European Commission

An operational concept for a European Cancer Patient Digital Centre

EU MISSIONS CANCER

Independent Expert Report

EXECUTIVE SUMMARY

ABSTRACT

The European Cancer Patient Digital Centre (ECPDC) aims at increasing the quality of life of cancer patients and survivors, which is often characterised by a lack of understanding or insufficient consideration of patient needs during and after the treatment. In 2022, the European Commission awarded contract RTD/2022/MVP/0012 to the Berlin Institute of Health at Charité for delivering a study on an operational concept for a European Cancer Patient Digital Centre. In this study a blueprint for implementing an ECPDC is developed considering existing infrastructures and further initiatives, along three different complementary concepts that are coherent with the goals of the EU Mission on Cancer and Europe's Beating Cancer Plan. Concept 1 covers a novel approach to present cancer information in a standardised way for citizens and patients. Concept 2 covers personalised 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.

Research and Innovation

1. Introduction

Scope of the report

Cancer remains one of the main causes of mortality in Europe, exceeding 25%[1]. In recent years, individual treatment approaches and precision oncology have shown tremendous potential in improving chances of cancer survival. These approaches heavily depend on the availability of personal health data of patients, survivors, and their families since relevant factors of successful prevention and treatment can be derived from genetic and non-genetic factors (including environmental and/or lifestyle factors).

This report covers a discussion of the utility of a European Cancer Patient Digital Centre (ECPDC) for the different stakeholders: patients, survivors, families, caregivers, industry, and researchers. Our analysis includes an alignment check with the EU Mission on Cancer[2] and the proposed European Health Data Space (EHDS)[3] architecture. Together with relevant initiatives, stakeholders, and infrastructure platforms, we established and refined functional and non-functional requirements forming the basis for the proposed implementation approach of the three concepts.

We define three concepts that outline how to build national ECPDC nodes that are consistent with regulatory requirements. National ECPDC nodes will be interoperable with other ECPDC nodes, so that the final goal of the ECPDC can be realized in a federated network of national nodes. Coordination of the national ECPDC nodes will be done via a central umbrella node. The result will be a *"Good ECPDC"*, where *"good"* means it meets patients' and survivors' needs and demands first, and *"European"* means it **needs to be possible for each Member State to join the ECPDC effort in a federated manner**.

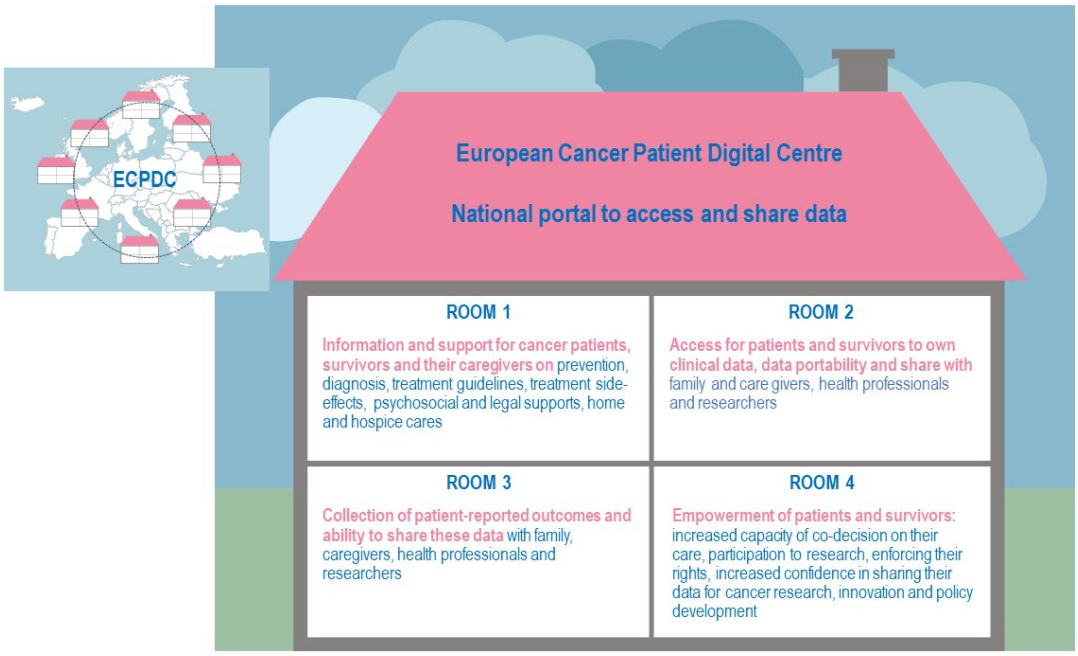

Figure 1. The European Cancer Patient Digital Centre as described in the Implementation Plan of the Cancer Mission

[1] Eurostat Database
[2] https://research-and-innovation.ec.europa.eu/system/files/2021-09/cancer_implementation_plan_for_publication_final_v2.pdf
[3] https://www.european-health-data-space.com/

One stop-shop covering all requirements and needs ("better than Google")

The four core goals of the ECPDC as outlined by the Implementation Plan of the Cancer Mission:

- Offering general and tailored information about all aspects of cancer (prevention, diagnosis, treatment, legal and psychosocial aspects) based on scientific evidence ("**Room 1**")
- Providing patients and survivors with access to personal health data ("**Room 2**")
- Establishing the ability to collect and share self-generated data from smart devices and patient reported outcomes ("**Room 3**")
- Providing ways to give patients the options for self-determined care and participation in research relevant for the patients and survivors ("**Room 4**")

These four core goals are derived from the EU Mission on Cancer Board's depiction of the House of ECPDC (Figure 1), thus we call them Rooms 1 to 4. These goals were refined further in the project as outlined in the final report, which resulted in a clearly defined critical path from information to self-determination.

2. Concept 1. ECPDC Information portal

Well informed for better survivorship

Evidence based information on cancer prevention, diagnosis, treatment, and survival is the foundation for patients to deal with cancer in a positive way. The ECPDC information portal is the first step towards a patient centric data driven approach to dealing with cancer.

Possible contributors to and stakeholders of the ECPDC information portal are existing Cancer Information Services (CIS) within Member States, e.g. members of the International Cancer Information Services Group[4]. Another sustainable financed component, which could contribute to national ECPDC information portals (Room 1), would be the Knowledge Centre on Cancer (KCC)[5], which is a knowledge-based information service with different tools tailored for policy makers. It includes population-based cancer burden statistics of Member States over time for different categories of cancers. But there are other components as well: The KCC develops and publishes evidence-based guidelines for screening and diagnosis, which receive regular updates to incorporate the latest scientific research for breast cancer[6] and colorectal cancer[7]. It provides a platform for healthcare professionals and stakeholders to collaborate and share knowledge and best practices in cancer screening and diagnosis. Information provided by KCC are by design verified peer reviewed information for ECPDC. In return, ECPDC could provide patient-centered aggregated information to the KCC for policy makers.

Clinicians and researchers often neglect that the patient journey does not end with the end of treatment. Aftercare for survivors with follow-up diagnostic checks often are necessary for the rest of the survivors' lives. One key phrase of patient organisations is: "We want survivors to survive well too". To achieve this, patients and survivors need high quality, easy to understand information in plain language: on outcome statistics as well as long-term and late effects like fatigue, hair loss, infertility, pain, inflammation, skin issues, lymphoedema, mucositis, skin issues etc. Side effects and late effects are rarely clarified in a relatable way for patients when discussing treatment options. A well-established ECPDC information portal that provides all relevant information about all stages of treatment and care is essential for patients to have high quality conversations about co-decisions on their treatment.

[4] https://icisg.org/
[5] https://knowledge4policy.ec.europa.eu/cancer_en
[6] https://healthcare-quality.jrc.ec.europa.eu/ecibc
[7] https://healthcare-quality.jrc.ec.europa.eu/ecicc

Psychological and legal support

Cancer patients and survivors do not only have to deal with the physical trauma and impact of their disease and treatment, but also with psycho-social issues in multiple areas, such as the potentially life-threatening impact of the diagnosis. Besides the side and late effects mentioned above, topics such as uncertainty about the future, stigmatisation and discrimination, and social isolation need to be covered. Since ECPDC is planned to be a one-stop-agency for patients and survivors, these issues and appropriate support need to be provided by a "*Good ECPDC"* as well.

ECPDC clearing house and monitoring components

The ECPDC information portal should be run by the Member States through national ECPDC nodes that provide contents and quality assurance-services for their citizens in local languages, leveraging on MS Cancer Information Portals. It is built with a federated network including both centralised and decentralised secure data exchange.

The setup of a federated ECPDC information portal could start with a pilot of voluntarily participating Member States. The governance framework provides Member States with the tools to ensure equal availability of high-quality digital cancer information for patients in participating Member States. The ECPDC Board adopts rules and agreements where Member States propose common quality standards, which will be enforced through a common clearing house and information monitoring. Translation and integration of the information into the national ECPDC information portal should stay within the responsibility of each Member State.

Scoping of a pilot

Building a federated ECPDC as a one-stop agency that provides information and services for cancer patients on all aspects concerning cancer along the patient journey is a very complex undertaking. We propose to start with a limited scope targeting patients with high needs for active online participation, access to information, data exchange with peer groups, support, and patient agency. A good initial scope for an ECPDC information portal pilot could be to address paediatric and/or aggressive cancer types that affect young adults. Young adults are considered to have a high digital affinity, ECPDC should have the highest impact in terms of improving their quality-of -life long-term and receive the best feedback from them to further improve and mature the ECPDC.

In addition, patients and survivors should have full authority over their health data. To enable this, ECPDC needs to provide patients and survivors with the ability to access and handle their own clinical and healthcare data.

3. Concept 2. Patient access to personal clinical data and the ability to collect and share personal health data

The current situation

Current initiatives in the EHDS context like MyHealth@EU are early steps in the development of European data sharing infrastructures that provide semantic and platform interoperability in the scope of cross-border data exchange. HealthData@EU opens the market for secondary use in ways that are promising to overcome the current regulations, which are preventing progress in the secondary healthcare market and inhibit large-scale use of health data.

Patients first

The differentiating feature of the ECPDC compared to previous approaches is a) a comprehensive approach to providing patients and survivors with information they require and understand and b) that the primary and only focus of the ECPDC is the benefit for patients and survivors. It follows that patient requirements and concerns have priority when designing the ECPDC, and topics like data altruism are a secondary concern.

Relevance for the EU Health Data Space

Both EHDS initiatives are very important and will also be of the highest relevance for ECPDC as we outlined in Concept 2. However, the EHDS does not cover one major aspect that is relevant for the "P" in the ECPDC: the patients themselves. Nonetheless, we see the development of a federated ECPDC as a premier use case for an approach to data driven health initiatives that should be enabled by EHDS.

A *Good ECPDC* must be designed in a patient centered way from the very onset. This results in several strict preconditions when selecting technological approaches such as privacy by design principles, which must be taken into consideration for a successful, patient centered ECPDC. In terms of patient access to data this means we need to develop regulatory and technological frameworks under which patients have access to their own health data.

Technological building blocks for a *Good ECPDC*

Further technological considerations are very relevant for a successful ECPDC, for example: Clinical interoperability, platform interoperability, dataspace technologies, consent management, privacy by design as well as EU wide secure and unique identity management. All these topics will be covered in detail in Concept 2.

Clinical interoperability is state of the art in large-scale healthcare projects. Clinical interoperability can be typically divided into three standardisation sections: The semantic, the exchange and the persistence standard, as represented in Figure 2. The most prominent examples in the field of data semantics are LOINC[8] for laboratory data and SNOMED CT[9] for health terminologies. HL7 FHIR[10] is the champion for clinical data exchange in the world of structured data, and IHE[11] current best practice for medical unstructured data. The standards for the two areas of exchange and transfer areas are used in some national electronic health records (EHRs, e.g., in some major German EHR solutions) but also notably in MyHealth@EU.

In the field of persistence standards, several solutions exist: openEHR[12], OMOP[13] and others. We will discuss these in more detail in Concept 2.

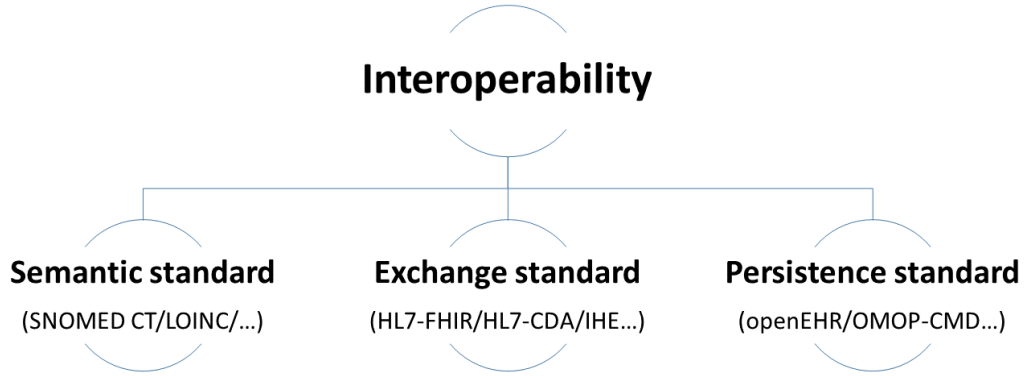

Figure 2. Clinical interoperability

[8] https://loinc.org/
[9] https://www.snomed.org/
[10] https://www.fhir.org/
[11] https://www.ihe.net/
[12] https://openehr.org/
[13] https://www.ohdsi.org/data-standardization/

Centralized, federated and personal health data spaces

In terms of platform interoperability, we believe dataspace technologies to be the current best approach to guarantee interoperability. Since many different platforms need to interact for a *Good ECPDC*, interoperability concerns are not just about data, but also about platforms if ECPDC is to fulfil its ambitious goals. The two most promising approaches here are SIMPL[14] and Gaia-X[15]. SIMPL is an EC funded approach to an interoperability middleware, while Gaia-X is a community effort developing an architectural model and common dataspace federation services as open-source solutions, allowing interested parties to build dataspaces with easily available technologies. As both SIMPL and Gaia-X mostly address the need for dataspaces in a business-to-business environment, this needs to be complemented with a personal health dataspace to give patients and survivors full control over their health data. Personal health dataspace in this context means that patients and survivors can manage their data, either within an electronic healthcare record system providing a personal data vault, or even more personalized, as a collection of relevant primary and secondary health data on a personal device. The funded Gaia-X projects HEALTH-X[16] and TEAM-X[17] are two example platforms that investigate this approach of the personal health dataspace. The personal health dataspace will be outlined in more detail in Concept 2.

Data authority with the patients and survivors

To put patients and citizens in control of their health data within ECPDC, a personal health dataspace needs to be developed with privacy by design principles, support secure processing approaches such as Secure Multi Party Computing and similar approaches to secure processing that are currently state of the art in the healthcare and research sector to prevent unintended and/or unauthorized access to sensitive personal and clinical health data of patients and citizens. A comprehensive, modern approach to cyber security needs to be part of an ECPDC design during all phases from design, inception, implementation, to operation of an ECPDC.

Equally critical for security and privacy is strong digital identity management of all stakeholders and users of ECPDC. Strong digital identities are a prerequisite for access to sensitive clinical data. The currently established eiDAS[18] approach will provide harmonised self-sovereignty identity (SSI) based implementations. We foresee that soon this will be the basis for a reliable and safe identity to be used within ECPDC.

Individual consent allows citizens full agency over the use of their data. In the personal health dataspace as implemented by HEALTH-X, this is implemented using open standards which can easily be adopted by all participants in the larger health dataspace.

We also outline why patients and survivors wish and need to amend clinical health data with personally gathered health data from personal health devices and patient reported outcomes.

Concept 2 implementation proposal

Concept 2 concludes with a proposal to implement these technologies to build the federated ECPDC satisfying the requirements of Rooms 2 and 3 (general and tailored information about cancer, access to personal health data, ability to share personal data with others) in a way that is easy to adopt at a Member State level: We envision an umbrella node which coordinates the interexchange of information between individual Member State nodes. To underline the way Concepts 1 and 2 build upon each other to make strong foundations for Concept 3, we introduce a New Architecture for the ECPDC house in Concept 2 (see Figure 3).

[14] https://digital-strategy.ec.europa.eu/en/news/simpl-cloud-edge-federations-and-data-spaces-made-simple-updated-august-2023
[15] https://gaia-x.eu/
[16] https://www.health-x.org/home
[17] https://project-team-x.eu/
[18] https://digital-strategy.ec.europa.eu/en/policies/eidas-regulation

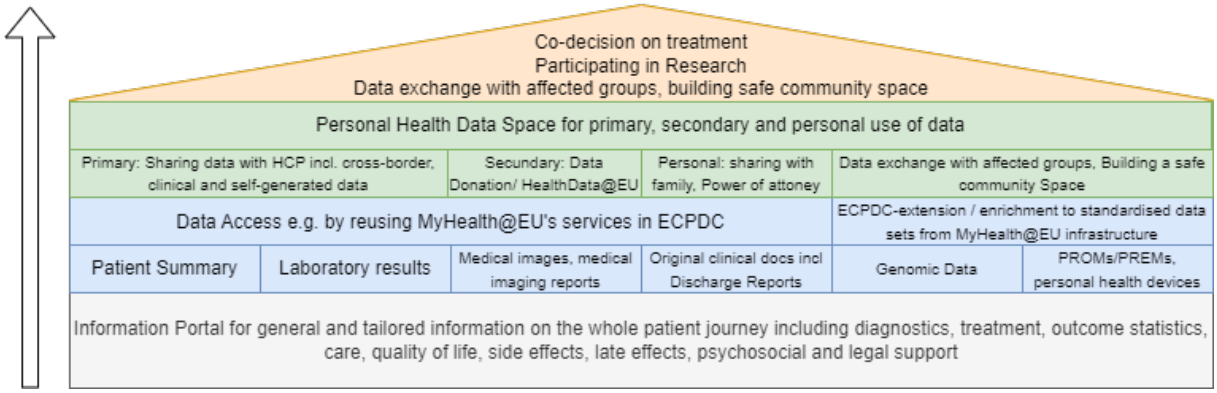

Figure 3: New architecture of ECPDC

4. Concept 3. Co-decision on treatment and participation in research

Outline of concept 3

The Cancer Mission Implementation Plan mentions the importance of the ECPDC providing patients with the means for co-decision on treatment (Room 4). This means that primary healthcare data must also be considered. We will address co-decision on treatment and data donation in Concept 3. As highlighted in Steering Committee discussions, the use of primary healthcare data is already covered by MyHealth@EU for cross-border uses, while national use and patients' access to their own data is a responsibility of each Member State. This may give rise to some conflicts regarding technology approaches and regulatory foundations for the use of primary healthcare data within ECPDC for co-decision on treatment. We will present some proposals to address these in an integrative solution.

Give patients and survivors a voice in treatment and research

General and tailored information, combined with health data from primary care and self-generated data, should serve two purposes: First: Provide patients with the means for co-decision on treatment (Concept 3), and second: Allow patients and survivors to participate in research as informed collaborators (Concept 2).

To ensure that patients and survivors can build trust in the ECPDC, all information provided should be labelled transparently as to the source of data and why it was decided to include it at a given point. The data provided must be actively curated and kept up to date. This requires cooperation with information experts in the field of cancer: (National) Cancer Information Services, (National) Patient Organisations, and (National) Research Organisations (Concept 1).

Data sharing in a safe community space

Patients want to share their data with family members and give electronic power of attorney. As of now, they do it in insecure environments such as photos, online chats, unsafe social media groups, email etc. That is why ECPDC needs safe community spaces for cancer patients to help patient organisations and others to offer cancer patient support groups in online formats without stigmatisation and the added risk of data abuse. To address this, ECPDC will need to provide a safe community space to be a better alternative to ad hoc sharing via unsafe channels. While the basis for this has its roots in Concept 1, full realization will only be possible in Concept 3.

Building trust among all stakeholders

ECPDC can only be effective when existing initiatives are coordinated, and their efforts aligned. For this, ECPDC needs directive power. This means that all stakeholders would need to be involved in an ECPDC steering body.

Together for the patients and survivors

As mentioned in the section about the implementation of Concept 2, we envision implementation of ECPDC as a federated system with an “umbrella node” interconnecting Member State nodes. All nodes will cover the same basic functionality, but Member States are free to add their own Member State specific functionality on top. Any data handling via ECPDC needs to be compliant with the EU’s General Data Protection Regulation (GDPR) and EHDS where applicable. As outlined above, EHDS will only cover parts of the ECPDC functionality, so GDPR is going to be the fall-back regulation unless national regulation or ECPDC-specific annexes to EHDS are being developed. We propose that all specifications of ECPDC should be agreed upon on the EU level so a common European approach to patient centered, data driven cancer treatment and research can be guaranteed.

The technologies listed above are essential to build a *Good ECPDC*. But apart from the data sources for the information portal, none of the technologies are cancer specific. In this way, ECPDC also could serve as a blueprint for a Common European Patient Digital Centre.

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