



canSERV

Gap analysis report on digital ELSI services for cancer research, including the identification of two exemplar areas for tool development.

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1 Introduction

The COVID-19 pandemic has highlighted weaknesses in global healthcare delivery systems and public health responses, particularly the long-term national underinvestment in digitization.[1] Many found it surprising that healthcare applications and data still predominantly exist in silos and are not easily accessible among healthcare systems (e.g., healthcare research institutions and/or infrastructures) because of human and technical factors (i.e., little collaboration between teams and a lack of interoperability) and a lack of data integrity (thereby compromising trust in those data), and they are underpinned by redundant or not-fit-for-purpose technology. It also became clear that healthcare data, including for cancer services, are unequally available across the world, ultimately compromising the integration of new guidelines into routine practice, as well as the quality of digital health outcomes for individuals and society.[2] Although there is no single agreed-on definition of digital health,[3] for the purposes of this deliverable, we consider digital health to mean digital tools, technologies, and services that enable health teams (including all public, private, academic and infrastructure organizations that provide or support healthcare) to transform care delivery and empower individuals and society to manage health and well-being.

The European context

Europe as a whole faces a significant cancer burden. While representing less than 10% of the global population, it is dealing with a quarter of all cancers, reflecting an increasingly ageing population with comorbidities, as well as significant and persistent social and healthcare provision inequalities.[4]. It is estimated that over 3.9 million Europeans were diagnosed with cancers in 2018 (immediately pre-pandemic) and that almost 2 million in the same year died from these diseases. A slight majority of cancer patients (55%) will gain a prolonged disease-free survival, and even cure, but big killers with a relatively low impact of treatment remain, such as lung cancer (20% of all cancer deaths), colorectal cancer, advanced breast cancer, and pancreatic cancer.[5] These numbers are hiding important differences, observable in terms of incidence, stage at diagnosis, treatment opportunities, access to research and innovation of systemic treatments, and healthcare coverage, both at the country level (a divide between northern and western Europe and southern, central and eastern Europe) and at the regional level within a given country. Though the mortality rates decrease in the occidental part, they remain high in the more oriental regions of Europe.

In the EU countries, the economic burden was calculated at €126 billion in 2009, €52 billion in productivity loss, €37 billion on health care and €13 billion on drug expenses. Spending on cancer drugs has increased from €7.6 billion in 2005 to €19.1 billion in 2014 due to an increased number of patients treated better, but at very high costs. [6-7] Therefore, more comprehensive approaches to the various cancer diseases are required in all fields, from cancer prevention to precision care, from basic research to clinical trials and cohort surveys, including the support dedicated RIs and RI networks. The patient contribution to research,

treatment decisions and healthcare policies, individually and collectively through their representatives is also mandatory to change the vision of cancer prevention and cure.

canSERV in context

Taking this more holistic view into consideration, the European Commission has funded very few flagship projects aiming to address the fragmentation of existing services and provide digital platforms for the access of research infrastructures (RIs) and services to European researchers and citizens. To this effect, canSERV is one of these flagship EU-funded projects under the Horizon Europe programme that provides cutting edge, interdisciplinary and customised oncology services across the entire cancer continuum (<https://www.canserv.eu/>). The canSERV aim is to offer a comprehensive portfolio of oncology-related research services available to all scientists in EU member countries, associated countries and beyond. The canSERV project unites a multidisciplinary consortium of 19 European partners, consisting of RIs, key organisations in the field of oncology, project management and sustainability experts.

At the core of canSERV stands the transformation of the field of personalized medicine by maximizing the synergy across different RIs in the field of oncology. Through a unified trans-national access (TNA) platform and unified service catalogue (inclusive of ELSI, short for ethical, legal and societal issues) where both standardised and cutting-edge services for cancer research are available, canSERV will contribute to the provision of innovative, customised and efficient multiple services for different disciplines across the oncology field, though the following key barriers would need to be addressed.

A key barrier to supporting excellent research is the awareness and engagement of potential users of the RIs services. [8-9] They need to be aware that the services are available, know where to find them, be able to access them in a timely and simple process, and know what to expect to be engaged properly during the provision of services to obtain the best results. A second potential barrier is alignment in terms of mission and services across the different RIs throughout Europe for the field of oncology. Regarding the first barrier, the provision of services catalogues, inclusive of partners' initiatives, should go some way towards raising the awareness of services provided, and would be complemented by an active information dissemination campaign as per the canSERV structure. For the second barrier, the alignment across RIs comes at different levels: a) alignment towards a common vision and mission. The canSERV consortium has previously collaborated in different projects or other types of collaborations, thus already strong alliances have been formed already. During this project, further efforts will be dedicated to align our mission and vision (virtually as well as in-person during the consortium annual meetings) in order to operate as one united ecosystem (pan-European RI consortium) b) alignment of services, with the first step being the creation of catalogues to be used as benchmarking reference points, as well as access points to services.

WP11 within the EU and canSERV context

There are distinct work-streams within canSERV separated into work-packages (WP), and the current report forms part of WP 11, entitled "socio-economic dimensions and public

health measures”.

The objective of WP 11 is to provide access to high-quality services via:

- i) an Ethical, Legal and Societal Issues (ELSI) and
- ii) cutting-edge toolkits, utilizing digital healthcare applications and socio-economic methodologies that will support the optimization of the existing BBMRI-ERIC ELSI Knowledge Base, thus contributing to the development of better-informed public health measures.

To date, the ELSI services landscape in Europe remains highly fragmented and diverse. There exist individual RIs, associations or institutions that have implemented innovative helpdesk components [10-12]. These, however, tend to work within institutional remits (e.g., clinical trials, biobanking) or geographical premises (e.g., member countries) and not across entire domains, such as cancer. The European Missions, e.g., Mission on Cancer, signified a step-change in approach, unifying efforts across domains, and this is reflected in the approach of all canSERV WPs and partners.

In particular Deliverable 11.3 will focus on the following two specific objectives:

- i) A gap analysis report on existing ELSI digital services for cancer research, and
- ii) Based on the above outcomes, the identification of two exemplar areas for tool development in the future, that will be complementing those ELSI services by empowering individuals, such as cancer patients, and society to manage their cancer pathway(s).

The results of Deliverable 11.3 are presented within the current report.

2 Methodology

The methodology was divided into two sets of activities: A) a desk-based gap analysis review of the existing ELSI digital services, with findings validated by direct input by the RIs of canSERV, and B) the identification of two exemplar areas for future tool development.

A. Classification and Gap analysis

The following 12 ELSI tools & services were selected for this study, as they are either managed by the canSERV Ris (wholly or partially), and align with the available provision of ELSI services for cancer research:

- BBMRI-ERIC, ELSI Helpdesk. Available at: <https://www.bbmri-eric.eu/elsi/helpdesk/>
- European infrastructure for translational medicine (EATRIS). Regulatory Services. Available at: <https://eatris.eu/services/regulatory-services/>
- The European life-sciences Infrastructure for biological Information (ELIXIR). ELSI guidelines and ELSI services, including ELSI advice upon request. Available at:

<https://elixir-europe.org/about-us/grants-support>

- European Distributed Infrastructure for Research on patient-derived cancer Xenografts (EuroPRX). Dedicated ethics WP (WP5), focusing on the 3R principles (Replacement, Reduction, Refinement). Available at: <https://www.europdx.eu/europdx-research-infrastructure/europdx-research-infrastructure-objectives>
- International Agency for Research on Cancer (IARC/WHO). Ethics guidelines toolbox. Available at: <https://ethics.iarc.who.int/guidelines-and-useful-links/>
- European Marine Biological Resource Centre (EMBRC). Ethics policy compliance check. Available at: <https://www.embrc.eu/services/how-to-access>
- Microbial Resource Research Infrastructure (MIRRI). Legal/Regulatory Issues & standards expert cluster. Available at: <https://www.mirri.org/expert-clusters/>
- Youth Cancer Europe mobile app. Available at: <https://www.youthcancereurope.org/mobile-app/>
- Oncology Compass (Switzerland), a library of selected key publications and congress updates which can be filtered and searched by clinical characteristics. Available at: <https://oncologycompass.ch/>
- Care Across (Europe), a personalised services platform for cancer patients. Available at: <https://www.careacross.com/patient-services>
- European Cancer Patient Coalition (ECPC), Policy toolbox (Societal Issues section). Available at: <https://ecpc.org/policy/>
- European Clinical Research Infrastructure Network (ECRIN). Regulatory and Ethical Tools. Available at: <https://ecrin.org/regulatory-and-ethical-tools>

A.1 Frameworks

To allow a comprehensive approach to classifying and evaluating digital health applications, we employed two frameworks: Digital tools against COVID-19: taxonomy, ethical challenges, and navigation aid developed by Gasser and colleagues [13] and the Classification of Digital Health Interventions (DHIs) developed by the WHO [14]. The former model was used due to its popularity during the pandemic (and as such ensuring comparability with other contemporaneous studies), the latter model was used as it has become a global reference point.

The two frameworks have similarities and differences, and although they were not specifically developed for cancer, we believe that combined they offer a comprehensive framework for our empirical context, and the identification of areas of future development opportunities. Below we explain each framework in more detail.

Typology Based on COVID-19 Digital Tools

For the classification of health applications, we utilized the Typology Based on COVID-19 Digital Tools, which encompasses four pivotal categorical variables: key actors, data types, data sources, and the model of consent. This framework categorizes digital health applications into four functional groups, including Proximity and Contact Tracing, Symptom Monitoring, Quarantine Control, and Flow Modeling. Moreover, it adheres to a set of ethical principles guiding digital health tools, namely autonomy, justice, non-maleficence, privacy,

solidarity, and beneficence. Additionally, we considered several safeguards, such as protecting privacy, preserving autonomy, avoiding discrimination, repurposing, setting expiration dates, preventing digital inequality, and ensuring ethical use.

Considerations of safeguards were made to ensure the ethical and responsible deployment of digital health tools derived from Gasser et al. [13]. The safeguards are to uphold fundamental ethical principles and mitigate potential risks associated with digital health applications such as privacy concerns, autonomy and consent issues, discrimination, repurposing and data exploitation, digital inequality, and the imperative of ethical use. The safeguards are necessary to help protect sensitive personal and health data, which otherwise raises concerns about data privacy, security, and the potential for unauthorized access or data breaches.

Classification of Digital Health Interventions (DHIs):

In parallel, we employed DHIs to categorize the list of health applications [14]. This framework was specifically designed to establish a common language for describing digital health functionalities, primarily targeting public health audiences and fostering effective communication with technology-oriented stakeholders. DHIs prove invaluable for synthesizing evidence, conducting inventories, guiding planning processes, and addressing challenges within the health system. Furthermore, it is highly recommended for use alongside the Health System Challenges (HSC) framework, as it aligns technological solutions with identified health needs. A noteworthy feature of DHIs is their ability to link digital health interventions to System Categories, ensuring seamless interoperability among different digital health implementations.

A.2 Impact and Gap Analysis

By initially studying the impact, number of subscribers, and/or reads of ELSI tools & Services, as well as the correlation between the two, desk-based research was conducted to gain insight into the impact of the 12 ELSI tools & services. We expected to find quantifiable public information such as numbers of subscribers or requests answered. The consultation of websites and public information such as annual reports, however, did not yield sufficient results for a comparative analysis. We also executed a search engine optimization (SEO) analysis with the free online tool Sistrix (<https://www.sistrix.com/>) to gain insight into overall visibility and discoverability of the apps, tools, and services. However, since the Sistrix only provides results for the whole domain and not for sub-sections of a website, where most toolkits in question are located, the method was deemed redundant. Typically, the tools & services assessed do not have their own unique domain name (e.g. Oncology Compass), but are a subsite of a larger organization (e.g. BBMRI-ERIC, ELSI Helpdesk or International Agency for Research on Cancer (IARC/WHO), Ethics guidelines toolbox.

Consequently, we adapted the approach to contact the tools & services via email and contact forms. We also included the question, if specific reporting requirements, such as impact assessments, were requested by funders. The response rate was underwhelming.

Out of the 12 ELSI services & tools that were contacted, only 2 replied with information on reporting requirements.

In a final adjustment, we broadened the research towards a qualitative assessment studying the accessibility and types of services that were provided. The overall categories “accessibility” and “content” consisted of the following elements: findability (on the website through browsing and search function), information on the process of the service and the intended audience, the requirements for receiving such services (registration, creation of an account) and the description of the intended audience as well as the content of the service that is being provided. The data gathered allowed us to cluster the services by types, assess their accessibility as well as usability and ultimately identify areas, such as user friendliness and transparency that are currently lacking. The lack of findings was also used as a finding in the way that it supports theories on visibility, accessibility and speculatively even the funding situation.

B) Performance analysis

The following key elements are examined for each application:

Core Function Description:

This description included an overview of each application's role and its relevance to various users, including doctors, scientists, patients, academics and other users. We also highlighted the application's primary area of work and major functions. This enabled us to provide a comprehensive overview of each application's role, its utility to various users, such as doctors, scientists, patients, academics, etc., and its primary area of operation.

Key Actors Analysis:

Key actors involved in each application's ecosystem were categorized, i.e., the various stakeholders and entities primarily involved in the usage and ecosystem of each digital health application. These actors are classified into three main groups: government, academics, and the private sector.

Data Type Classification:

To ensure a clear understanding of the data handled by each application, we categorized data into two distinct types: sensitive and non-sensitive. The terms "sensitive" and "non-sensitive" data are defined based on the inherent nature of the information processed. Sensitive data typically includes personal or health information that, if disclosed, could result in harm, discrimination, or unauthorized use. On the other hand, non-sensitive data refers to information that, if disclosed, is unlikely to cause harm or damage. These definitions are crucial for understanding the potential impact of the data handled by digital health applications and for ensuring appropriate safeguards are in place to protect sensitive information.

Data Source Assessment:

We investigated the various sources of data that each application relies upon. These sources included IP addresses, cell site data, phone numbers, GPS information, Bluetooth connectivity, third-party data providers, and data contributed by citizens. Understanding the data sources is essential for evaluating by proxy the data quality and reliability.

Consent Framework Identification:

The consent framework employed by each application was analyzed to determine how users' permissions are managed. We identified three consent categories: Opt In, Opt Out, and None.

Primary User Targeting:

The applications' relevance to Healthcare Providers and Data Services was investigated, highlighting the sectors in which these applications have the most significant impact. Healthcare researchers and providers encompass a wide range of medical professionals, including doctors, scientists, and caregivers involved in patient care. Data services refer to entities responsible for managing and utilizing health-related data, such as RIs, scientific associations, and patient coalitions. These applications were designed to have a significant impact on the healthcare sector by providing specialized research services, fostering precision medicine, and enabling innovative R&D projects for the benefit of cancer patients across Europe.

Website Analytics Review:

To gauge the public engagement with these applications, the following website analytics were assessed the Number of Website Visitors, Bounce Rate, Average Visit Duration, and the Data Snapshot Date. (AT Internet, n.d.)

Number of Website Visitors: Total visits is the sum of visits to a website during a particular period. This foundational metric measures website traffic and provides insight into a website's reach. The number of visitors reported will be smaller than (or equal to) the number of visits. For this study the time-period for all the applications is constant.

Bounce Rate: Bounce rate is an important engagement metric that measures the percentage of visitors who leave a website after only viewing one page, usually indicating the percentage of visitors disengaged in the content.

Average Visit Duration: Average visit duration is the average amount of time a user spends on a website during a session and is a key indicator of engagement. This can be a strong indication of the quality of engagement with your site. For most websites, the longer the visit duration, the better. However, on the contrary, it could also indicate a very efficient website that provides all the relevant information expected, hence not requiring the visitor to spend too much time. This metric, when looked at in combination with other metrics, provides a true picture.

Data Snapshot Date: This metric captures the date when the website analytics data is

recorded for the study.

In order to obtain the website analytics data, Similarweb (<https://www.similarweb.com/>), was used as a trusted source for web analytics. The tool Similarweb, helps provide almost accurate, comparable metrics that are available publicly.

Through this methodology, a comprehensive, descriptive, qualitative and quantitative understanding of the eleven applications, their data practices, user targeting, and overall impact was achieved.

3 Results

ELSI Helpdesk, BBMRI-ERIC

Impact

The ELSI Helpdesk had 61 requests in 2021, according to the annual report by BBMRI-ERIC¹ that is publicly available on their website. This publication also serves as a reporting requirement from funders alongside Key Performance Indicators (KPIs). The number of requests is not available at the ELSI Helpdesk site. A direct request via email yielded that in 2022 the helpdesk processed 134 requests (i.e., 286 person hours). The annual report for 2022 has not yet been published.

Accessibility

Once on the BBMRI-ERIC website, the ELSI Helpdesk can be found quite easily after a few clicks. The website has a search function that also leads to the ELSI Helpdesk, but not as one of the first results when searching the keywords “ELSI Helpdesk” or “helpdesk”. There is a thorough step-by-step explanation on the process of submitting a request with the helpdesk and the intended audience is described and the requirements for receiving help are laid out. Additionally, there is a disclaimer for topics and services that the helpdesk does not provide. The services can be reached via an email address and there are no further steps required to use the service.

Content

The helpdesk is geared towards researchers and offers expertise and sharing of knowledge regarding ELSI issues for the use and benefit of the biobanking community. Moreover, there is a reference to the ELSI Knowledge Base that provides guidelines, trainings, and reading materials based on the ELSI Helpdesk requests.

Findability

Can be found, but not a top result. Thorough explanation of the process and additional disclaimers for topics that are not covered. Intended audience and requirements are explained. Email address for contact. No further steps required.

Visibility

Difficult to find directly through the search function.

¹ <https://www.bbmri-eric.eu/wp-content/uploads/Annual-Report-BBMRI-2021-2.1-IMPLEMENTATION.pdf>

Regulatory Services, EATRIS

Impact

There is no information on the number of requests available for the Regulatory Services and the email request remained unanswered.

Accessibility

The regulatory services are easy to find on the EATRIS website, however the service does not come up with the help of the search function with keyword search “regulatory services”. There is no explanation of the process or the intended user base of the service. Requests can be made through a contact form. To access the regulatory database, an account must be created and access must be requested.

Content

It is implied that the service is geared towards researchers. It offers expert opinion, orphan drug designation and scientific advice application at the EMA, pre-clinical and clinical plan development, informal scientific advice with selected national competent authorities for highly complex projects, access to EATRIS Regulatory Database.

Findability

Easy to find with a search. No detailed explanation of the process. Account necessary, must request access.

Visibility

Easy to find after a few clicks.

ELSI Guidelines and ELSI Services, including ELSI advice through request, ELIXIR

Impact

There is no information on the number of requests available in either the annual report or the impact dashboard and the email request remained unanswered.

Accessibility

The service is easy to find through the search function with keywords “ELSI guidelines”, but difficult to find by browsing the website. The process is thoroughly explained and so is the intended audience. To access the service an application form needs to be filled in. An email address is also available. The service cannot be accessed without the application.

Content

The intended audience are project coordinators. The service includes the ELIXIR ELSI guidelines.

Findability

Website doesn't have a search function. Process, intended audience and requirements are explained. Request sent via email.

Visibility

Easy to find after a few clicks

EuroPRX Dedicated ethics WP (WP5), focusing on the 3R principles (Replacement, Reduction, Refinement)

Impact

No information available on the website and the email request remained unanswered.

Accessibility

It seems as if the service is not (yet) available. It is only described as part of a work package, but there is no way to request the service or contact anyone from the work package. The service might not be available to the public at all.

Content

The description states that the aim is to provide guidelines and consultancy to users as well as information to the general public.

Findability

Can be found, but not a top result. No explanation of the process. No further steps required.

Visibility

Easy to find after a few clicks

Ethics Guidelines Toolbox, IARC/WHO

Impact

No information available on the website and the email request remained unanswered.

Accessibility

The toolbox is easy to find on the website, but there is no search function. There is no explanation of the process, however, since the toolbox consists of a collection of links, an explanation is not required. The intended audience is not explicitly mentioned. There are no further steps required to access the toolbox, such as registration. There is a general contact email address available.

Content

The toolbox offers a collection of ethics guidelines and links to materials.

Findability

Can be found, but not a top result. No explanation of the process. Intended audience and requirements are explained. Request sent via email.

Visibility

Easy to find, after a number of clicks.

Ethics Policy Compliance check, EMBRC

Impact

The publicly available annual report from 2021 states that there were 92 service requests overall. Every service request is being evaluated for eligibility, feasibility, and ethics.

Accessibility

The service is easy to find on the website and through the search function. The process is explained step-by-step as well as the intended user base for the service. The service can be reached via email and there are no further steps required, such as registration. However, the ethics check is only available for projects applied for at EMBRC.

Content

The intended audience are researchers from a team or organisations in need of a facility or biological resource(s). All requests at EMBRC are being checked for compliance with their mission and ethics policy i.e. the service is only for projects that have been applied for at EMBRC.

Findability

Difficult to find on the website. Process not explained, assessment is required to receive further information. Intended audience and requirements are explained. Request sent via

email.

Visibility

Difficult to ascertain.

Legal/Regulatory Issues & Standards Expert Cluster, MIRRI

Impact

There is no information available on the number of requests, but an inquiry via email yielded that their KPIs requested that at least half of MIRRI partners in the cluster should participate and that they should implement 3 thematic clusters, which they achieved.

Accessibility

The service is easy to find both by browsing the website and using the search function. There is no explanation on the process, but the intended audience and requirements are explained. The service can be contacted via email and there are no further registration steps required to access the service.

Content

The intended audience for the service are researchers in the public domain, companies, and policy makers. The service includes a public forum, interaction with experts, and advisory services concerning legal/regulatory issues.

Findability

Thorough step by step explanation of the process. Intended audience and requirements are explained. Request sent via email.

Visibility

Easy to find after a few clicks.

Youth Cancer Europe mobile app

Impact

No information on the app itself, but the Youth Cancer Europe Instagram account has 1352 followers² and their Facebook account has 11000 followers³. However, the app could not be found in the iPhone app store and the Youth Cancer Europe website does not provide a link to the app anymore. An email inquiry about the existence of the app remained unanswered until 21.09.2023.

Accessibility

As stated above, the app can no longer be found in the app store or by browsing the Youth Cancer Europe website. It is only findable on the website through a direct link.⁴ The process of the service is not explained, but the intended user base of the app is stated. In order to use the app it has to be downloaded, but the link was missing.

Content

The app targets young cancer patients and aims to enable them to connect with other patients and share experiences (peer-to-peer support).

Findability

² Checked on 21.09.2023

³ Checked on 21.09.2023

⁴ <https://www.youthcancereurope.org/mobile-app/>

No explanation of the process. Intended audience and requirements are explained. Request sent via website.

Visibility

Can be found, but not a top result.

Care Across (Europe) Personalized Services for Patients and Caregivers

Impact

No information available and email requests remained unanswered.

Accessibility

The website does not have a search function, but the services are easy to find after a few clicks. There is no explanation of the process, but there is an assessment that needs to be completed in order to receive further information. The assessment includes questions on the type of cancer, date of diagnosis, treatment etc. The requirements and the intended audience are explained on the website. There is a contact form for further information. Users have to create an account and complete the assessment in order to be able to access the service.

Content

The service is geared towards cancer patients and caregivers and offers personalized support for cancer patients to improve quality of life. The service seems to be tailored for each type of cancer and moment of treatment.

Findability

No explanation of the process. Intended audience and requirements are explained. Request sent via email.

Visibility

Easy to find after a few clicks.

Oncology Compass

Impact

There is no information on the number of users or subscribers, only the number of publications available (610+ articles). Email requests remained unanswered.

Accessibility

The service is on the landing page; therefore, no further search is required. The process of using the service is explained, however no information on intended users, but it is implied that the service is geared towards physicians (e.g. images used). Users need to create an account in order to access the data base. There is a contact form in case of further questions.

Content

The service is intended for researchers and physicians. It entails a library of selected key publications and congress updates which can be searched by clinical characteristics.

Findability

The process is explained but not in detail. Request sent via website.

Visibility

Difficult to find via search engines.

Policy toolbox Societal Issues section, ECPC

Impact

No information available and the email request remained unanswered.

Accessibility

The toolbox does not appear in the search function of the website when using keywords “toolbox” or “societal issues”, but it is not hard to find through browsing. There is no explanation on the process or intended audience. An email address is provided for further questions. No further steps are required to gain access to the information.

Content

The intended audience are researchers, the general public, and patient advocates. The policy toolbox offers information on current policy issues, articles, and videos.

Findability

No numbers on toolbox users in the annual report. Request sent via email.

Visibility

Easy to find after a few clicks.

Regulatory and Ethical Tool CAMPUS, ECRIN

Impact

No information available, email requests remained unanswered.

Accessibility

The tools are rather easy to find when browsing the website. There is a thorough step-by-step explanation of the process (user guide as PDF⁵). The intended users are stated. However, there is no contact form, only a feedback form. There are no further steps required to use the tool.

Content

The tool is for people involved in planning, initiating and conducting clinical trials on a national and international level. CAMPUS is a service for promoting and facilitating multi-national clinical research projects in Europe that provides access to regulatory information.

Findability

No explanation of the process. No reporting requirements. Only general info provided. No reply to email requests sent.

Visibility

Can be found, but not a top result.

The obtained results on typology and performance are summarized in the two tables below:

⁵ http://campus.ecrin.org/media/cms_page_media/7/Guidance%20User%201.0_Amended%20151215_WLxnvO3.pdf

		BBMRI-ERIC, ELSI Helpdesk	EATRIS Regulatory Services	ELIXIR, ELSI guidelines and ELSI services, including ELSI advice upon request	EuroPRX Dedicated ethics WP (WPS), focusing on the 3R principles (Replacement, Reduction, Refinement).	IARC/WHO Ethics guidelines toolbox	EMBRC Ethics policy compliance check	MIRRI Legal/Regulatory Issues & standards expert cluster.	Youth Cancer Europe mobile app	Care Across (Europe). Personalised Services for Patients and Caregivers	Oncology Compass	ECPC Policy toolbox Societal Issues section	Regulatory and Ethical Tool CAMPUS (ECRIN)
info on impact publicly available	impact	numbers of requests published in BBMRI-ERIC annual report; available to the public;	annual report includes numbers for EATRIS services, but not specifically for regulatory services	website has an impact dashboard that includes information on publications, policy impact and patents, but not on ELSI services; the annual report only features the life sciences login, but not the ELSI services;	no information on impact available; it seems that the services are not yet available, since there is no contact information	no information on impact or requests available	only annual report from 2021 available; 92 service requests, for the whole service catalogue which is: ecosystem access, biological resources, experimental facilities, technology platforms, e-services, training & library services, accommodation & catering -> all service requests are being evaluated for eligibility, feasibility and ethics	no info on requests for the expert cluster	1306 followers on Instagram	no info on impact or requests available	no info on subscribers/users	no numbers on annual report	no numbers on CAMPUS tool in annual reports
reporting requirements (inquiry via email)	impact	no reporting requirements	general info on EATRIS services in annual report; not specifically about regulatory services	no reply	no reply	no reply	no reply	no specific reporting requirements from EU but KPIs for EU Infradev project IS_MIRRI21: Participation of at least half of MIRRI partners in the clusters + Implementation of 3 thematic clusters. Both KPIs were achieved.	no reports available, no numbers, no info on app users/downloads	no reply	no reply	no reply	no reply
findability on the website through search function	accessibility	can be found, but not top result	difficult to find through search function	easy to find with search	website doesn't have search function	website doesn't have search function	easy to find with search function	can be found, but not top result	website doesn't have search function	website doesn't have search function	no search function, service is on landing page	doesn't come up in search	can be found, but not top result
findability on the website through browsing	accessibility	easy to find after a few clicks	easy to find after a few clicks	difficult to find on the website	rather difficult to find on the website	easy to find after a few clicks	easy to find after a few clicks	easy to find after a few clicks	difficult to find on the website	easy to find after a few clicks	service is on landing page	easy to find after a few clicks	easy to find after a few clicks, has its own domain
information on process	accessibility	thorough explanation of the process and additional disclaimers for topics that are not covered	no explanation of the process	process explained	no explanation of the process	no explanation of the process	thorough step by step explanation of process	no explanation of the process	no explanation of the process	process not explained, assessment is required to receive further information	process explained	no explanation of the process	thorough step by step explanation of process (user guide PDF)
intended audience/requirements email address/contact form	accessibility	intended audience and requirements are explained	no explanation	intended audience and requirements are explained	no explanation	no explanation email address for questions concerning the IARC ethics process	intended audience and requirements are explained	intended audience and requirements are explained	intended audience and requirements are explained	intended audience and requirements are explained	no explanation	no explanation	intended audience and requirements are explained
account necessary? Or other steps	accessibility	email address	contact form	application form + email address	only general contact email address for project	no further steps required	application form	email address	email address	email address	contact form	contact form	email
findability from search engine who is the service for? Researchers, general public, patients, patient advocates	visibility	no further steps required	account necessary to access regulatory database, must request access	must apply for access	no further steps required	no further steps required	must apply for access and create account	no further steps required	no further steps required	no further steps required	must register an account and answer questions beforehand	account necessary	no further steps required
	content	researchers	it is implied that the service is for researchers, but not directly spelled out expert opinion; Orphan Drug Designation and Scientific Advice application at the EMA; Pre-clinical and clinical plan development; Informal scientific advice with selected national competent authorities, for highly complex projects; Access to EATRIS Regulatory Database (free of charge)	project coordinators	users, general public	no info	researcher, team/organisation in need of a facility or biological resource(s)	researchers in the public domain, companies, policy makers	caner patients	patients, caregivers	researchers, physicians	researchers, general public, patient advocates	people involved in planning, initiating and conducting clinical trials on a national and international level.
what does the service entail?	content	expertise and sharing of knowledge regarding ELSI issues for the use and benefit of the biobanking community		among others the ELIXIR ELSI guidelines	providing guidelines and consultancy to users as well as information to the general public	collection of ethics guidelines and links to materials	Eligibility & ethical check the requests are being checked for compliance with their mission and ethics policy i.e. service is only for projects that have been applied for at EMBRC	public forum, interaction with experts, advisory services concerning legal/regulatory issues	enables young cancer patients to connect with other patients and share experiences (peer-to-peer support)	personalised support for cancer patients to improve quality of life	library of selected key publications and congress updates which can be searched by clinical characteristics	information on current policy issues, text, videos	promoting and facilitating multi-national clinical research projects in Europe, CAMPUS provides simple and easy access to regulatory information

Application Service	Core Function Description	Key Actors	Data Type	Data Source	Consent	Targeted primary user	Number of Website Visitors	Bounce Rate	Avg Visit (in Minutes)	Data Snapshot Date
BBMRI-ERIC, ELSI Helpdesk	ELSI SERVICES & RESEARCH Conduct research relating to ethical, legal and societal issues (ELSI) Facilitating compliance with regulatory requirements and best practice standards Provide training and workshops on ELSI issues	Academics	Non-Sensitive	Third Party	Opt In	Data Services	31800	46.65%	00:02:12	Jul-23
EATRIS Regulatory Services	EATRIS is the European infrastructure for translational medicine. Brings together resources and services for research communities to translate scientific discoveries into benefits for patients. Research Services Innovation Services Education & Training	Academics	Non Patient Identifiable Information	Third Party	None	Data Services	41100	78.92%	00:00:18	Jul-23
ELIXIR, ELSI guidelines and ELSI services, including ELSI advice upon request	ELIXIR is an intergovernmental organisation that brings together life science resources from across Europe. These resources include databases, software tools, training materials, cloud storage and supercomputers.	Govt	Non-Sensitive	Third Party	None	Data Services	36000	63.45%	0:01:33	Jul-23
EuroPRX Dedicated ethics WP (WPS)	Developing a user-friendly public repository to facilitate access to the +1500 PDX models from over 30 different cancer types currently curated by the EuroPDX Consortium	Academics	Sensitive	Third Party	Opt In	Data Services	9500	NA	NA	Jul-23
IARC/WHO Ethics guidelines toolbox	The major role of IARC in ethical appraisal is the final assurance to the international community that whatever constitutes ethical approval, transparently demonstrates the fundamental principles of doing no harm, respect, beneficence and justice. IARC is the guarantor of protection for study participants by its insistence on internationally consistent and complete ethical review of research.	Academics	Sensitive	Third Party	Opt In	Data Services	682600	43.16%	00:05:38	Jul-23
EMBRIC Ethics policy compliance check	EMBRIC is a European 'research infrastructure' that provides researchers and companies with access to marine organisms and the facilities to study them, including experimental facilities and technological platforms.	Academics	Non Patient Identifiable Information	Third Party	Opt In	Data Services	32400	77.67%	00:00:47	Jul-23
MIRRI Legal/Regulatory Issues & standards expert cluster.	MIRRI brings together 50+ microbial domain Biological Resource Centres (mBRCs), culture collections and research institutes from ten European countries. MIRRI serves the bioscience and the bioindustry communities by facilitating the access, through a single point, to the broadest range of high-quality microorganisms, their derivatives, associated data and services, with a special focus on the domains of Health & Food, Agro-Food, and Environment & Energy.	Academics	Non Patient Identifiable Information	Third Party	Out Out	Data Services	29000	NA	00:00:33	Jul-23
Youth Cancer Europe mobile app	Youth Cancer Europe is made up of youth cancer organisations from across Europe. Together we can help shape European policy, collaborate in and promote research, fight for better access to care, for better treatments, better conditions and help fix disparities that exist across Europe for young people fighting cancer.	Private	Sensitive	Third Party	Opt In	Data Services	14700	NA	NA	Jul-23
Care Across (Europe)	Personalised services for patients and caregivers	Private	Sensitive	Third Party	Opt In	Data Services	20300	22.88%	00:01:35	Jul-23
Oncology Compass	Oncology Compass features a library of selected key publications and congress updates which can be filtered and searched by clinical characteristics	Academics	Non-Sensitive	Third Party	Opt In	Healthcare Provider	13700	52.68%	NA	Jul-23
ECPC Policy toolbox Societal Issues section	ECPC ensures the voice of cancer patients in Europe is represented in all relevant policymaking decisions in the European Union. It is the largest European non-profit cancer patients' association. Covering all 27 European Union Member States, and many other European and non-European countries, we represent those affected by all types of cancers, from the rarest to the most common.	Academics	Non-Sensitive	Third Party	Opt In	Data Services	32300	41.93%	00:07:50	Jul-23

4. Discussion and next steps

It becomes evident from this current report that none of the services provided any data directly on their websites concerning number of requests, users or subscribers of the selected services and toolboxes, or impact. EATRIS and ELIXIR, for instance, published data on their services, but grouped the toolboxes or apps in question in larger departments or service clusters. Only BBMRI-ERIC and EMBRC provide data on the numbers of requests in their annual reports. We can speculate that each tool & service provider knows the answers to our questions and deliberately chose not to publish it or simply does not have capacity to respond to our survey. In contrast, we would be surprised if such data would not be collected at all. Not having had the possibility to follow up further is certainly a shortcoming of our research, which by design largely focused on publicly available data. All 12 services were contacted directly via email in order to enquire about their reporting requirements. Only 2 out of the 12 replied to us (BBMRI-ERIC and MIRRI). We can speculate that this is due to a resource issue in only being able to respond to actual users or our request was filtered out in spam, among other possibilities. To extend the research towards an in-depth qualitative study was out of scope of the study.

In return, focusing on the intended purposes of the 12 selected tools & services and their limitations regarding their content and accessibility proved insightful. We were able to focus on overall user-friendliness by describing accessibility in terms of findability on the respective websites and the kind of information that was provided concerning the process of receiving help or gaining information. Moreover, we determined if users needed to take any further steps (e.g. registering for a profile) in order to use the services on offer.

All the ELSI tools & services are not located on the landing page of their respective host organizations' websites, with Oncology Compass being the notable exception. It is a standalone service and has its own domain. All ELSI tools & services are specialized and geared towards a certain audience, e.g.. ELSI Helpdesk (BBMRI-ERIC) for researchers in the wider biobanking community, Care Across (Europe) for cancer patients and caregivers. Simple search engine inquiries, however, often do not lead users to their sites. Rather, the findability of these services relies heavily on word of mouth, advertisement among peers at conferences and other meetings, the organizations' newsletters and social media, and patient representatives. The focus of our study, however, was not assess findability of ELSI tools & services per se, but rather a quick study of the findability within the respective host organization's websites. Overall, the tools and apps are quite easy to find, if users know what they are looking for. Certainly, some of the services seem to be hidden by choice. One might suspect due to a lack of funding and capacities to answer many requests, especially those helpdesk formats that offer individual consultation or guidance. Another explanation could be that it is one tool of many of the organization.

There are two trends when it comes to the access of services: immediate easy access on the one hand versus required registration or assessment for the benefit of information on their user pool on the other. The service with the highest hurdles to put forward a query, Care Across (Europe), is also the one that offers the most personalized support. In this specific case, lack of easy accessibility is by design, filtering out serious user requests and providing tailored, quality responses. A number of services offers low-threshold access to their quality content, which is less tailored but more general (i.e. databases, collections of links, further readings).

Generally, it can be said that there is a demand for guidance, knowhow and information on ELSI and regulatory aspects from a variety of groups: the public(s), patient representatives, patient groups, policy makers, project coordinators, and researchers. Most services are clearly set up to cater to a specific audience and communicate their services well by

providing a description for whom their service is intended (i.e., biobankers). This adds immensely to the overall accessibility of the tools, since users are more likely to access a service if they know whom it is for and what it entails. It also implies that the services have a clear understanding of their user group and tailor their services accordingly.

The content of the service differs greatly between the different toolboxes and apps. There are services like the ELSI Helpdesk of BBMRI-ERIC that offers 1:1 expert advice and guidance for any researcher of the wider biobanking community from one of the member or observer countries of BBMRI-ERIC. In contrast, the ethics policy compliance check by EMBRC is only offered to projects that apply at the organization. There are services, such as the IARC/WHO Ethics Guidelines Toolbox and the Oncology Compass that are a collection or database of articles and research. The Youth Cancer Europe App and Care Across (Europe) are targeted to patients and offer a communication platform on the one hand and personalized services on the other. Access to regulatory information is provided by the CAMPUS tool by ECRIN, the EATRIS database and MIRRI Experts Cluster.

The findings above provide important background information for the development of the catalogue of services and subsequently dissemination strategy (including website placement, findability in search engines, etc.). Amplifying visibility and increasing user traffic must be a critical goal for any service or tool, besides user satisfaction (quality of service provided) and a graphically appealing design that is fit for purpose.

The research also emphasizes the existing wide and non-uniform methodology deployed to get in touch with the providers/ELSI expertise, the extra actions needed to obtain the services, and the differences in search engine visibility. Based on insights from successful, best-practices from successful non-profit, non-governmental cancer organizations with a global reach a number of strategies can be proposed for improving the current impact. These strategies include setting aside money specifically for audience development, putting in place a continuous improvement module, using Google Ad campaigns, guaranteeing live availability, implementing SEO and SEM tactics, maintaining dynamic content, incorporating digital services into workflows, and using animations to engage audiences. To effectively report the impact and effectiveness of digital cancer services and web applications to funders, it is essential to track and report on key metrics, however, these yet remain to be defined.

Next steps - Internal to canSERV

The results from the two WP11 Deliverables, 11.1 and 11.3 will be presented to the canSERV consortium as part of the internally scheduled reporting cycle. Feedback will be sought regarding the two areas of potential development highlighted in the subsequent sections.

External to CanSERV

The results from the two WP11 Deliverables, 11.1 and 11.3 will be disseminated in appropriate scientific meetings on the subject of digital health, as they represent the first such comprehensive analysis of impact for ERICs in relation to cancer research and treatment. Any dissemination will take place according to the existing canSERV internal guidelines.

Limitations

This study is not without limitations. Firstly, the study has looked into the digital health tools identified by Deliverable 11.1. It is understood that more such digital health tools exist, created as part of EU-funded initiatives. As such this study should only be viewed as indicative and not representative of the entire spectrum of digital cancer services available. Secondly, the lack of uniformity for the format, reporting and structure (within the website) of these digital health tools has hampered direct comparability. Finally, while there are certain areas of overlap between the two classification frameworks, neither is specifically appropriate for this kind of research. Some limitations include the accuracy, granularity, and quality of data that vary greatly across the different data sources.

Areas identified for potential future tool development.

- 1) Informational add-on, modular tool that can explain the process. A generic tool can be created that explains the access and response process – sufficiently generic that can be used as a template, and then adapted for use by each infrastructure. As it is not possible for such a tool to account for all eventualities and complexities, it would need to be based on first principles primarily.
- 2) Improvement and optimization of the 3 top-scoring existing applications, so that they constitute case studies for the future, and can be used for the development of a generic blueprint for future studies and applications.
- 3) Informational add-on what is within/outside the scope of the service provided (e.g., competency in contrast to legal departments and research ethics committees).

4 Link to other deliverables and milestones

The below section lists the links to other deliverables and milestones, the recommendations as part of the current Deliverable (D11.1), as well as any deviations from the original grant agreement with appropriate justification.

Deliverable number	Deliverable title	Remarks
D5.1	Report of the clinical trial helpdesk procedure	Ensure that there is complementarity while avoiding duplication of work
D7.3	Ethics Review	The findings from WP11 will inform the within-consortium ethics review
D7.4	Update on Ethics Review	The findings from WP11 will inform the within-consortium ethics review
D8.1	Implementation of the canSERV access management system	Ensure that there is alignment for information provided
D10.1	ccess report on material/ data requested by TNA activities. Report of user demands – needs and problems	Ensure that there is alignment on information provided

Recommendations

Through the above work the following recommendations are made:

- 1) That the results of this work are presented to the canSERV consortium, and following feedback are presented at appropriated scientific conferences.
- 2) That a list of optimization action points is made and distributed to all canSERV consortium members, to drive a grassroot improvement in the presentation, performance, findability, outreach and impact of existing digital services.
- 3) That the two highlighted areas for further development are discussed with the consortium members for further refinement prior to proof-of-principle tool development.

Deviations

The canSERV consortium member ECPC was withdrawn from the consortium during the conduct of this work, relating to some minimal delays, which have since been addressed successfully through additional workload by both BBMRI-ERIC and IARC/WHO.

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Disclaimer

Where authors are identified as personnel of the International Agency for Research on Cancer/WHO, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/WHO.

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