IN FOCUS

UNCAN.eu: Toward a European Federated Cancer Research Data Hub

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Summary: To enable a collective effort that generates a new level of UNderstanding CANcer (UNCAN.eu) [Cancer Discov (2022) 12 (11): OF1], the European Union supports the creation of a sustainable platform that connects cancer research across Member States. A workshop hosted in Heidelberg gathered European cancer experts to identify ongoing initiatives that may contribute to building this platform and discuss the governance and long-term evolution of a European Federated Cancer Data Hub.

INTRODUCTION

Recognizing the urgent need for a new level of investment and action against cancer, Europe's Beating Cancer Plan and the Mission on Cancer illustrate the institutional commitment to unite efforts across Europe to better understand this disease and enhance the management of patients. The first of the 13 recommendations of the Mission on Cancer (1) and one of the 10 flagship initiatives of the Europe's Beating Cancer Plan converge in supporting the launch of a European initiative to increase our UNderstanding of CANcer, UNCAN.eu (https://uncan.eu). To implement this objective, the European Commission proposed the creation of a European platform where researchers from Member States and all over the world may share and access cancer research data that address the greatest challenges in cancer research. This platform has been conceived as a federated network that connects national nodes and feeds from multimodal cancer data emerging from a series of pioneering research use cases. Through a Coordination and Support Action (CSA) named 4.UNCAN.eu, we are preparing a blueprint to guide the creation of a fully fledged, sustainable UNCAN.eu platform in Europe. Launched in September 2022, 4.UNCAN.eu will deliver this blueprint on November 30th, 2023.

A Strategic Road Map for UNCAN.eu

To enable the creation of a strategic road map that effectively contributes to a better understanding of cancer, 4.UNCAN.eu designed a bottom-up process involving hundreds of researchers and patient representatives across Europe to prioritize the most critical questions—research use cases—that need to be tackled in cancer research. Following this consultation, the CSA identified a defined number of ambitious, large-scale projects that form the basis of the UNCAN.eu platform proposed to the European Commission (2). These use cases are envisioned to be addressed by interdisciplinary, supranational, equitable research consortia working collaboratively. The ultimate goal is that these use cases generate transformative breakthrough discoveries in the six areas predefined by the 4.UNCAN.eu CSA, namely: prevention, early diagnosis, resistance to therapy, cancer and aging, pediatric cancer, and survivorship. This research agenda seeks to achieve three overarching goals:

- Cocreate an inclusive UNCAN.eu platform with participation from basic and translational researchers, data scientists, physicians, patients, and citizens from all over Europe to accelerate the implementation of this initiative.

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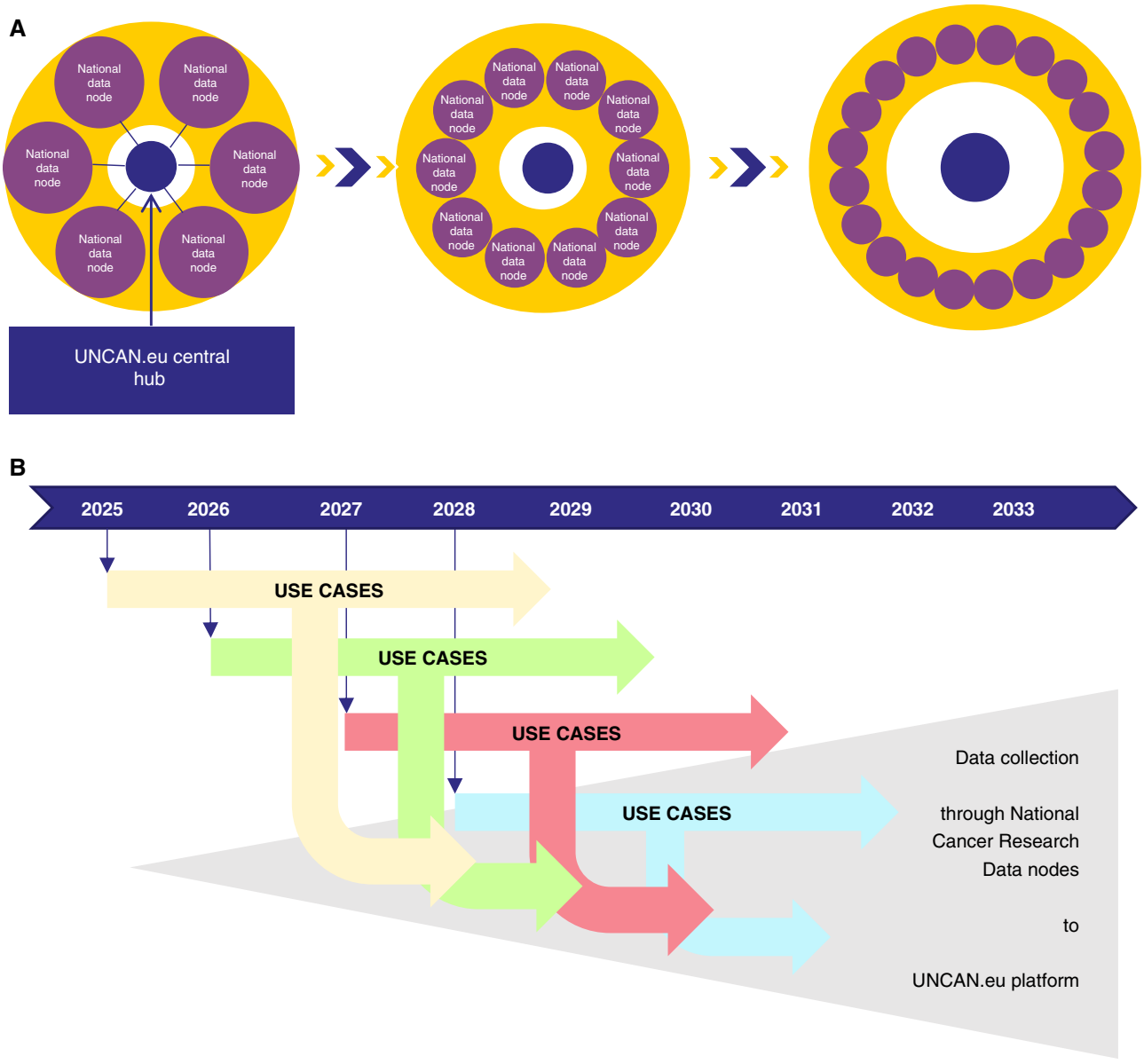

Figure 1. Strategy road map for the creation of the UNCAN.eu platform. **A,** Stepwise implementation of the UNCAN.eu platform through the creation of a National Cancer Research Data Node in every Member State of the European Union. **B,** A series of use cases will be launched every year, each of them addressing collectively a key challenge in cancer research, thereby generating or collecting cancer research data that will be used to leverage the creation of National Cancer Research Data Nodes and feed the UNCAN.eu platform.

- Tackle critical research challenges in basic and translational cancer research consistent with the need for a new level of understanding of disease mechanisms, as mandated by the Mission on Cancer. Key to these research programs is the development and implementation of frontier technologies, including all -omics, imaging, and artificial intelligence, which enable the generation of data sets at unprecedented scales. The UNCAN.eu platform will also be used for capacity building to reduce disparities in research capabilities across Member States.
- Promote and facilitate access to existing or newly generated research data sets from model organisms and clinical cohorts, including imaging, molecular, epidemiologic, and clinical data. Crucial to this end is to structure and learn how to disseminate these data between research teams across Member States and ensure these data comply with data handling regulations at national levels and the FAIR principles—findable, accessible, interoperable, and reusable (3)—through UNCAN.eu (Fig. 1A) to maximize their reuse potential and utility.

To identify collectively key questions in cancer research, the CSA 4.UNCAN.eu designed a Delphi process that concluded with two international face-to-face workshops organized in Barcelona and in Rome in 2023. During this consultation,

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researchers, policymakers, and patient representatives participating in the expert working groups discussed the key questions that must be addressed in the six predefined areas of investigation (2). The prioritization of research use cases considered their societal impact, innovation potential, technological challenges, and issues around the integration of the resulting data in a European Federated Cancer Research Data Hub as a platform to accelerate discoveries in these areas. The expert working groups further joined roundtable discussions to debate issues related to patient engagement; diversity of career stage, gender, and geographical distribution; and funding and innovation. Collectively, this open consultation pinpointed scientific challenges in need of transformative breakthroughs and identified ways to bridge inequalities among Member States and homogenize scientific productivity in Europe.

From an operational perspective, a Strategic Scientific Board will evaluate the wealth of cancer research data emerging from these use cases and advise the European Commission on new research challenges and strategies to enrich continuously the UNCAN.eu platform for maximizing the potential of collaborative data-driven cancer research.

With this setting in mind, 4.UNCAN.eu organized a workshop in Heidelberg in order to identify ongoing initiatives across Member States and at the European level that may contribute to building the UNCAN.eu platform and discuss a first framework of this platform.

National Nodes to Feed a European Federated Data Hub

Several national initiatives have been launched in recent years across Europe to connect cancer data. For instance, the Health Big Data (HBD) project coordinated by Alleanza Contro il Cancro, the largest Italian oncology research network, has set up a federated data platform to enable the collection, storage, sharing, and analysis of clinical and molecular data from 51 national research hospitals. Within each participating hospital, a local IT platform connects to a centralized platform within the national infrastructure for supercomputing, with original data remaining at local nodes. Based on specific projects and following established policies, features extracted from anonymized patient data are made available through a centralized platform for these to be used for research projects. As a reference project, 26 research hospitals are currently collecting high-resolution multidimensional data (eCRF, somatic and constitutive genomics, radiomics) in the context of a multicentric clinical trial focused on breast/ovary and colon cancers (GerSom trial). Within this context, the HBD could represent the national node to connect Italian research groups to the European UNCAN.eu federated data platform.

In France, the OSIRIS project is a collaborative national initiative launched by the Integrated Cancer Research Sites (SIRIC) accredited by the French National Cancer Institute. The aim is to create a network of federated databases to retrieve summary clinical and genomic features from across the network (4). In March 2021, the OSIRIS consortium released a first stable version of the project, providing a minimum data set for sharing clinical and biological data in oncology, organized with scalable and modular terminology. Major commitments of the project include using a bottom-up approach based on a national consensus, abiding to internationally established terminologies, and defining implementation rules to guarantee data consistency across institutions. By adopting a technology-agnostic format, OSIRIS is conceived as a data model compatible with other initiatives and infrastructures able to integrate any type of data. OSIRIS may therefore provide the basis to standardize different data modalities across French institutes and oncology hospitals and generate a national node that works as the connecting point to the UNCAN.eu data hub.

As part of the National Data Infrastructure initiative, Germany has established the German Genome-Phenome Archive (GHGA) as a nationally coordinated, interdisciplinary, federated data infrastructure for genome research and healthcare (5). This national node, coordinated by the German Cancer Research Center (DKFZ), seeks to enable the secure storage and controlled access to omics and related health data consented for scientific research in compliance with established ethical and legal frameworks and General Data Protection Regulation (GDPR) regulations. The node is part of the federated European Genome-Phenome Archive (fEGA) and seeks alignment with key European initiatives and standards, including the Genomic Data Infrastructure Initiative (GDI), ELIXIR (the European life-sciences infrastructure for biological information) and 1M+ Genomes. As a national node, GHGA connects a growing repertoire of data providers in Germany, including the National Centres for Tumor Diseases (NCT), the National Decade against Cancer, the German National Cohort (NAKO), and the national model project (genomeDE), and is positioned to connect to the UNCAN.eu platform.

In Spain, the National Network of Biomedical Research in Cancer (CIBERONC) spearheads the creation of a national data hub that homogenizes cancer registries and databases associated with national strategic programs in oncology. Building on a federated framework, this platform is envisioned to integrate data sets fed from national infrastructures in precision medicine such as IMPaCT-Genomics, INGENIO (INtegrative GENomic, digital Imaging and clinical information towards Precision Oncology Optimization), or the recently launched platform Immune4ALL in clinical immunooncology, supported by the Instituto de Salud Carlos III and the Spanish Ministry of Science and Innovation. This national node seeks to align with other national (IMPaCT-Data) and European initiatives (ELIXIR, 1M+ Genomes) and define a minimal data set that follows established standards to facilitate the secure storage, visualization, analysis, and interoperability of clinical, molecular, and imaging data. In alignment with existing European data platforms, once established and fully functioning, this national node will connect and feed the UNCAN.eu data hub and continuously evolve to incorporate additional initiatives that enrich the European platform.

In Hungary, the National Tumor Biology Platform includes the goal of establishing a centralized national data hub. This will include a federated, nationally coordinated, interdisciplinary genomic database containing somatic and germline genetic data, detailed pathology reports, and structured clinical data, which will serve as a decision-making platform for personalized cancer care. This centralized data hub will include the National Cancer Registry and provide a platform for

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outcomes research activities, especially those connected to European initiatives.

European Data Initiatives

The European Open Science Cloud (EOSC, https://digital-strategy.ec.europa.eu/en/policies/open-science-cloud) is an initiative launched under Belgian law in 2015 by the European Commission and European research stakeholders that seeks, in its own words, to "champion research data management to guarantee scientists' access to data-driven science." EOSC ambitions to develop a "Web of FAIR (Findability, Accessibility, Interoperability and Reusability) Data and services" for science that provides researchers and citizens with a federated and open multidisciplinary environment where they can publish, find, and reuse data, tools, and services for research, innovation, and educational purposes. In the foreseeable future, EOSC might evolve as an aggregator of existing services, rather than as a provider of new, centralized tools, with UNCAN.eu being one of these platforms.

Supported by the EOSC ecosystem and the European Commission, EOSC4Cancer (https://eosc4cancer.eu) is developing a coherent infrastructure for the exploitation of cancer research data, based on existing infrastructures, international standards, and open services and will allow for the storage, access, sharing, and processing of research data across Member States and associated countries, from basic to clinical cancer research. By bringing together a wide range of cancer research centers, research infrastructures, hospitals, and supercomputing centers in 14 European countries, EOSC4Cancer catalogs well-curated data sets and leverages the power of artificial intelligence (AI) and machine learning techniques to boost the analytical capabilities and elevate the potential of the cancer data ecosystem into new levels. Taking colorectal cancer as an initial working case, five subprojects were initiated that cover the continuum of a patient's trajectory, from cancer prevention to optimization of cancer screening programs, data-driven treatment selection, analysis of circulating DNA for clinical decision-making, and connect -omics data to clinical support systems. Every step of the patient's encounter with the use cases leaves a trail of data that are systematically organized and made available for reuse in research. We expect that the data trajectories and workflows as well as analysis infrastructure established in the context of EOSC4Cancer sets the ground for the UNCAN.eu platform.

The EUCAIM (EUropean Federation for CAncer IMages, https://cancerimage.eu), as UNCAN.eu, is a flagship of the Europe's Beating Cancer Plan. It aims to foster innovation and deployment of digital technologies to achieve more precise and faster clinical decision-making, diagnostics, treatment, and predictive medicine for cancer patients. It brings together 76 partners to deploy a pan-European digital federated infrastructure of FAIR, deidentified, real-world cancer images. Building on previous EU-funded projects such as the AI for Health Imaging (AI4HI) network (6), running European research infrastructures (Euro-BioImaging, BBMRI, EATRIS, and ELIXIR), and national/regional repositories, EUCAIM addresses the fragmentation of existing cancer image repositories. This platform pursues the creation of an atlas of cancer images that allows to develop and benchmark AI tools and contributes to integrate imaging data within the UNCAN.eu framework.

Lastly, an additional platform synergistic with the goals and vision of UNCAN.eu is CanSERV (https://www.canserv.eu), an EU-funded project embedded in the EU Cancer Mission and Europe's Beating Cancer Plan. This initiative blends a multidisciplinary consortium of 19 European partners consisting of research infrastructures and oncology organizations that provide innovative, interdisciplinary, and tailored oncology research services across the cancer continuum, with a comprehensive portfolio of over 200 oncology research services offered to cancer researchers through a unifying, single-access platform.

A Unified European Health Data Space

The use of patient data for research entails critical ethical issues, including the risk of reidentification from genomics data, the patients' right to informational self-determination, and their participation in research cocreation and governance. Best practice solutions and policy recommendations have been developed by multiple initiatives in Europe such as the EURAT consortium (ethical and legal aspects of next-generation sequencing), the GHGA, the 1+Million Genome Project and the Global Alliance for Genomics and Health (7–9), and others.

One of the recommendations of the Mission on Cancer to harness the potential of AI tools for enhancing oncological care is to create a European Cancer Patient Digital Center. This federated network of national infrastructures and nodes is aligned with the UNCAN.eu data hub and will be dedicated to patient-controlled and secure access to health data. Its primary goal is to support the quality of life of cancer patients and survivors. In addition to providing high-quality, reliable information in simple language for the patients and their caregivers, this initiative aims at empowering patients and survivors in codeciding their treatment and long-term care.

In the short term, the European structures and initiatives will need to adhere to the data governance framework and policies elaborated by the European Commission to establish the European Health Data Space (EHDS; ref. 10). This health-specific data ecosystem aims to define rules of access, common standards, and a governance framework for the use of health data that catalyzes research and innovation activities and can be used to inform health and policy making. By contrast to the European GDPR regulation that was subject to diverse interpretations by Member States, EHDS policies aim to be universal across Member States, preventing discrepancies in their interpretation and deployment. This harmonized approach will set the framework and regulatory entities that define the rules of access to health data and pave the way for the development of the UNCAN.eu data hub.

Toward a European Federated Cancer Research Data Hub

The sharing of patient data across borders, currently regulated by the GDPR, is paramount toward creating a functional European data hub that accelerates research progress. For improving data use while protecting privacy and data security, our expectation is that cancer research data generated from patients and their tissues are stored where these are generated (11) and be made accessible through a federated framework of national nodes connected to the UNCAN.eu

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platform. These national nodes will elaborate catalogs of metadata internally stored and available for reuse that are disseminated and may be queried by interested researchers from participating countries or regions. Accordingly, UNCAN.eu will be a European Cancer Research Data Hub organized as a federation of federations (12) that follows a stepwise implementation over time (Fig. 1A).

The research use cases proposed by UNCAN.eu will form the basis for this stepwise implementation of the federated data hub. High-quality data produced or collected in the context of large research consortia that address major challenges in cancer research will be shared through the European Federated Cancer Research Data Hub and expand gradually through consecutive calls that address new challenges in cancer research and enrich UNCAN.eu (Fig. 1B).

As the UNCAN.eu platform becomes more elaborate in the technical aspects of data management and processing, it can provide secondary access to cancer research data generated by independent initiatives at the national or international level, as well as to real-world cancer data, thereby increasing the opportunities for secondary use of these data. As cancer research questions and related data types continue to evolve, the flexibility and adaptability of UNCAN.eu will be essential to meet the expectations of the research community and the needs of patients. Ultimately, the fully fledged UNCAN.eu platform will reduce disparities in access to cancer research data and related tools and services.

We envision that the operational governance of UNCAN.eu platform will be structured in several domains. In addition to connecting to use cases and European-wide research projects, it will cover technical aspects of data curation, standardization, access, and interoperability. It will also oversee legal and ethical issues, to ensure compliance with the regulations by the European Health Data Space and develop strategies to reduce inequalities in access to cancer research data across European Member States (13). Furthermore, it will incorporate patient organizations to provide training to researchers, manage the dissemination of available cancer research data, and increase the awareness of European citizens (14). Lastly, as an interface between data providers and users, UNCAN.eu will interact with industrial partners. Although such interactions are justified and sometimes mandatory, the rules to regulate their participation need to be clearly defined and transparent to build users' trust and ultimately maximize the social impact of research activities (15).

CONCLUSION AND PERSPECTIVES

The CSA 4.UNCAN.eu will deliver a blueprint that was designed with the input of the full community of stakeholders and seeks to generate a sustainable strategic road map for cancer research in Europe. The European Cancer Research Data Hub, expected to be fully functional by 2026, and the research use cases identified through consensus consultation represent the cornerstones of UNCAN.eu (16). In the implementation stage, the European data hub will feed from data generated by consortia addressing the first wave of research use cases. In a subsequent stage, new research challenges identified through expert consultation will be proposed to the Mission Board for Cancer to launch competitive funding calls, and the federated data hub will organically evolve and enrich from new data sets and AI-powered tools. Research consortia addressing these research use cases are expected to mobilize challenge-focused, multidisciplinary teams across Member States that combine their creativity and expertise to provide concrete solutions to the most pressing challenges in cancer.

The UNCAN.eu is expected to set the grounds for a European Virtual Cancer Institute by 2030. This supranational platform should allow researchers to ask complex questions, combine diverse data types, and leverage technological advances and infrastructures to catalyze continuous, transformative progress against cancer.

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