Milestone 26
Pilots' guidelines for the European Comprehensive Cancer Centers

WP4 – Sustainability

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Project information

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Coordinator: INCa

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1.0	19/02/2025	Initial version

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Abbreviations and acronyms

AE: Affiliated Entities

CA: Competent Authority

CCC: Comprehensive Cancer Centre

COO: Coordination (WP1)

DKG: Deutsche Krebsgesellschaft

EBCP: European Beating Cancer Plan

EC: European Commission

EU: European Union

GA: Grant Agreement

HaDEA: European Health and Digital Executive Agency (funding agency)

INCa: Institute National du Cancer

JA: Joint Action

KOM: Kick-off Meeting

KPIs: Key Performance Indicators

MDT: Multidisciplinary Team

NIJZ: Nacionalni Institut Za Javno Zdravje

NSG(s): National Support Groups

OECI: Organization of European Cancer Institutes

WP4: Work Package 4

Glossary

CCC Pilot sites (or pilots) – Hospitals/Universities/other institutions, including both OECI or DKH established CCCs and non-certified institutes, centers, or consortia. These sites test different configurations within the EUnetCCC JA (WP4) to develop CCC-compliant structures, adapting to local needs, building governance frameworks, and assessing their maturity levels.

Competent Authority (CA) – partner of the JA representing Member State. Nominated by their ministry of health.

Affiliated Entity (AE) – a partner to the project with official links with their CA. Nominated by their ministry of health.

Summary notes

<u>Objectives of the milestone</u>

- The document provides comprehensive guidelines for the pilot phase, offering a clear understanding of WP4 milestones, deliverables, working structure, and the expectations for pilots within the EUnetCCC project. It covers aspects such as communication between WP4, pilots, and partners, as well as templates for the pilots, etc.
- It functions as a reference document for best practices and operational procedures for all participating pilots.

Format
What will the deliverable look like?

- PDF document

Target audience
Who will read/use the deliverable?

- Work Package leaders and co-leaders,
- National Competent Authorities,
- Affiliated Entities,
- All partners involved in the pilot phase.

Content of the guidelines
What will the guidelines include (parts, themes, functionalities)?

- Introduction and objectives,
- Objectives and Scope of the WP4 and the Pilots,
- Roles and Responsibilities,
- Expected Activities and Deliverables,
- Timeline,
- Financial and Reporting Flow.

What will not be included in the guidelines?

- Detailed presentation of all the WP4 objectives and milestones (*see the Grant Agreement*),
- Detailed description of all the Tasks (*see the Grant Agreement*).

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Introduction and objectives of the guidelines

The implementation of a sustainable European network of Comprehensive Cancer Centers (CCC) is a cornerstone of the EUnetCCC project. These guidelines aim to provide a clear and structured framework for the pilots engaged in Work Package 4 (WP4), while allowing for adaptation to diverse national and regional contexts.

The guidelines are designed to ensure effective coordination among participating institutions, promote the exchange of best practices, and enhance the sustainability of CCC configurations. By supporting cross-border collaboration, these guidelines contribute directly to EUnetCCC's overarching goal: to improve quality of cancer care through improved patient pathways as well as enhanced oncology research and improved education and training of professionals in cancer care across Europe, in alignment with strategic initiatives such as the European Beating Cancer Plan and Digital Europe.

The approach outlined in these guidelines is built on three key pillars:

1. **Clarity and guidance**: Clearly define expectations and critical milestones for the pilots to ensure smooth progress.
2. **Contextual flexibility**: Allow pilot configurations to adapt to specific local, national, and transnational conditions.
3. **Strategic alignment**: Ensure coherence with European objectives while leveraging pilot outcomes to inform future health policies.

These guidelines will provide concrete tools, standardized templates, and support mechanisms to assist pilots throughout their journey. By following these recommendations, each pilot will contribute not only to local success but also to the development of an integrated European network that meets the highest standards in cancer care, research, and innovation.

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Objectives and scope of the WP4

WP4 is dedicated to advancing the sustainability and integration of Comprehensive Cancer Center (CCC) configurations across Europe. It aims to establish a robust framework that ensures the long-term viability and effectiveness of the CCC network beyond the duration of the EUnetCCC Joint Action.

The primary objectives of WP4 are as follows:

1. **Develop a sustainability roadmap**: Create a strategic plan informed by pilot studies and use cases to outline clear pathways for sustaining CCC networks across diverse contexts (Deliverable D4.1, 2027).
2. **Produce a comprehensive sustainability report**: Consolidate pilot outcomes, conclusions, and policy recommendations into a detailed report that will guide future European cancer care initiatives (Deliverable D4.3, 2028).
3. **Foster European synergies**: Strengthen connections with major EU health initiatives, including the European Beating Cancer Plan (EBCP) and Digital Europe, to ensure the alignment of local implementation with broader European objectives.
4. **Support pilot implementation**: Facilitate testing of various CCC configurations to evaluate their adaptability and effectiveness in different national and regional contexts (Deliverable D4.2, 2028).

To achieve these objectives, WP4 will:
- **Adapt to local and regional needs**: Tailor pilot configurations to address the unique challenges and opportunities of individual countries, regions, and institutions. This includes working with single institutions, regional clusters, or national and transnational networks.
- **Build governance structures**: Support the development of governance frameworks that are scalable and compliant with CCC certification standards.
- **Evaluate maturity levels**: Assess the readiness of participating institutions, from those already certified by recognized organizations (e.g., OECI, DKH) to those developing their CCC capabilities from scratch and those who will develop CCC-compliant structures.
- **Collaborate with Work Package 5 (WP5) on certification**: Ensure alignment between pilot activities and the CCC certification process, facilitating the refinement of certification standards based on real-world pilot experiences.

- **Collaborate with Work Package 6 (WP6) on capacity building**: WP6 will support pilots in achieving certification through tailored capacity-building plans based on their maturity levels. Feedback from WP4 pilots will help WP6 refine its maturity model and framework, ensuring alignment with real-world challenges and needs.
- **Collaborate with Work Package 8 (WP8) on standards**: WP8 will support pilots in applying standards and ensure the viability and sustainability of the structures in the case of newly developed CCCs and CCC-compliant structures.

By focusing on sustainability, adaptability, and alignment with European priorities, WP4 will provide a foundation for the continuous evolution and impact of CCCs across Europe, contributing to improved patient outcomes and integrated cancer care.

As part of WP4, pilots are expected to test the feasibility and robustness of different configurations while establishing appropriate governance structures for their chosen configurations.

In preparation for the certification process being developed by WP5, pilots will also collaborate closely with the WP5 and WP6 teams. This collaboration will ensure that the certification scheme is adapted to the unique characteristics of each configuration. When WP5 launches the "real-life" testing phase, **some voluntary pilots (ideally representing at least one of each of the proposed typologies)** will play a critical role in refining and validating the certification process for the EUnetCCC framework.

Additionally, each pilot will write a report outlining their experiences, challenges, success assessments, and recommendations. These reports will be consolidated for WP4 deliverables in month 46 (July 2028) and used to inform policy recommendations. Through these efforts, all pilots will actively contribute to the development and strengthening of the EUnetCCC network.

Objectives and scope of the pilots

Types of pilot configurations

In the context of WP4, pilots are designed to test the feasibility, adaptability, and robustness of Comprehensive Cancer Center (CCC) configurations across various contexts.

These **configurations reflect institutional and collaborative approaches** observed internationally. International cooperation and integration into networks are transversal elements that apply to all configurations, addressing specific gaps and adapting to the needs and goals of each pilot.

Therefore, pilots can either work towards becoming a:

- **Institutional CCC**: a single institution integrating care, research, training, and prevention, operating autonomously while actively collaborating with its local ecosystem and broader networks.
- **Consortium-based CCC**: a collaborative structure involving multiple institutions (hospitals, research centers, universities) operating at local, regional (or inter-regional), national, or international levels. A particular solution for this subtype will be adapted to the specific situation and needs of the small member states.

Maturity levels of participating institutions

Maturity levels reflect the development stage of each CCC pilot within the EUnetCCC framework, comparable to a strategic plan for achieving certification. Two main maturity levels are identified

- **Institutions certified or in-process of certification (or re-certification):** These are institutions already certified by recognized organizations (e.g., OECI, DKH) or currently undergoing certification or re-certification.
- **Non-certified institutions:** These institutions have not yet pursued the above-mentioned certification but aim to meet EUnetCCC standards.

Existing institutional cancer centers, including those already certified by recognized organizations, are free to join pilots aiming to establish consortium-based CCC within the EUnetCCC. This flexibility allows diverse configurations, fostering collaboration and enabling the network to adapt to various institutional and national contexts.

<u>Objectives across all configurations</u>

The objectives of the pilots are aligned with the EUnetCCC framework and informed by the <u>D7.2 reference framework of CraNE</u> which defines a CCC as an integrated entity combining care, research, education, and innovation to improve outcomes for patients and society.

These objectives include:

1. **Integration of functions**
   - Ensure the seamless integration of patient care, clinical and translational research, training, and prevention within the pilot configuration.
   - Align all activities with the overarching goals of improving patient outcomes and fostering innovation in oncology.
2. **Coordination and cooperation**
   - Develop and enhance governance structures that facilitate effective coordination and cooperation across local, regional, and international levels.
   - Foster collaboration across multidisciplinary teams (MDTs - healthcare providers, researchers, educators...) through regular meetings, shared resources, and joint initiatives.
3. **Capacity building**
   - Enhance institutional capacity to meet CCC standards through targeted training and implementation of improvement plans.
   - Enhance the skills and expertise of staff through training programs and collaborative initiatives.
4. **Harmonization and standardization:**
   - Ensure the harmonization of practices across pilot configurations, contributing to the standardization of CCC criteria and processes.
   - Facilitate knowledge exchange and the adoption of best practices through participation in European and international networks.
5. **Patient-centered innovation**
   - Place patient needs and outcomes at the core of pilot activities, ensuring access to innovative treatments and clinical trials.
   - Develop strategies to integrate patient feedback into governance and operational frameworks.
   - Involve national or institutional patient advisory committees in the assessment of the pilots

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6. **Impact measurement**
   - Establish KPIs to evaluate the impact of pilot activities on patient care, research outcomes, and capacity building.
   - Use these insights to refine policies and recommendations for broader adoption within the EUnetCCC network.

7. **Collaboration beyond borders**
   - Strengthen cross-border collaboration by establishing joint projects and sharing resources between local and international partners.
   - Leverage international expertise to address specific gaps and enhance the overall efficacy of the CCC network.

Objectives specific to each configuration

Pilot configuration / Maturity level	Institutional CCC	Consortium-based CCC
Institutions certified or in-process of certification or re-certification	- Maintain existing quality standards. - Regularly communicate lessons learned through reports, meetings, and joint workshops to support non-certified institutions. - Support capacity-building for non-certified institutions: offer mentorship or resources to help non-certified institutions progress toward certification. - Test the interoperability of existing certification with the EUnetCCC certification framework (in collaboration with WP4 and WP5 leaders). - Align existing criteria and standards (when needed) with EUnetCCC certification requirements.	- Maintain existing quality standards. - Share multi-institutional best practices: contribute lessons learned from the consortium-based certification process to improve the network and inform future certifications. - Test the interoperability of existing certification with the EUnetCCC certification framework. - Align existing criteria and standards (when needed) with EUnetCCC certification requirements. - Collaborate across institutions to pool resources, knowledge, and expertise to maximize impact and efficiency. - Ensure consistency across consortium members: maintain alignment with EUnetCCC standards across all institutions within the consortium, ensuring uniformity in practices and quality of care and research. - Test configurations as a joint pilot by developing a governance structure that connects multiple institutions across regions, the entire country or countries, addressing resource limitations. - Strengthen the capacities of affiliated hospitals through knowledge and technology transfer. - Facilitate access to clinical trials and specialized care in underserved regions.

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Pilot configuration / Maturity level	Institutional CCC	Consortium-based CCC
		- Foster collaboration between institutions at different levels (vertical and horizontal) to ensure efficient decision-making and resource allocation.
Institutions not certified	- Conduct a comprehensive audit of practices, resources, and gaps to identify areas that need improvement to meet EUnetCCC standards. -Develop and implement improvement plans: create an actionable roadmap with clear milestones to align the institution's capabilities with EUnetCCC standards. - Establish necessary governance model: define leadership roles, accountability structures, and operational processes necessary for certification readiness. - Provide targeted training and capacity-building activities to staff, ensuring the necessary skills to meet EUnetCCC standards. - Monitor progress towards certification: regularly evaluate and report on progress in addressing identified gaps and meeting certification criteria. - Leverage shared experiences: participate in knowledge exchange activities (workshops, forums) with other institutions to learn from successful certification journeys.	- Conduct a collaborative assessment of practices, resources, and gaps within each institution to identify alignment with EUnetCCC certification standards. - Collaborate across institutions to pool resources, knowledge, and expertise to maximize impact and efficiency. - Ensure consistency across consortium members: maintain alignment with EUnetCCC standards across all institutions within the consortium, ensuring uniformity in practices and quality of care and research. - Formulate a collaborative governance model: develop a clear governance structure involving multiple institutions, ensuring alignment with EUnetCCC requirements. - Strengthen the capacities of affiliated hospitals through knowledge and technology transfer. - Facilitate access to clinical trials and specialized care in underserved regions. - Foster collaboration between institutions at different levels (vertical and horizontal) to ensure efficient decision-making and resource allocation.

Table 1: Objectives specific to each configuration

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Roles and responsibilities

WP4 Leaders

WP4 leaders play a critical role in guiding and supporting pilots to ensure the sustainability of the European CCC network. Their responsibilities include:

1. **Fostering collaboration:** Organizing European-wide meetings and interactive platforms to share experiences and best practices.
2. **Providing tailored guidance:** Conducting individual meetings with country representatives to address specific needs and ensure alignment with WP4 objectives.
3. **Promoting documentation:** Encouraging the recording and dissemination of lessons learned and successful strategies to enhance collective capacity.

WP4 leaders also oversee the systematic rollout of pilot projects, addressing challenges proactively and ensuring outcomes contribute to a robust CCC network.

National Competent Authorities

National Competent Authorities act as key intermediaries between pilots and WP4 leaders.

Their role includes:

1. **Supporting pilots through:** Offering guidance during development and certification processes based on WP4 input.
2. **Coordinating efforts:** Establishing *National Support Group (NSG)* with diverse stakeholders to align pilot activities with national and EUnetCCC objectives.
3. **Reporting progress:** Collecting updates on pilot status and challenges to inform WP4 leaders.
4. **Preparation of the appropriate legal settings** (when necessary)**:** All relevant national authorities must establish formal written agreements with their stakeholders.

Pilot teams

Pilot teams, consisting of clinicians, researchers, and staff, are essential for the success of WP4.

Their responsibilities include:

- **Implementing pilots:** Designing, executing, and evaluating pilots aligned with CCC certification criteria.
- **Communicating effectively:** Participating in regular WP4 meetings and maintaining open communication with national and European stakeholders.
- **Documenting progress:** Submitting regular reports detailing activities, challenges, and solutions to support evaluation and certification refinement.

Pilot teams are also encouraged to collaborate within their networks, share resources, and participate in capacity-building activities to strengthen the broader EUnetCCC framework.

Expected activities and deliverables

Each pilot is required to submit a detailed report that:
- Outlines experiences based on configuration and maturity level.
- Highlights obstacles and challenges encountered.
- Provides a final assessment of success, including conclusions and recommendations for future CCCs.
- Evaluates the ability to address local needs and integrate into broader networks.

These reports will be consolidated into WP4 deliverables by month 46 (July 2028) and translated into policy recommendations to guide the development of future CCCs. Targeted support will be offered to ensure compliance and alignment with broader EUnetCCC objectives.

Core activities for each pilot

1. Establishing governance structures

Defining roles and responsibilities: Allocate key roles within the governance structure, including governance bodies, leadership, project management, and oversight committees.

Developing policies and procedures: Create or adapt institutional policies and guidelines to meet CCC standards.

Regrouping multiple institutions: Coordinate the integration of institutions (e.g., hospitals, research centers) under a unified governance structure, ensuring streamlined communication, collaboration, and alignment with CCC objectives.

2. Preparing for the certification process

Understanding certification criteria: Ensure all pilot teams are familiar with CCC certification requirements.

Gap analysis and process improvements: Identify gaps and implement necessary improvements to meet certification standards, including revising workflows and adopting new technologies.

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Collaborating with WP5: Provide feedback to WP5 to adapt certification processes to the specific needs of each pilot configuration.

Documentation and record keeping: Prepare necessary certification documentation *(please note that the list of recorded documents will be set up by the WP5 and communicate as soon as possible).*

By systematically addressing these core activities, pilots will be better equipped to meet CCC standards, address local needs, and contribute to the broader goals of the EUnetCCC framework.

Day-to-day activities and monitoring will be organized by the Competent Authority and other participating institutions (Affiliated Entities) of the pilot site/s.

WP4 will organize preliminary meetings with the pilot sites, that will be scheduled from late February to early April 2025. These will primarily be in-person, with some initial online meetings. The goal is to hold at least one in-person meeting with each pilot site or national team by the end of the pilot phase.

Each pilot will be monitored and supported by one of the two WP4 team members from NIJZ – Dr Jelena Isailović *(e-mail: jelena.isailovic@nijz.si)* and Dr Tija Hubej *(e-mail: tija.hubej@nijz.si)* - distribution to be circulated together with an introduction letter to all pilot sites after the KOM.

Distribution of Countries Included in the First Wave

Coordinated by	Tija Hubej tija.hubej@nijz.si	Jelena Isailović jelena.isailovic@nijz.si
	Lithuania	France
	Ireland	Norway
	Poland	Spain
	Romania	Luxembourg
	Greece	Slovenia
	Belgium	Sweden
	Denmark	Latvia
	Cyprus	Bulgaria

Table 2: Distribution of Countries Included in the First Wave

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Monitoring will be conducted partly through a combination of bi-weekly online meetings with pilot site teams and partly through semi-structured reports (template provided in the Appendix). Written reports are expected monthly from pilot sites by the 5th of the month for the previous month.

Competent Authorities are expected to organize National Support Groups (NSGs) in order to discuss open issues and progress on pilot sites when national (of regional) action is needed, whether legal, financial, managerial or with other types of resources and support.

Expected deliverables and outcomes:

The pilots within WP4 are designed to test and refine the processes for certifying CCCs across various configurations and contexts. To ensure transparency, track progress, and achieve tangible results, several key deliverables and outcomes are expected from each pilot. These deliverables will guide participants and ensure alignment with the broader objectives of the EUnetCCC network.

Key deliverables are as follow:

1. **CCC Pilot Progress Report:**

Purpose: Provide detailed updates on activities, challenges faced, solutions implemented, and progress toward meeting CCC certification criteria.

Submission: Reports will be submitted to both national representatives and WP4 leaders.

Role in assessment: These reports will be integral to evaluating the ongoing success and readiness of each pilot for certification.

Template availability: A standardized template for periodic reports will be provided to pilot teams before the start of reporting cycles to ensure consistency and comprehensiveness. This template for periodic reports will be made available not only to the national competent authorities and pilot teams but also on SharePoint in the "CCC PILOTS" folder, as explained in section "Resources and support documents from WP4 leaders", on page 27.as explained in section "Resources and support documents from WP4 leaders", on page 27.

Each national competent authority will be responsible for updating and submitting CCC pilot progress report to SharePoint for the respective pilot country, in the "CCC PILOTS"

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folder, within the folder corresponding to their country. Alternatively, the reports may be submitted to one of the two designated WP4 pilot team members responsible for each country., within the folder corresponding to their country. Alternatively, the reports may be submitted to one of the two designated WP4 pilot team members responsible for each country.

2. **EUnetCCC pilot's outcome (final CCC pilot report):**

Content: Comprehensive documentation of the pilot experience, including:
   a. Configuration-specific insights.
   b. Challenges and solutions.
   c. Final assessment of success.
   d. Recommendations for future CCCs.

Timeline: All final reports will be consolidated into WP4 deliverables by month 46 (July 2028).

Outcome: The consolidated report will inform policy recommendations and refine CCC certification standards.

Template availability: A standardized template for EUnetCCC pilot's outcome report will be provided to pilot teams at the end of each pilot wave. WP4 leaders will oversee compiling all reports into a final one to be submitted to the European Commission. The template for the EUnetCCC pilot outcome report will be accessible on SharePoint, in the "CCC PILOTS" folder, which can be accessed as explained in section "Resources and support documents from WP4 leaders", on page 27., which can be accessed as explained in section "Resources and support documents from WP4 leaders", on page 27.

Additionally, the template will be distributed to the national competent authorities and pilot teams in a timely manner. Each national competent authority for the respective pilot country will be responsible for updating and submitting EUnetCCC pilot's outcome report to SharePoint, specifically in the "CCC PILOTS" folder, within the folder corresponding to their country. Alternatively, the reports may be submitted to one of the two designated WP4 pilot team members responsible for each country., within the folder corresponding to their country. Alternatively, the reports may be submitted to one of the two designated WP4 pilot team members responsible for each country.

Timeline

Common timeline

The timeline outlines key phases shared by all pilots, including major milestones such as initial setup, mid-point evaluations, and final reporting.

Phases	Date	Milestones	Deliverables	Explanation
Mapping of confirmed modalities	January 2025	Mapping of pilot configurations and assessment criteria		This initial step involves mapping out the modalities for each participating country and confirming the different pilot configurations, including single institutions, regional networks, and national frameworks. Additionally, the maturity assessment criteria will be developed and finalized during this phase.
Assessing pilot maturity	January 2025 + KOM February 2025	Finalizing maturity criteria for each pilot		During the kick-off, the task leader team will present and discuss the maturity assessment criteria, ensuring that each pilot is assessed based on consistent and agreed-upon standards. This is crucial for the later evaluation of pilot readiness and success.
Bilateral WP4/member state meetings	March–April 2025	Tailored guidance and alignment meetings		WP4 leaders will conduct one-on-one online meetings with each participating country to provide specific guidance, ensure alignment with certification standards, and address any challenges encountered. These meetings will help clarify pilot needs and fine-tune support strategies for each country.
Launch of 1st set of pilots	March 2025	Official start of pilot implementations		This phase marks the formal launch of the first set of pilots. The pilots will begin testing the CCC certification process across the selected configurations in real-world settings.
Assessment of 1st phase	November 2025	Evaluation of first-phase pilots		A comprehensive evaluation of the first set of pilots will be conducted to assess progress, identify challenges, and gather insights for refining the certification process. This assessment will inform us of the next steps and improvements.

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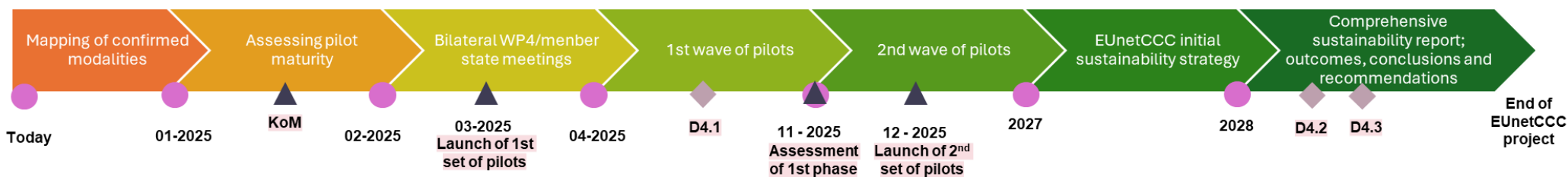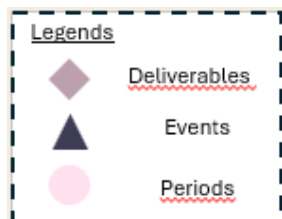|				
Launch of 2nd set of pilots	December 2025	Launch of the 2nd set of pilots		The second set of pilots will be launched, incorporating lessons learned from the first phase. This will expand the testing and refinement of the certification process, ensuring its adaptability and scalability.
EUnetCCC initial sustainability strategy	2027		D4.1 EUnetCCC initial sustainability strategy	This report will outline the initial sustainability strategy for EUnetCCC, informed by pilot results, and will set the stage for continued expansion and integration of CCCs across Europe.
Pilots: outcomes, conclusion, and recommendations	2028		D4.2 Pilots: outcomes, conclusion, and recommendations	A detailed report summarizing the pilots' results and conclusions. This will also include recommendations for refining and scaling the CCC certification process.
Comprehensive sustainability report	2028		D4.3 Comprehensive sustainability report	The final report will integrate all pilot findings and provide a roadmap for the sustainable development of CCCs, ensuring long-term integration and impact within European healthcare systems.

Table 3: Pilot Timeline

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Figure 1: Pilot Timeline

Legends
- Deliverables
- Events
- Periods

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Individual pilot roadmap and tailored milestones:

Each pilot site will develop its own timeline in the framework of the 18–24-month period available for the pilot site development and activities. Given the different starting points and readiness of the different sites and countries, as well as different periods of summer holidays, it is not realistic to set precise milestones for all. The main milestones are the launch of the pilot site and the conclusion with the final report on the pilot's completion to the WP4.

In the CCC pilot progress report, as outlined in the template in the section "Resources and support documents from WP4 leaders", on page 27, pilot sites will have the opportunity to include estimated timelines and desired milestones in 'Section One: Summary.' Additionally, this information may be entered into the **calendar** provided on SharePoint with a designated subfolder for each country.

This approach ensures that the progress of development is transparent not only to the pilot sites but also to one of the two WP4 team members responsible for the respective pilot country, facilitating oversight and ensuring adherence to the project schedule.

Financial and reporting flows

Financing

In the initial budget, there is €6,466,403 dedicated for the pilot sites activities (task 4.2.1). This budget covers the funding of all pilots included in first wave. Additionally, a coordination fund of around 12 million euros was set up to finance additional activities for WP4, WP6 and WP8.

In order to fund additional pilots during the 2nd wave, WP4 leaders need to propose a budget plan to be approved by the EUnetCCC Steering Committee, as stated in the Grant Agreement *(part A "list of work packages – WP1" and part B section 2.6)* signed and the financial policy developed by WP1 *(milestone MS2 of the Joint Action)*.

Pre-financing

HaDEA has transferred all the prefinancing (50%) to the coordinator (Institute National du Cancer, INCa) in M1 and, as agreed in the Grant Agreement Core Document (Data Sheet Point 4.2 - page 17, Prefinancing payments and guarantees, Prefinancing amount is specified). As agreed in the Consortium Agreement, this prefinancing is then divided into two payments (article 7.2.2). The first payment of prefinancing has been transferred from INCa towards all 31 beneficiaries (corresponding to 25%). The second payment is based on written requests from partners and the rest of the prefinancing will be transferred at M13, after 2 first financial internal reporting.
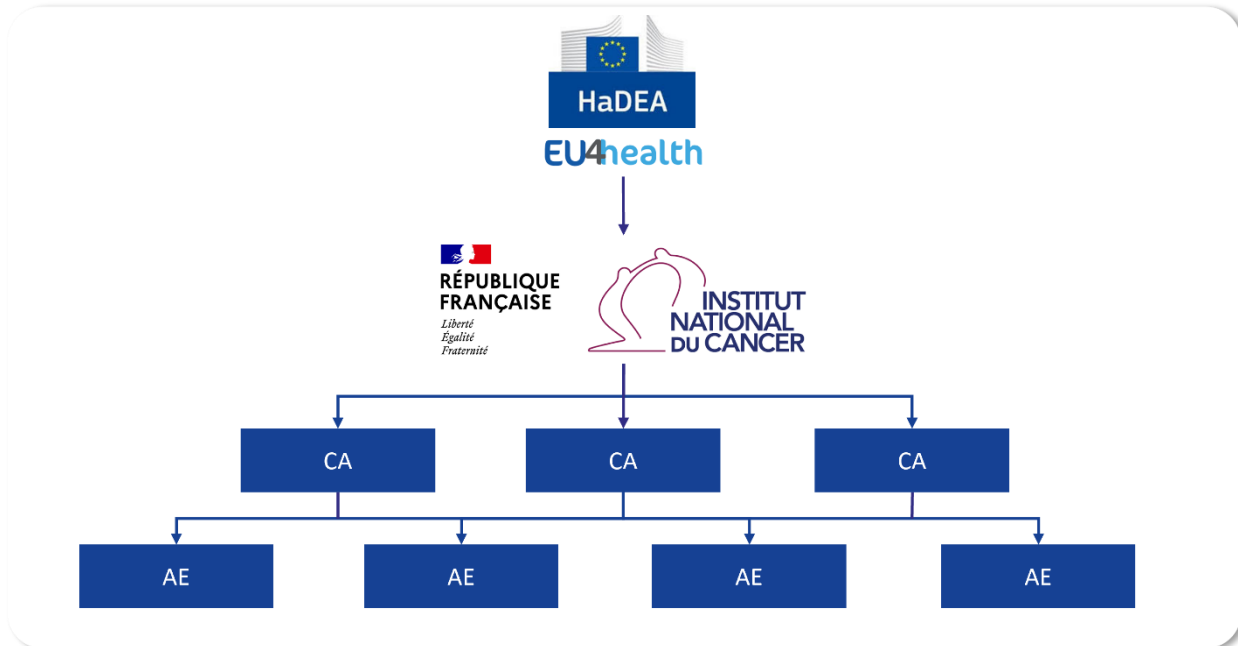
Figure 2: EUnetCCC Financial Flow

CA: Competent Authority
*** AE: Affiliated Entities*

Periodic reporting and grant disbursement

As agreed in the Grant Agreement, each partner of the consortium **has to report their cost** in order to receive reimbursement from the European Commission (HaDEA).

For experts involved in pilot, it is crucial to **keep track of their time spent on the project and every related cost** (such as travel cost for meetings).

For your information, all entities have 2 months to submit the periodic reporting after the end of the reporting period that includes financial statements and technical reports. After receiving the periodic reporting, HaDEA has 3 months to make the payment. The coordinator (INCa) then has to distribute the payment to CAs without unjustified delays.

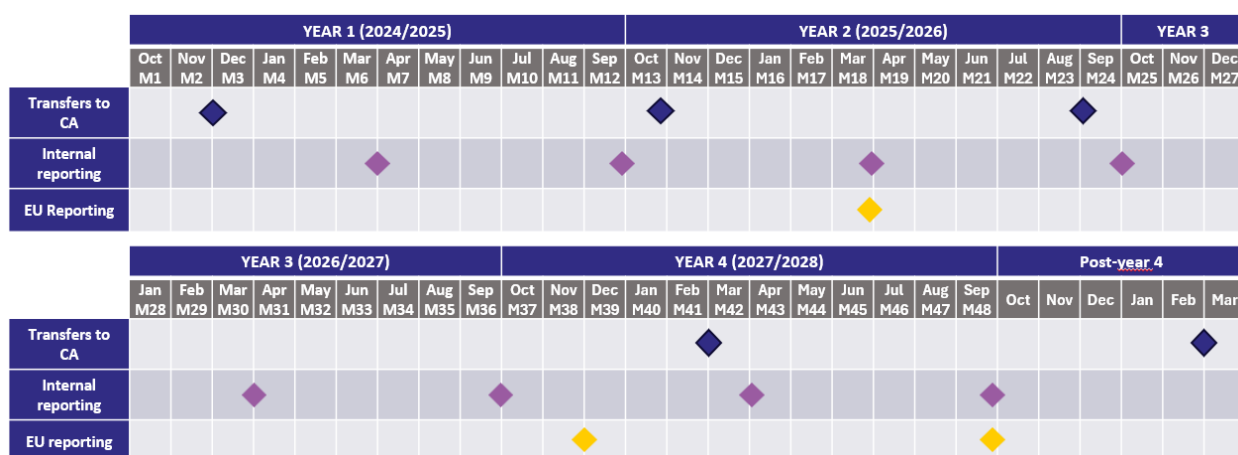|	YEAR 1 (2024/2025)												YEAR 2 (2025/2026)												YEAR 3		
	Oct M1	Nov M2	Dec M3	Jan M4	Feb M5	Mar M6	Apr M7	May M8	Jun M9	Jul M10	Aug M11	Sep M12	Oct M13	Nov M14	Dec M15	Jan M16	Feb M17	Mar M18	Apr M19	May M20	Jun M21	Jul M22	Aug M23	Sep M24	Oct M25	Nov M26	Dec M27
Transfers to CA		◆											◆										◆				
Internal reporting						◆						◆						◆						◆			
EU Reporting																		◆									

	YEAR 3 (2026/2027)									YEAR 4 (2027/2028)												Post-year 4					
	Jan M28	Feb M29	Mar M30	Apr M31	May M32	Jun M33	Jul M34	Aug M35	Sep M36	Oct M37	Nov M38	Dec M39	Jan M40	Feb M41	Mar M42	Apr M43	May M44	Jun M45	Jul M46	Aug M47	Sep M48	Oct	Nov	Dec	Jan	Feb	Mar
Transfers to CA														◆												◆	
Internal reporting			◆						◆						◆						◆						
EU reporting											◆										◆						

Figure 3: Financial calendar and main time points for grant payment and reporting

Key financial responsibilities for the partners

1 Every partner is responsible for its own costs and financial statements.
Each beneficiary entity (CAs) is responsible for its own eligible costs and integration of those from its affiliated entities (AEs).

2 **GA Article 6 – Eligible costs**
- Must be actually incurred by the beneficiary / affiliated entity
- Incurred in the period of the JA; Retroactive start of eligibility: 1st October 2024
- Incurred in connection with the JA; Reasonable and justified
- Comply with the requirements of applicable national law on taxes, labour and social security

3 **GA Article 191** – The no double funding rule prohibits that two different EU grants fund the same cost.

4 **GA Article 202 –** Amount of the grant and extension of audit findings. Even if the project is closed and your financial officer has approved all the costs, the EC keeps the right to do post-checks and investigations up to 5 years after project end.

5 **GA Article 232 –** Record keeping: "European political parties shall keep all records and supporting documents pertaining to the contribution for five years following the last payment related to the contribution".
➔ Awaiting HaDEA's validation that digitalized records and supporting documents will be accepted for record keeping.

For any questions regarding financial and budgetary aspects, please contact Kaiwen Zhang (kzhang@institutcancer.fr) or the coordination team at INCa (EUnetCCC@institutcancer.fr).
For all other questions about financial reporting, please refer to the EUnetCCC - MS4 - Financial Policy - WP1.pdf

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Resources and support documents from WP4 leaders

To assess the certification criteria and standards, the pilots will refer to D7.2 Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centers, which contains the set of criteria and standards developed during the CraNE joint action and is currently being finalized by WP5. These criteria are currently being tested by the pilots and will be reviewed and adjusted, if necessary, based on feedback. WP5 of EUnetCCC (Inclusion, Certification and Adherence to EUCCC Network) will oversee any necessary modifications to ensure the standards are fit for purpose.

WP4 will also develop reporting templates to support the pilots in documenting their implementation phases and following up on their progress. These templates will facilitate consistent reporting and tracking of pilot activities and outcomes and will be made available not only to the national competent authorities and pilot teams but also on SharePoint in the "CCC PILOTS" folder. Access path to this folder is as follows: on the home page "WP documents" > "4. WP#4 – Sustainability" > "CCC PILOTS".

WP8 will provide various tools to the pilots to support them in accessing and meeting the certification criteria. These tools will support the pilots by providing the necessary tools and frameworks to ensure they meet certification criteria. It will focus on enhancing clinical and managerial practices within the CCCs involved in the pilots, helping to improve both the quality and efficiency of care. WP8 will also facilitate the optimization of clinical data use, encouraging the secondary use of data for research and governance, which is vital for driving evidence-based decision-making throughout the pilots. Additionally, WP8 will enable knowledge exchange among pilot participants by creating platforms for sharing best practices, challenges, and solutions, fostering continuous learning and improvement. Finally, WP8 will contribute to the development of a European Clinical Trials Engine, ensuring that the pilots have access to a robust framework for conducting clinical trials, which will enhance trial execution and provide patients with better access to clinical research opportunities. These efforts will collectively support the pilots and contribute to the long-term success and sustainability of the CCC network across Europe.

Additionally, WP4 will work with WP6 on capacity building, as WP6 will assist the pilots in becoming certified through a tailored capacity-building plan based on their maturity level. Feedback from WP4 pilots will contribute to refining WP6's models and frameworks.

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Key contact points

Who should I contact?

Work package 4 - Sustainability

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Main contact for pilots

Pilot Support	Jelena Isailović Jelena.Isailovic@nijz.si	Tija Hubej Tija.Hubej@nijz.si

Financial questions

INCa	Kaiwen Zhang kzhang@institutcancer.fr	Coordination team EUnetCCC@institutcancer.fr

Key reference documents

The table below lists 5 key reference documents that are essential for understanding the development of CCC. These documents, which include legal agreements, deliverables, are referenced throughout this management handbook and will provide additional, complementary information to support your work. Please refer to SharePoint for access to these documents.

Name of the document	Purpose and content
Grant Agreement (GA)	**Contract between the funding authority (HaDEA) and the Coordinator**, with Competent Authorities (Beneficiaries) signing an accession form to formalize their participation. **The GA Core document** outlines the rights and obligations of both the European Commission and the project partners. **Annex 1 – Description of Action (DoA)**, divided into **Parts A and B**, is particularly important, as it details the project objectives, Work Package (WP) activities, deliverables, milestones, and their due dates. Additionally, **Annex 1 includes** the detailed budget, which serves as a key reference for financial reporting. Together, these documents provide the foundational guidance for the project throughout its duration.
Consortium Agreement (CA)	**Contract binding all consortium members**, including Competent Authorities (CAs), Affiliated Entities (AEs), and Associated Partners (APs). **This legal document** outlines the governance structure of the Joint Action (JA) and establishes rules for periodic and internal reporting, intellectual property management, and other operational aspects of the project.
CraNE deliverables	D7.2 Set of criteria and standards and their application in a certification process for EU Comprehensive Cancer Centers, which are only two of many deliverables in CraNE, that contributed to strengthening the infrastructure that supports European and international research collaborations.
Templates	• CCC Pilot Progress Report, • Timeline and Meeting Calendar, Excel file, • Final CCC Pilot Report.
Financial policy	Milestone 4. A document detailing financial rules, procedures, and templates for budget management and reporting. Means of Verification

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