Study providing an operational concept for a European Cancer Patient Digital Centre

Offered by

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SHORT SUMMARY

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1. Abstract

Cancer remains one of the main causes of mortality. Compared to traditional approaches, new therapies and research improve the quality of life and treatment results. In this dynamic environment, it is of utmost importance that patients and survivors have the tools to manage their own cancer journey, namely co-decision on treatment and active participation in relevant research.

The European Cancer Patient Digital Centre (ECPDC) was proposed by the EU Mission on Cancer (MoC) as a technical solution enabling patients to be actively controlling their cancer journey using state of the art digital health services.

The Charité won the eTender by the European Commission for a study providing an operational concept for a European Cancer Digital Centre. In this study we developed a blueprint for implementing an ECPDC in correlation to existing infrastructures like MyHealth@EU, HealthData@EU and further initiatives, providing three different concepts to realize the goals of the EU Mission on Cancer.

Concept 1 covers a novel approach to present cancer information in a standardized way for citizens and patients. Concept 2 covers personalized access to and sharing of personal cancer related data in a uniform and interoperable way in all Member States. Concept 3 combines the results of the first two concepts towards a novel sustainable way to make the ECPDC portal the one stop agency for all citizens and patients dealing with cancer, facilitating co-decision in treatment and active participation in research.

2. Introduction

This study developed a blueprint for implementing an ECPDC for the benefit of patients. The starting point of the ECPDC study was the input of the MoC Board and the MoC Implementation Plan, where the ECPDC was suggested as an online stop agency for cancer patients. The features of the ECPDC were categorised into “four rooms” of the “ECPDC house” (see Figure 1 below).

- Room1 (top left): Cancer patients, survivors and caregivers should use the ECPDC as an information source of relevant information on treatment, care and support.
- Room2 (top right): Cancer patients and survivors should be able to access their own clinical data and to share their data with healthcare professionals, family members, caregivers and researchers.
- Room3 (bottom left): Within ECPDC cancer patients should be able to collect patient-reported outcomes (PROs) data and to share these data.
- Room4 (bottom right): Through the ECPDC cancer patient and survivor empowerment should be facilitated and confidence to participate in research through patients’ and survivors’ data should be enhanced.
3. Methodology

After setting up a governance that includes representatives from infrastructure operators and initiatives, patient organisations, practitioners and partners from the European Commission (EC) we identified and analysed existing and planned (EU) initiatives and infrastructures. The available information was matched with patients’ needs of a good ECPDC (see Figure 2).

Figure 2: Timeline, work packages and deliverables of the ECPDC study project

In order to identify components required for a good ECPDC, we first identified initiatives, platforms and organisations that could contribute to an ECPDC. Second, we developed standardized questionnaires to collect requirements from the above-mentioned organizations and initiatives. We conducted surveys and interviews with patient organisations, infrastructure providers, and related initiatives. The gathered information was used to refine a set of requirements that we co-developed with the ECPDC Steering Committee to decide what features and information an ECPDC must, should, could or won’t provide. In parallel, we analysed through further surveys and interviews with initiatives and existing infrastructures to what extent they would be willing and able to contribute to the ECPDC. In addition, we conducted meetings with selected organizations and initiatives to refine our understanding of the needs of patients and survivors.

Third, we developed the outcomes from the refined set of requirements into a gap analysis. This gap analysis informs our three concepts. In the three concepts we investigate different approaches towards building a good ECPDC, considering three main principles:

- Reuse what is available instead of building from scratch
- Identify the areas of highest needs for improvement
- Derive an order of implementation steps

Finally, we transferred the results from surveys, requirements, interviews and upstream gap analysis into three concepts, which have been summarized in the final report.

**4. Gap-Analysis**

The gap analysis used the list of requirements and several existing infrastructures, projects and initiatives to identify which of the requirements aren’t already covered by existing or ongoing work. This effort was complemented by the surveys.

We identified the following preconditions projects and initiatives must fulfil to contribute to the ECPDC:

- Their willingness to engage with the ECPDC team through online meeting and/or survey
- Their scope has to fit into one of the “four rooms” (Figure 1)
- The funding needs to be secured
- A willingness to cross-linking their initiatives to the ECPDC infrastructure
- A minimum requirement towards sustainability of their results, e.g., standards or infrastructure components

Gaps to most existing EU-funded initiatives/projects:

- Most initiatives are research related.
- Most initiatives do not interact with other initiatives.
- Most initiatives consider themselves as projects within their funded timeline and scope.
- Most projects start from scratch and are largely ignoring what components with potentially synergistic effects already exist outside their project.
5. Concepts

The three concepts complement each other for the realization of a fully featured ECPDC which will be realised after implementation of Concept 3 which requires the realisation of Concept 1 and 2. Concept 1 already scores well in terms of utility for cancer patients and survivors but needs expansion via Concepts 2 and 3 to fully implement a good ECPDC. Our recommendation is to implement Concept 1 in a way that a toolbox for a federated ECPDC information portal is provided for adaptation by Member State. In Concept 2 among other things a “new architecture” of the ECPDC house is suggested, iterated from the initial “four rooms” mentioned above using state of the art data space technology to build a scalable and a good ECPDC.

5.1. Concept 1

Concept 1 shows how an ECPDC builds on current technical, organizational and regulatory circumstances. Existing data sources and other sources of information like the Knowledge Centre on Cancer (KCC)\(^2\) and other Cancer Information Systems (CIS) could be combined to build the primary patient facing component of the ECPDC, the ECPDC information portal (Room 1). Cancer patients and survivors use it to find evidence-based information about all aspects of their disease that are relevant to them, in a form that is easy to understand (including information in national languages and lay terms).

Survey results indicate that the largest information gaps for patients and survivors are trusted information on treatment including guidelines and side effects, diagnosis, and psychosocial support. Access to this information is in high demand and should be available via a cancer patient information portal. Further, survey results indicate a need for immediate introduction of ECPDC cancer information service portals in national languages as the information situation is deficient in languages other than English.

In addition, we envision the information portal to be the face and first point of contact of users with the ECPDC. Only if cancer patients and survivors see and feel a real benefit from the ECPDC portal, the users’ active engagement can be achieved. Patient organisations agree that the availability of information differs between Member States and even within Member States between regions. The ECPDC information portal should help to overcome these inequalities and address stigmatisation of cancer patients and survivors during the whole patient journey as patient organisations say: that patients are affected by discrimination and stigma during diagnostic phase, treatment phase, pain management in care, rehabilitation, and survivorship.

Everyday discrimination by society often manifests itself by disadvantages, e.g., when re-entering the job market or applying for a loan. In addition, unwanted impairment can also occur in private environments due to "cancer ghosting": family members and friends are overwhelmed by the situation and lacking guidance about how to communicate with those affected, causing strain on personal relationships. In effect, cancer patients face a multitude of physical and psycho-social challenges, ranging from the traumatic processing of the diagnosis/illness to the side effects of the treatment, and finally to social isolation (this list is incomplete).

\(^2\) https://knowledge4policy.ec.europa.eu/cancer_en
Taking advantage of existing resources, the ECPDC itself should cooperate with existing initiatives such as European Cancer Information System (ECIS)³ and the Knowledge Centre on Cancer (KCC)⁴. It should further facilitate closer cooperation between ⁵ Cancer Information Services (CIS) within the Member States, e.g. members of the International Cancer Information Service Group⁶ and other initiatives and entities. The ECPDC should not multiply existing information of CIS in a separate portal. Doubling information reduces findability through the google algorithm. Information needs to be refined to be applicable and useful for patients and survivors in their local language and lay terms. Existing CIS would evolve and benefit from higher visibility and cross-border integration, in particular, CIS with low budgets can profit from synergies created. To achieve this, we suggest fostering cooperation between cooperating ECPDC information platforms to develop a common content generation scheme within a pilot of participating Member States in the first concept phase.

5.2. Concept 2
Concept 2 suggests iterations on existing infrastructures following our “Patients First” tenet.

Figure 3: Governance instrument and structure

On a technical level, this requires agreement between the Member States regarding common data and infrastructure interoperability and federation standards: An effective ECPDC should be created on the basis of existing data standards, data sources, and registries on the one hand and existing infrastructures which are developed in the framework of EHDS⁶ and can be re-used for the ECPDC in a safe and secure way.

³ https://ecis.jrc.ec.europa.eu/
⁴ https://knowledge4policy.ec.europa.eu/cancer_en
⁵ https://icisg.org/
⁶ https://www.european-health-data-space.com/
We propose an ECPDC architecture where the three concepts build upon each other (Figure 3). An ECPDC pilot implementation could be separated into these deliverables:

1. Building up a governance model for a shared content toolbox for Cancer Information Services within the Member States (Ground Floor),
2. Data access through EHDS infrastructures (First Floor),
3. Data sharing for primary, secondary and personal use cases (Second Floor),
4. Fully functional and optimised ECPDC which includes AI-tailored personalised information, co-decision on treatment, participation in research, fully engaged Safe Community Spaces (Top Floor: Detailed information is laid out below in Concept 3).

ECPDC’s priority should be to use EHDS structures wherever they are applicable. ECPDC won’t build a parallel infrastructure to MyHealth@EU for the ECPDC use case. Therefore, ECPDC is a use case of the EHDS-regulation, MyHealth@EU, and HealthData@EU7.

Finding synergies to other initiatives like UNCAn8 is a priority when building a good ECPDC. Therefore, existing registries, sources of data and information pathways should be used wherever these are available within the scope of ECPDC.

1. Using the existing EHDS infrastructure (MyHealth@EU) for cross-border data access in the ECPDC is the most obvious solution for data access. Relevant clinical data in a standardised data exchange format such as patient summaries, laboratory results, medical images, and hospital discharge reports are and will be exchanged through MyHealth@EU9 and are also of most importance for the ECPDC. Patients need to trust in the ECPDC environment, and the aligned infrastructures to be successful. The ECPDC proposes requirements towards existing infrastructures to be implemented to become more patient-centric. Direct data access for patients is highly needed but very unequally provided within Member States. In MyHealth@EU right now, only healthcare professionals can act on behalf of citizens. The citizens themselves have currently no direct data access. Therefore, MyHealth@EU would need a state –of–the art ID management for citizens.
2. To maximise the benefits for the cancer patient use case, further data exchange standards are needed, e.g. patient-reported outcome measures (PROMs)/patient-reported experience measures (PREMs), medical device data and genomic data are currently not included in MyHealth@EU’s National Contact Points (NCP). Although these data are not used regularly in the day-to-day treatment and caregiving activities, they might have high potential to improve treatment, care and Quality of Life.
3. The infrastructures used in the ECPDC need a uniform European ID management. Here, deliverables from other running projects and initiatives could be integrated such as EUDI-Wallet10/ eIDAS 2.0 or projects like PATHeD11 if they achieve interoperable and scalable solutions.

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7 https://ehds2pilot.eu/
8 https://uncan.eu/
10 https://eudiwalletconsortium.org/
11 PATHeD - Enabling Patient Access to Their Health Data — EU4H-2021-DGA-MS-IBA, Grant Agreement nº 101084817
4. The ECPDC needs to be a patient-centric platform for information and personal health data. Therefore, a state-of-the-art consent management system is needed which includes a full transparency for patients who had access to their data (and for what purpose).

5. (Clinical) interoperability and platform interoperability needs to be enforced between electronic health record (EHR) systems within and beyond Member States. We recommend combining FHIR for transfer and openEHR for persistence of health data according to current best practice.

5.2.1. ECPDC Use of Data

The ECPDC would be a federated infrastructure where different data categories are made available for cancer patients and survivors through different infrastructures. This way, the ECPDC would become the link between cancer patients and multiple research infrastructures such as UNCAN\textsuperscript{12}, 1+MG\textsuperscript{13}, EUCAIM\textsuperscript{14} and others. By participating in an environment that patients trust, research initiatives will profit from greater visibility and transparent consent management, increasing the likelihood of patients’ participation in studies. More data of higher quality would be included into studies to get more context from all relevant personal health data for cancer patients and survivors. The ECPDC would increase the visibility of data driven research initiatives, the acceptance of the individual infrastructures as well as their visibility and recognition in society. To do so, the ECPDC should use data space technologies such as Gaia-X\textsuperscript{15} or SIMPL\textsuperscript{16} to interface with other upcoming platforms and systems such as the HealthData@EU central platform and MyHealth@EU infrastructure. In particular existing Gaia-X solutions in the healthcare field such as developed in HEALTH-X dataLOFT\textsuperscript{17} from Germany should be taken into closer consideration.

The architecture of the ECPDC will consist of different major components which could be addressed in different projects. E.g. The data access and data management platform need an access point for cancer patients and survivors to find, access, share and use their data. Patients should be able to provide own personal health data (clinical data, documents, structured data, images, genomic data, PROMs & PREMs and wearable data) in the platform for all kinds of data use. The foreseen data use case scenarios are:

- **Primary use** cases, e.g., by sharing data through the MyHealth@EU data transfer or co-decision on their treatment

- **Secondary use** cases: In the ECPDC a consented data aggregation for specific studies and research scopes could be achieved through consented data donations by patients and survivors. For patients’ participation in research a standardised cross-border consent module is needed. Patients need to know what research they participate in through their data and if possible, what the outcome of these studies was.

- **Personal use of data**: Patients and survivors share their data right now through insecure environments such as email, WhatsApp. That is why cancer patients and survivors need a

\textsuperscript{12} https://uncan.eu/
\textsuperscript{13} https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
\textsuperscript{14} https://cancerimage.eu/
\textsuperscript{15} https://gaia-x.eu/
\textsuperscript{17} https://www.health-x.org/home
secure environment for data exchange in safe community spaces. Another use of data for cancer patients is giving electronic power of attorney e.g., to family members.

5.3. Concept 3

Concept 3’s overarching goal is to further support and enable patient empowerment (in ECPDC we call it “patient agency”). To do so, Concept 3 builds on the existing ECPDC functionalities of the information portal, data access, data sharing and data use and creates synergies for patients (Fig. 4).

![Figure 4: Components of Concept 3 to facilitate patient agency by improving and connecting the different aspects of the ECPDC information portal, data access and data sharing components.](image)

In its core, Concept 3 lays out, how “patient agency” can be achieved and where close cooperation is essential for a functional ECPDC for the benefits of the users. We also cover and highlight further development of co-decision on treatment, the Safe Community Space, participation in research and propose, how the ECPDC could benefit of the use of AI for patients.

“Patient agency” in the ECPDC means patient empowerment by putting patients into an active role. To fulfil the promise of patient agency, the ECPDC increases literacy and gives context for patients to better understand patients’ and survivors’ situation and treatment options. They are provided with all relevant information, data and context they need to make informed decisions on treatment and data use. This is how the ECPDC enables participation in research and expert exchange in moderated safe community spaces.

AI can be helpful within the ECPDC for several reasons such as AI-supported information aggregation for Cancer Information Services and customized AI-tailored information access for cancer patients. The use of AI needs to be aligned with future AI regulation and potential harmonizing initiatives and actions or boards. AI could help users with personalized information access, e.g., through chatbot and AI-supported understanding of clinical documents for patients and survivors for understanding explaining and contextualizing doctor’s findings in doctor’s letters or hospital discharge reports.

Co-decision could further be enabled through AI for patients within the ECPDC by providing more specific information for patients (in lay term) tailored towards the patients’ individual situation. This way the ECPDC has the potential to uplift communication between patients and doctors to enable co-decision on treatment options.
Providing full transparency and the possibility to give remote consent to participate in studies through someone’s data, cancer patients and survivors are given the tools to decide on a case-by-case basis if they want to provide their data for specific research projects, studies or initiatives. Patients know and decide what their data is used for and by whom. Patients must know how to change or remove consent settings and should be able to do it effortlessly.

One of the most important benefits of cancer support groups is the exchange between cancer patients and survivors to share experiences, learn from others and offer support without stigmatisation. Safe Community Spaces enable patient organisations to provide their services online and moderate expert exchange for cancer patients and survivors. They mitigate the psychological stress and the negative effects of social isolation as a side effect of their disease.

6. Conclusion and Recommendations

The three concepts complement each other for the realization of a fully featured ECPDC. Initially it is based on four rooms which were proposed in the Mission on Cancer Implementation Plan. The ECPDC study iterated the functionalities and features proposed by discussing them with relevant stakeholders, especially patient organisations, EC and initiatives. The ECPDC study proposes a “new architecture” following an implementation strategy instead of a thematic coordinated approach.

The full benefits of the ECPDC will only be realized after the implementation of Concept 3 but implementing Concepts 1 and 2 are important preparatory steps which deliver value on their own.

Our recommendation is to implement Concept 1 in a way that a toolbox for a federated ECPDC information portal is provided for adaptation by Member States and setting up a proper governance instrument in parallel. This governance instrument will guide and cover the implementation of Concepts 2 and 3 at the start of their implementation cycles, which will follow Concept 1 but may overlap in terms of project progress.

Concept 1 already scores well in terms of utility for cancer patients and survivors but needs expansion via Concepts 2 and 3 to fully implement a good ECPDC.

We also recommend separating funding between the strategic scope and the operational implementation of the concepts. This is of particular importance due to the integrative nature of the ECPDC as outlined in our concepts: strategy and governance must be open to invite representatives from all initiatives and stakeholders, and the operational implementors must strive to connect for a good ECPDC.

Current public-private partnerships such as Bilbomatica and the SmartCARE to establish a Cancer Survivor Smartcard are a good approach to kickstart an economy around ECPDC offerings. If these expand to building platforms that enable state of the art data space and data economy approaches, the ECPDC could well develop towards a blueprint for a general European Patient Digital Centre as a use case of EHDS infrastructures. Once its utility is proven for cancer patients in ECPDC, implementation projects and the basic infrastructures for interoperable centralised, federated, and personal data spaces are put in place, which could be further rolled out in additional phases and towards other use cases within the healthcare sector and beyond.
### Glossary

<table>
<thead>
<tr>
<th><strong>Bilbomática</strong></th>
<th><a href="https://bilbomatica.es/en">https://bilbomatica.es/en</a></th>
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<tbody>
<tr>
<td>Bilbomática is a software consultant and engineering company that develops an interoperable smart card app within the smartCARE initiative (see below) usable across a variety of healthcare infrastructures and readily available to survivors, their families and other end users.</td>
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<tr>
<th><strong>Cancer Image Europe</strong></th>
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<tr>
<td>Cancer Image Europe provides a robust, trustworthy platform for researchers, clinicians, and innovators to access diverse cancer images, enabling the benchmarking, testing, and piloting of AI-driven technologies.</td>
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<th><strong>EHDS HealthData@EU Pilot</strong></th>
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<tr>
<td>The HealthData@EU Pilot project is a two-year long European project which will build a pilot version of the European Health Data Space (EHDS) infrastructure for the secondary use of health data “HealthData@EU”. This cross-border project will connect data platforms, develop services to support the user journey for research projects, and provide guidelines for data standards, data quality, data security and data transfer.</td>
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<td>ECIS provides the latest information on indicators that quantify cancer burden across Europe. It permits the exploration of geographical patterns and temporal trends of incidence, mortality and survival data across Europe for the major cancer entities</td>
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<td>The Recommendation on a European electronic health record exchange format seeks to facilitate the cross-border interoperability of electronic health records (EHRs) in the EU. For persistence standard openEHR and for transfer standard FHIR are strongly recommended in concept 2. The electronic health record exchange format will help citizens to quickly access and share their health data with healthcare professionals. This format is used in MyHealth@EU and could be a basis for accessing personal clinical health data via PATHeD.</td>
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<tr>
<th><strong>European Health Data Space</strong></th>
<th><strong>EHDS</strong></th>
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<tr>
<td>The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at:</td>
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<tr>
<td>1. Empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide.</td>
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2. Fostering a single market for electronic health record systems, relevant medical devices and high-risk AI systems.
3. Providing a trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data).

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<tr>
<th>International Cancer Information Service Group</th>
<th>ICISG</th>
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<tr>
<td>The ICISG is a worldwide network of more than 70 organizations that deliver cancer information. Members share information and expertise and assist organizations interested in starting or enhancing a Cancer Information Service (CIS).</td>
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<th>Knowledge Centre on Cancer</th>
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<td>The Knowledge Centre on Cancer fosters independent scientific alignment, coordination and support to EC cancer-related policies and activities. It acts as</td>
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<tr>
<td>1. evidence-clearing house for policy making on cancer prevention, early detection, treatment and survivorship.</td>
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<td>2. manager of the EU Cancer Information System.</td>
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<td>3. developer of European guidelines and quality assurance schemes on cancer.</td>
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<td>4. data hub for cancer and ‘honest data broker’ via the European Health Data Space.</td>
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<th>MyHealth@EU</th>
<th>MyHealth@EU</th>
<th><a href="https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en">https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en</a></th>
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<tr>
<td>Under the brand “MyHealth@EU” citizens can easily recognize the availability of digital health services that gives EU countries the possibility to exchange health data in a secure, efficient and interoperable way. Currently two electronic cross-border health services are being introduced in all EU countries: Patient Summaries, ePrescription and eDispensation.</td>
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<th>smartCARE</th>
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<tr>
<td>smartCARE is a flagship initiative in Europe’s Beating Cancer Plan. The project is developing a cancer survivor smart card (mobile app) to improve the health and wellbeing of cancer survivors throughout Europe.</td>
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