development of new models, research, and outcomes.

		Level 1	Level 2	Level 3	Level 4
Research in Screening and Early Detection	There is ongoing research on screening and early detection and implementation of new discoveries within the CCI.	SE211 Initial discussions about funding for research in screening and early detection mechanisms and identification of potential funding have taken place. SE212 The CCI has recognized the potential of *state-of-the-art technologies* for research in screening and early detection but not yet implemented any.	S221 The CCI has secured funding mechanisms for research in screening and early detection. SE222 *State-of-the-art technologies* for research in screening and early detection have been adopted in parts of the CCI.	SE231 Funding mechanisms are sustainable and continuously support research in screening and early detection efforts of the CCI. SE232 *State-of-the-art technologies* for research in screening and early detection are fully integrated into the whole CCI.	SE241 Multiple funding sources, including government, private, and collaborative funding, are established and diversified for research in screening and early detection. SE242 The CCI adopts, develops and contributes to the evaluation of *state-of-the-art technologies* for research in cancer screening and early detection.

		Level 1	Level 2	Level 3	Level 4
ng Programs, Protocols, and Guidelines	Identification of Screening Population	SE311 Various types of population-based screening programs are considered, but they have not yet been implemented (e.g., breast, bowel, cervical).	SE321 Age range-based screening programs have been developed and are being implemented. SE322 One or more types of other/opportunistic screening programs are considered and assessed, but have not yet been implemented (ex.: lung cancer).	SE331 Targeted screening programs have been implemented. The screening population reach is over 70%. SE332 One or more types of other/opportunistic screening programs are implemented in practice or assessed within the CCI (e.g., lung cancer). SE333 *Non-participating individuals* have been identified and strategies to encourage participation are worked on. SE334 Initial cost-effectiveness assessments have been conducted, providing insights into the efficiency of screening programs.	SE341 Over 85% of the population, is consistently reached with screening programs of the CCI. SE342 Targeted screening programs have been implemented for individuals with increased risk of cancer. SE343 Strategies to engage *non-participating individuals* are implemented. SE344 More detailed and regular cost-effectiveness assessments are conducted to identify areas for improvement and resource allocation to enhance the efficiency of screening programs. SE345 The CCI actively collaborates in data analysis of data from the screening population, contributing to research and continuous improvement efforts.

Screening: Screening of healthy population, opportunistic screening, high risk population.

Early detection: Is made of two components - early diagnosis and screening. Early diagnosis focuses on detecting symptomatic patients as early as possible, while screening consists of testing healthy individuals to identify those having cancer before any symptoms appear.

State-of-the-art technologies: Examples of state-of-the-art technologies: Artificial Intelligence (AI), digital pathology, biomarkers, spectropic techniques, liquid biopsies etc.

Non-participating individuals: Involving the vulnerable populations (socio-economic, geographical etc.)

Screeni	Continuous education and training in screening and early detection of professionals, patients, and citizens	SE312 Initial discussions have taken place about educating primary healthcare professionals on early detection. SE313 First information on training programs for professionals related to the identification of high-risk populations was collected. SE314 Initial discussions have taken place about educating patients in screening programs. SE315 Initial discussions have taken place about educating patients in early detection. SE316 Initial discussions about citizens' awareness have taken place.	SE323 Training programs for primary healthcare professionals have been developed and are being implemented to enhance early detection skills. SE324 Formal training programs for professionals focused on the identification of high-risk populations have been established within the CCI. SE325 Education in screening programs for patients are available in parts of the CCI. SE326 Education in early detection for patients is available in parts of the CCI. SE327 Citizens' awareness campaigns are performed in parts of the CCI.	SE335 Regular assessments of training programs in screening and early detection are conducted, and improvements are made based on feedback from professionals. SE336 Education in screening programs for patients is available in the whole CCI. SE337 Education in early detection for patients is available in the whole CCI. SE338 Citizens' awareness campaigns are performed in the whole CCI.	SE346 Training programs are continuously refined and updated to align with the latest guidelines and best practices on screening and early detection. SE347 Patient education is continuously refined and updated to align with the latest advancements in screening programs. SE348 Patient education is continuously refined and updated to align with the latest advancements in early detection.

CCI4EU MM-Theme 08: Patient Pathway

Definition:

Patient pathways should cover the entire pathway from diagnosis to palliative care/long-term survival/survivorship. Based on national health system structures, the tumour-specific patient pathway should be comprehensive and guideline based. They should be assessed e.g. with the help of quality indicators (QIs) and Patient Reported Outcomes (PROs). A patient pathway should help to deliver high-quality care and foster improved access to research by bringing researchers and care providers together. Patient Pathway should improve cooperation and coordination between partners within the tumour-specific networks including the transversal aspects of the tumour-based pathways in the CCI.

According to the JA iPAAC, "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."

The patient pathways are intended to achieve that:

1. quality of care and
2. predictability of the process for patients and caregivers are improved,
3. cost control and
4. patient experiences and engagement are taken into account.

		Level 1	Level 2	Level 3	Level 4
Patient Pathway in Use	For all tumour entities a patient pathway is in use	PP111 Initial discussions regarding the development and usage of shared patient pathways within the CCI have taken place.	PP121 Shared patient pathways are developed at least for the most common tumour entities treated within the CCI and their implementation is prepared.	PP131 Shared patient pathways are actively used for the tumour entities with the highest number of cases treated within the CCI (TOP5).	PP141 Shared patient pathways are actively used for the majority of tumour entities treated within the CCI (min. 90%)*.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Development, Application and Technical Implementation of Patient Pathways	There is an implemented agenda how the used patient pathways in the CCI are developed and updated	PP211 Initial discussions to prepare a process for a systematic development and updating of patient pathways within the CCI have taken place and a responsible coordinating team (*persons and institutions*) have been named.	PP221 Criteria for the evaluation of patient pathways within the CCI including the instruments, *methods and processes* to be used has been defined.	PP231 The process for patient pathway development and updating is actively maintained, controlled and evaluated. PP232 An easily accessible overview of available patient pathways is provided to all partners within the CCI, e.g., via the CCI website.	PP241 A continuous evaluation and improvement process for the patient pathway development and updating process within the CCI is established. PP242 Patient versions of the patient pathways are available for patients within the CCI.
	Data collection points should be indicated in the patient pathways		PP222 A concept for indication of *data collection points* in patient pathways has been drafted.	PP233 *Data collection points* are indicated for some of the patient pathways used within the CCI.	PP243 *Data collection points* and, if possible data fields, are indicated for all patient pathways used within the CCI.
	Patient pathways are embedded in the technical infrastructure of the CCI (MM-WG: = Level 4)		PP223 A (step-by-step) concept for the digital integration of patient pathways within the CCI has been drafted.	PP234 The digital integration of patient pathways within the CCI has been started according to the (step-by-step) concept.	PP244 Patient pathways are embedded in the technical infrastructure of the whole CCI. PP245 [optional] Remote monitoring systems based on digital technology, such as tele-health or tele-monitoring, are fully operational and integrated into the patient pathway.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Structure of the Patient Pathway	Patient pathways are comprehensive (scope of the patient pathway)	PP311 Initial steps discussions to define the scope of the patient pathways within the CCI, the involved institutions, roles and necessary tasks have taken place.	P321 The patient pathways address the tumour-specific multi-professional team (MDT) and describe the roles and tasks of one of the three *specialist groups* (diagnostic, therapeutic and patient-centered care specialists) involved. P322 The patient pathways cover and describe MDT meetings with clearly defined roles, responsibilities, and documentation. P323 Patient pathways clearly outline the various institutions, their interfaces and roles in the patient journey. P324 The patient pathways have a comprehensive scope, addressing all stages from diagnosis to palliative care, long-term survival, and survivorship.	P331 The patient pathways address the tumour-specific multi-professional team (MDT) and describe the roles and tasks of two of the three *specialist groups* (diagnostic, therapeutic and patient-centered care specialists) involved. PP332 (Tumour-specific) highly specialised services (e.g. breast reconstruction) are offered centralized in a CCI, while standard oncological care (e.g. breast conservation therapy) is provided in several tumour-specific networks. PP333 [If applicable] Link to non-clinical institutions, like cancer registries, biobanks, research centres/departments are implemented and described in the patient pathway.	P341 The patient pathways address the tumour-specific multi-professional team (MDT) and describe the roles and tasks of all three *specialist groups* (diagnostic, therapeutic and patient-centered care specialists) involved. P342 The patient pathways cover referral from screening/prevention/survivorship to hospitals/networks and referral back to primary care/ambulatory care/local hospitals and social services. PP343 [optional] Cooperation with other national and/or cross border groups/networks for patients/clinicians are integrated in the patient pathways.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Requirements for Patient Pathways	Patient pathways include tumour-specific characteristics		PP421 Initial discussions to formalise and systematically describe the *tumour-specific needs* in patient pathways within the CCI have taken place.	PP431 The patient pathways contain a reference to the underlying evidence-based guidelines (name, version, recommendation). PP432 The patient pathway contains an algorithm for the identification of hereditary tumour diseases including, if necessary, human genetic examination and counselling (at least for the entities: breast, ovarian, colorectal, renal and paediatric tumour).	PP441 Tumour-specific environmental and lifestyle risks (e.g. asbestos, smoking, obesity, infectious factors) are included in the patient pathway and are addressed in the communication/therapy (e.g. smoking cessation, vaccination). PP442 Specialised disciplines or questions that are tumour/therapy-specific are addressed in the patient pathway with the aim to prevent long-term effects (i.e. cardiologists for Herceptin-therapy, or information about and application of fertility-preserving measures, specific topics for adolescents and young adults (AYA)).
	Patient pathways support the enrolment of patients in studies and encourage the conduct of studies			PP433 The patient pathway includes obtaining informed consent and screening for possible study inclusion.	
	Patient pathways include the patient perspective		PP422 Initial discussions regarding the incorporation of the *patient perspective* in pathway development have taken place.	PP434 The *patient perspective* is included in the patient pathways.	PP443 A continuous evaluation and improvement process for the integration of the *patient perspective* in the patient pathway is established.

* Using ICD-10 codes as basis.

Persons and institutions: These could be for example representatives from the participating CCCNs.

M**ethods and processes:** E.g., Quality indicators, interviews/questionnaires with the partners of the tumour-specific network or discussion in the coordination board meetings (see Theme 1).

Data collection points: These should include the data needed for the QI collection and needed by the cancer registries and, if possible, study data collected along the patient pathway. For possible representation of collection points along the pathway see e.g. iPAAC patient pathway templates.

Specialist groups:
I) Diagnostic specialist disciplines: pathology, radiology, nuclear medicine, and molecular diagnostics (including bioinformatics)
II) Therapeutic specialist disciplines: surgery, endoscopic therapy, radiotherapy, interventional radiology, systemic therapies (including personalized therapy)
III) Patient-centred care: palliative and supportive care including psycho-oncology, social service, rehabilitation/sports and physical activity counselling, nursing, nutritional counselling, pain management, patient engagement initiatives, patient organisations and support groups

Tumour-specific needs: Underlying evidence-based guideline, algorithm for genetic risk identification, environmental (occupational, infectious factors) and lifestyle risks control, prevention of long-term side effects.

Patient perspective: For example, the collection and use of PROs, the involvement of patient representatives, the concepts of patient-centred care, shared decision-making, care-customization, and identifying key patient needs and concerns.

	Patient pathways include minimum technical, personnel and structural resources		PP423 Initial discussions regarding the inclusion of requirements for sufficient staff and adequate equipment have taken place.	PP435 The process for the inclusion of *requirements* for minimum technical, personnel and structural resources has been started (for example addressed in associated documents).	PP444 The inclusion of requirements for minimum technical, personnel and structural resources is implemented for all patient pathways used in the CCI.
		Level 1	**Level 2**	**Level 3**	**Level 4**
Evaluation	A regular evaluation of the patient pathways takes place		PP521 *Criteria* for the evaluation of patient pathways within the CCI, including the instruments, *methods and processes* to be used, have been defined. PP522 *Quality indicators* are defined for the evaluation.	PP531 A patient pathway evaluation concept is in use and first evaluation results are available.	PP541 The results of the evaluation are used for the updating process of the patient pathways within the CCI.

Requirements: E.g., based on known requirement catalogues such as certification criteria from the Joint Actions iPAAC and CraNE, ECIBC, Essential Requirements ECO, ECC and other national guidelines (if available).

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Introduction

Goal of the Data Overview Document

The Data Overview Document, serves the purpose of gathering quantitative data from each potential Comprehensive Cancer Infrastructure (CCIs). This could be for example number of tumour entities treated and/or number of clinical trials.

Reasons for the need of this document and for collecting the outlined information are twofold:
- Assessing the scope and comprehensiveness of potential CCIs requires both qualitative and quantitative data related to cancer care and research.
- Comparing potential CCIs requires standardized information and data collection. The indicated figures in the Data Overview Document will also be used to calculate the proposed Quality Indicators (QIs) for the respective themes.

Structure of the Data Overview Document

The Data Overview Document comprises four Excel Tabs:
- Overview CCI total": Provides an overview of participating entities and their focus within the CCI.
- Cancer Care": Provides an overview of tumour entities, infrastructure, and related processes for cancer care.
- Cancer Research": Provides an overview of tumour entities, infrastructure, and processes relevant to cancer research.
- Quality Indicators": Provides an overview of eight QIs for theme 1 „Structure of the CCI", theme 4 „Discovery and Translational Research", theme 5 „Clinical Research", theme 6 "Outcomes Research", theme 8 „Patient Pathway"

What has to be done

Potential CCIs are asked to complete each of the four Excel Tabs (see above), if applicable.
The fields with a grey background within the four different excel tabs are the ones that have to be filled.

If this document was sent to individual institutions, please fill it in and send it completed to the coordinator of your region/country for CCI4EU.

Afterwards the filled-in document will be integrated into the Maturity Model Webtool to assess the scope and comprehensiveness of potential CCIs.
If you have any questions, please do not to hesitate to get in touch with us: cci4eusurvey@cci4eu.eu

Yours faithfully,

Your CCI4EU-Team

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Overview Comprehensive Cancer Infrastructure

Name of the participating entity within the CCI*	Cancer Research	Cancer Research Focus	Cancer Care	Other (e.g. education and/or training)
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		

		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		
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		☐ Theme 4: "Discovery and Translational Research" ☐ Theme 5: "Clinical Research" ☐ Theme 6: "Outcomes Research" ☐ Theme 7: "Screening and Early Detection"		

*** In case you cannot fill in the list of participating entity:**

What is the current status in terms of collaboration on Cancer Care and Cancer Research in your region?

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Overview Cancer Research Data Sheet

Infrastructure	Accessible in the CCI: (Information applies to whole CCI (= all participating entities))														
Research Groups	Tumour entities represented by research groups within the CCI	**Breast**	**Gynaecology**	**Colorectal + Anal**	**Pancreas**	**Gastric + Esophageal**	**Liver**	**Haematological**	**Skin**	**Neuro-oncological**	**Sarcoma**	**Head and Neck**	**Paediatric**	**Lung**	**Prostate**
	Research category represented within the CCI	**Basic / Preclinical**	**Clinical Phase I /II**	**Clinical late Phase**	**Outcomes research**	**Screening & Early detection**									
	Number of publications														
	Number of publications with Impact factor >10														
Research support	Animal facilities accessible within the CCI														
	Omics center/s open for whole CCI (Core facility)														
	Whole-genome/ NGS sequencers														
	Mass spectrometers														
	Bioinformatics resource (infratstructure and personel)														
	Local Ethical board/s														
	Biobanks within the CCI														
	Legal support office/s														
	Technology Transfer Office/s														
	Grants Office/s														
	Number of Grants, public/ governmental														
	Number of Grants, Industry														
	Number of Grants, private/ foundations														
	Early drug developement Unit														
Clinical Trial Units (CTUs)	Clinical Trial Units														
	First in Human Units														
	Number of clinical studies, Early Phase - ongoing & recruiting														
	Number of patients in Clinical studies, Early Phase trials														
	Number of clinical studies,Phase II/III - ongoing & recruiting														
	Number of clinical studies, Phase IV - ongoing & recruiting														
	Number of academic studies - ongoing & recruiting														
	Number of industry sponsored studies - ongoing & recruiting														

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Overview Cancer Care Data Sheet

Data recorded		Tumorspecific networks (ICD-10)														
		Total	**Breast** C50, D05.1/7/9	**Gynaecology** C51.-;C52;C53.-; C54.-; C55; C56; C57.-; D39.1;C48	**Colorectal + Anal** C18; C20; C21.1; C44.50	**Pancreas** C25	**Gastric + Esophageal** C15.2; C15.5; C16; C15; C16.0; D00.1	**Liver** C22.0; C22.1;C23	**Haematological** C91.0-; C92.0-; C93.0-; C94.0-; C95.0-; C81.-; C82.-; C83.-; C84.-; C85.-; C86.-; C88.-; D45; D46.-; D47.1; D47.3; D47.4; D47.5; C96.-; D47.7; D47.	**Skin** C43; C44	**Neuro-oncological** C47, C70, C71, C72, C75.1, C75.2, C75.3, D32, D33, D35.2,D35.3, D35.4	**Sarcoma**	**Head and Neck** C00; C01; C03; C04; C05; C06; C07; C08; C09; C10; C11; C12; C13; C14; C30; C31; C32; D00.0; D02.0; D02.3	**Paediatric** C00.-; C02.-; C03.-; C04.-; C05.-; C06.-; C07; C08.-; C09.-; C10.-; C11.-; C12; C13.-; C14.-; C15.-; C16.-; C17.-; C18.-; C19; C20; C21.-; C22.-; C23; C24.-; C25.-; C26.-; C30.-; C31.-; C32.-; C33; C34.-; C37; C38.-; C39.-; C40.-; C41.-; C43.-; C44.-; C45.-; C46.-; C47.-; C48.-; C49.-; C50.-; C51.-; C52; C53.-; C54.-; C55; C56; C57.-; C58; C60.-; C61; C62.-; C63.-; C64; C65; C66; C67.-; C68.-; C69.-; C70.-; C71.-; C72.-; C73; C74.-; C75.-; C76.-; C77.-;C78.-; C79.-; C80.-; C81.-; C82.-; C83.-; C84.-; C85.-; C86.-; C88.-; C90.-; C91.-; C92.-; C93.-; C94.-; C95.-; C96.-; D30.0; D32.-; D33.-; D35.2; D35.3; D35.4; D37.-; D38.-; D39.-; D40.-; D41.-; D42.-; D43.-; D44.-; D45; D46.-; D47.-; D48.-; D61.0; D61.3; D61.9; D70.0; D76.1; M72.4	**Lung** C34; C78.0	**Prostate** C61
No of newly diagnosed* cancer cases ***Newly diagnosed = First diagnosis of the resp tumour (including M1 at first diagnosis), pt. counted only once**																
	CCI all participating entities	*0*														

Infrastructure	**Accessible in the CCI:** (Information applies to whole CCI (= all participating entities))	
Radiotherapy	Number of megavoltage linear accelerators	
	Therapy planning (3D and IMRT), virtual simulation or therapy simulator	
	Planning CT	
	Brachytherapy	
Radiology/ Nuclear medicine	Number of CT	
	Number of MRT	
	Number of PET/PET-CT	
	Interventional radiology (Transarterial chemoembolisation (TACE)/TAE, Percutaneous ablation)	
Palliative Care	Palliative care ward	
	Hospice	
	Palliative Care Team (ambulantory/ outpatient)	
Procedure	**Accessible in the CCI:** (Information applies to whole CCI (= all participating entites))	
Radiotherapy	3D-conformal radiotherapy	
	IMRT/VMAT or comparable procedure	
	Radiotherapy with respiratory management	
	Image-guided radiotherapy (IGRT)	
	Stereotaxy of cerebral tumours	
	Palliative radiotherapy	
Systemic therapy	Antibody therapy, Immunotherapy, chemotherapy	
	CAR-T cell therapy	
	Autologous stem cell transplantation	
	Allogeneic stem cell transplantation	
Pathology	Immunohistochemistry	
	In situ hybridisation	
	Molecular pathology	
	NGS diagnostics	
	Accredited molecular pathology (DIN EN ISO17020)	

Example Breast Cancer:
How should the cases treated in the respective CCI be indicated in the "Cancer Care" Data Sheet?
A) 2 participating entities within the CCI working independently of each other: Hospital A and CCC each indicate their cases individually in the "Cancer Care" Data sheet.
B) 1 participating entity within the CCI consisting of (at least) the two example hospitals (A, CCC): only the field "No of newly diagnosed cancer cases" is filled in

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Overview Quality Indictaors

Data recorded*

Themes	IN	Quality Indictaor Defintion and objective	Numerator	Denominator	Target	Target value		Comments	Example/Explanation
Theme 1 "Structure of the CCI"	1	As many inciden cases as possible in the region are treated within the CCI	Incident cases of the denominator that are treated in the CCI	Number of incident cases in the region covered by the CCI (data provided by the official clinical cancer registry)	90%	Numerator	0		The region has an incidence of 3,000 new cases per year (according to the cancer registry). Within the CCI, 1000 new cases are treated (= 33%). Incident cases CCI = First diagnosis of the resp tumour (including M1 at first diagnosis), pt. counted only once within the CCI and once in the resp year
						Denominator			
						%			
	2	As many tumour entities as possible are treated within the CCI	Tumour entities (not cases!) of the denominator that are treated in the CCI	Number of tumour entities (not cases!) recorded in the regional cancer registry of the Member State	90%	Numerator			Denominator: A list of tumour entities that are recorded in the regional clinical cancer registry of the Member State with at least 1 incident case in the year under consideration. Numerator: treated in the CCI = at least 1 case of the resp tumour entity is documented in the HIS
						Denominator			
						%			
	3	Adequate number of institutions involved in the CCI	Number of independent participating entities of the denominator included in the scope of the CCI (see criterion "Scope of the CCI")	Number of independent entities in research, education, care in the catchment area of the CCI	Min 3	Numerator	0		
						Denominator			
						%			
Theme 4 "Discovery and Translational Research"	4	As many patients as possible are screened for an early phase/phase I clinical trial	Incident cases of the denominator who have been screened for an early phase/phase I clinical trial	Number of incident cases that are treated in the CCI	No target value	Numerator			
						Denominator	0		
						%			
Theme 5 "Clinical Research"	5	As many as possible Phase I clinical trials within the CCI	Number of Phase I clinical trials - ongoing & recruiting	Total number of ongoing clincial trials* within the CCI (see example)	No target value	Numerator			*Clinical trials, Phase I - ongoing & recruiting Clinical trials,Phase II/III - ongoing & recruiting Clinical trials, Phase IV - ongoing & recruiting - "ongoing" = still recruting Pt
						Denominator			
						%			
	6	As many patients as possible are enrolled in clinical trials	Incident cases of the denominator enrolled in clinical trials	Number of incident cases that are treated in the CCI	≥10%	Numerator			
						Denominator	0		
						%			
Theme 6 "Outcomes Research"	7	Clincal trials/studies within a CCI which adress patient reported outcome measures	Clinical trials of the denominator which adressed PRO/PREMS	Total number of ongoing clinical trials* within the CCI	No target value	Numerator			*Clinical trials, Phase I - ongoing & recruiting Clinical trials,Phase II/III - ongoing & recruiting Clinical trialss, Phase IV - ongoing & recruiting - "ongoing" = still recruting Pt Definition "clinical trial" = Actively recruiting trials of Phase 1- Phase IV
						Denominator	0		
						%			
Theme 8 "Patient Pathway"	8	A patient pathway is in use for as many tumour entities as possible that are treated at the CCI	Tumour enitites of the denominator with implemented PP	Number of treated tumour entities in the CCI (= Numerator QI 2)	No target value	Numerator			PP = according to the definition in Theme 8 "Patient Pathway"
						Denominator	0		
						%			

* General requirement for the Quality Indictaor:
The numerator is a subgroup of the denominator
The results are reported for 1 calendar year