



Unlocking the Potential of Digitalisation in Cancer Care No Stopping Us Now!



Digital Health Network



The Digital Health Network is one of the European Cancer Organisation's Focused Topic Networks, established as part of our Strategy for 2020-2023. The Digital Health Network was launched in July 2020.

More information is available on our [website](#).

If you would like to find out more about the Digital Health Network, please contact us at: info@european-cancer.org

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Contents

Acknowledgements	4
Executive Summary	5
Introduction	8
Section 1: The Power Of Data	10
Section 2: Telemedicine	26
Section 3: Artificial Intelligence	31
Section 4: Other Digital Solutions	40
References	50

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^a Community 365 is a group of charity, philanthropy and industry contributors to the Focused Topic Networks of the European Cancer Organisation. Community 365 provide ideas, guidance, practical support and resources for our work in convening stakeholders and building consensus in the European cancer community. Community 365 contributors do not have a decision-making role in our policy work. Rather, policies of the European Cancer Organisation, such as those represented in this document, are agreed by our Board after consultation with our Member Societies and Patient Advisory Committee, via our Policy Pathway process. More information here: www.europeanecancer.org/community-365

Executive Summary

Digital transformation will play a key role in meeting the post-pandemic world's challenges related to healthcare. However, achieving this will require that relevant policies are implemented to address critical challenges around accessibility, data interoperability and digital literacy to ensure that no one is left behind during this digital transformation. A successful digital health transition requires empowering patients and rethinking education and life-long training, as well as bringing about strong governance models that inspire and sustain public trust.⁴

It is with these perspectives and objectives in mind, that the Digital Health Network of the European Cancer Organisation has embarked on the writing of this paper. Several distinct areas have been selected to illustrate the opportunities and challenges related to the digitalisation of oncology. Our paper aims to contribute to a facilitative policy environment for digital healthcare's contribution to cancer care and treatment by providing several particular recommendations to inform present and upcoming policy initiatives at the European level.

The Power of Data – Getting the Balance Right

The Covid-19 pandemic has shed fresh light on the power of data for improving outcomes in cancer care, from real-time observation of the impacts of the pandemic to optimisation of care. The insights we can gain from comprehensive and quality data have the potential to bring enormous benefits both to patients, health systems and society, guiding decisions for care, research, and regulatory issues. But the pandemic has also revealed long-standing barriers in our health systems that limit the optimal collection, use and sharing of data: with data systems that are not interoperable, regulations lagging behind technical advances and poor integration of data into clinical practice and levels of e-health literacy struggling to keep pace with developments.

Telemedicine – Harnessing Digital Potential for Quality Care and Better Access to Cancer Care

Telemedicine provides promising opportunities in helping to ameliorate challenges of access to care and workforce shortages by allowing for some efficiencies in the deployment of the oncology workforce. If wisely utilised, telemedicine can result in improved access to clinical cancer services. Minimising the disruption caused by the disease to patients, increasing patient satisfaction and increasing cost efficacy also provide specific rationales for the implementation and expansion of telemedicine in cancer care. Telemedicine can contribute to an increase of the number of cases managed daily by healthcare professionals, helping to ensure continuity of care, and facilitating the connection between large and small cancer centres.

While enhanced accessibility of cancer services for patients is to be welcomed, more consideration is required as to how telemedicine is best deployed in routine cancer care over the longer term.

Despite the above benefits and European initiatives, telemedicine is still far from being widely used in Europe. Difficulties include the costs of implementing a telemedicine service, hindrances with the interoperability of technical infrastructures, concerns about confidentiality and privacy of health data, lack of ethical rules specifically applicable to telemedicine, hesitations from health professionals regarding their liability exposures, and uncertainties regarding the legal framework of telemedicine in Europe.

Artificial Intelligence – The Potential of Artificial Intelligence to Enhance Cancer Care: Reality or Illusion?

Artificial Intelligence systems have the ability to identify patterns within large amounts of data and to thereby bring forward unique insights for clinical decision-making. In so doing, AI has the potential to help transform cancer care with more automation, accuracy, optimisation, and efficiency for cancer patients, and also for those at risk of developing

cancer, as well as for healthcare systems overall. As a result, investment in AI in healthcare has dramatically increased in the past decade. Policy discussion about AI's application to cancer care is now frequent and common among healthcare decision makers, governments, investors, innovators, and the EU institutions.

The possibilities and applications of AI can play an important role in enhancing the quality of cancer detection, treatment, and overall cancer care, particularly at a time when Covid-19 is impacting upon diagnosis and treatment of cancer. Indeed, AI is being indicated as a means to improve the quality and timeliness of cancer detection as well as the quality of life of patients, in facilitating the appropriate selection of treatment for different cancer subtypes, and facilitating digital monitoring for clinical trials, leading to an enhanced overall delivery of cancer care and ultimately helping in removing inequalities in access to healthcare services.

However numerous challenges, including scientific, technical, and ethical questions remain to be solved to assess whether AI will keep its promises for cancer care. While promises and potentials are promising, we need to clearly assess where and when AI can support cancer care.

Other Digital Solutions – Blockchains, Virtual Reality and Robotics. New Digital Frontiers in Cancer Care

As Artificial Intelligence technology and digital transformation mature, there are great expectations of their potential to further promote the advancement of medicine through a wide range of new applications. The Digital Health Network has identified blockchain, virtual reality, and robotics as key applications to put the spotlight on.

These new technologies provide their own digital frontiers in cancer care innovation. Relying on the availability and quality of vast amounts of robust unbiased data:

- Blockchain technology could contribute to new ways of managing and sharing health data, offering solutions to several privacy-related healthcare issues.
- Virtual Reality could offer novel means of delivering specialist medical training, for both doctors in training and students, patient treatment, medical marketing, and educating people about a medical condition, with potential to reduce both centralisation and cost of medical specialisation.
- Robotics promise improvements all along the disease pathway: prevention, medical diagnosis, surgical interventions, treatment, and long-term care.

However, a significant amount of work remains to be done before fully integrating these new technologies into clinical practice. Not every healthcare system across the European Union is able to accommodate and afford such innovation. Dedicated regulatory frameworks are necessary. In addition, to fully reach this new frontier, a cultural transformation is needed. It is important that healthcare professionals and patients/citizens are trained and aware of these new tools, know their potential and their shortcomings, and are knowledgeable enough to understand when and how they can be applied. The infrastructure could even be already there but if there is not any cultural transformation, there is no implementation of digital tools and services.

Key Policy Recommendations:

The Digital Health Network of the European Cancer Organisation believes that the European Union should seize this moment of opportunity to unlock the full potential of the digital transformation of cancer care and to build trust in these solutions.

- » The European regulatory framework needs to be updated to accommodate the new challenges brought by the digital transformation of cancer care. The cancer community welcomes the European Health Data Space as a new framework encompassing all other initiatives and legislations to have a dedicated framework for health data, supporting the digitisation of cancer care and reducing the implementation pitfalls of the European General Data Protection Regulation (GDPR).
- » Various European funding schemes should support:
 - Education and training programmes, with practical orientation, for healthcare professionals to ensure that they are able to fully use digital technologies.
 - Awareness programmes and digital literacy programmes for patients and citizens to ensure they are able to benefit from the digital transformation of care.
 - Healthcare systems and institutions to implement and have access to innovation and technology.
- » The true potential of digitalisation can only be reached if authorities and organisations collaborate on creating robust and workable standards for the governance and exchange of data. To energise the agenda, we recommend the establishment of targets and benchmarks for data interoperability. Within this, the lack of standardisation and fragmentation of data sets should be addressed with guidelines and European standards and processes.
- » **Patient first:** the digital transformation of cancer care should follow the principle of co-creation, including the patients, as well as the healthcare professionals from the start in decision-making processes.

Introduction – Great Opportunities Often Come with Great Challenges

The advance of digital technology revolutionises all our lives on an ever-increasing basis. Cancer care is no different in this respect. The Covid-19 pandemic has shown the potential of digitalisation to transform the ways in which we live, bringing more efficiency, transparency and convenience. With the pandemic, we have witnessed the importance of having access to high-quality and reliable data and being able to share it across borders, for example, to monitor the spread of disease, rapidly share research findings, and to test and compare policy approaches.

Our Digital Health Network passionately believes that by unlocking the potential of digital health and data-driven solutions, we can accelerate the shift towards patient-centred cancer care, with increased access and improved patient outcomes.

Digital health is a broad, multidisciplinary concept that applies digital transformation to the healthcare field, incorporating software, hardware and services. Under its umbrella, digital health includes mobile health, apps, electronic health records, telehealth and telemedicine.

The Covid-19 pandemic has further exposed many pre-existing problems and challenges facing health care and cancer care in Europe. But from moments of crisis there are opportunities to learn, improve and find new solutions. Such known challenges include an ageing population, unequal quality and access to healthcare services and shortage of health professionals. Digital transformation is a crucial tool to help bridge not only the gap between the demand for healthcare and the supply of healthcare professionals and other resources, but also the gap between the experience and quality of care that patients across Europe receive.

With the rise of new digital technologies, cancer care and research has been inundated with an avalanche of more and more data, often also more complex. While such data can be extremely useful in improving patient empowerment and patients' outcomes, such quantity and complexity of data is also very complex to proceed with. However, with the right tools and models, this data can be used to improve care for underserved communities, to improve therapeutics, precision health, care delivery

and prevention, allowing clinicians and patients to become proactive in disease management. Data can be turned into actionable knowledge either for care, research but also policy and regulatory purposes. However, doing so in an effective and cost-efficient manner is very challenging. Careful consideration is required with respect to such issues as implementation pitfalls, best practices, and the overall vision of future practice that is being sought. While numerous policies to help drive digital transformation have been initiated at both the European Commission and EU Member States, progress has not kept pace with stakeholder expectation, and digital maturity varies both within and between countries.

- » Digital literacy among all, including healthcare professionals and patients, is paramount for the successful, effective and ethical implementation of digital solutions in healthcare: education and training relating to digital health has been recognised as a priority for developing the future healthcare workforce and allowing patients to benefit from better health services.
- » Similarly, while patients are often among the drivers of the digital revolution in healthcare, it remains uncertain whether all patients in Europe are ready to increase uptake of the use of digital services. Sensitivity in approach is required to reflect this.
- » To ensure that data-driven health delivers promises, such as in the area of personalised medicine, it will require system investment in infrastructure, novel algorithms and validated techniques to create an ecosystem that truly optimises data use.
- » Regulatory barriers at the European level still hamper the potential of digitalisation and must be addressed.

One of the key initiatives that resides in the 'European Health Union'¹ package is the creation and implementation of Europe's Beating Cancer Plan² which, in turn, is connected to two top priorities the EU Commission has put forward on its agenda: digitalisation and personalised health. The digital

transformation can produce significant benefits for the health sector since 30% of the world's stored data are currently produced by health systems, and as cancer care is one of the major disease areas that will benefit from the European Digital Strategy, it is also one of the sectors which will benefit more thanks to better exploitation of real-world data and the use of Artificial Intelligence (AI). Digitalisation can also efficiently provide cross-border services and cooperation between countries, improve the sharing and flows of data, as well as support telemedicine as a new eHealth Digital Service. The European Health Data Space³ (EHDS) is aiming to remove barriers that persist around interoperability, exchange, and access to different types of health data (such as the Electronic Health Records EHR, genomics data, data from patient registries etc.), legal and ethical standards, governance, cybersecurity, technical requirements, and compliance with personal data protection rules. In this regard, it is extremely important to ensure that health data exchange in Europe truly does operate on the core principles of openness, transparency, and wide stakeholder engagement.

Finally, the digital revolution challenges the status quo. It demands both a cultural and regulatory shift to fully unlock the potential of digital health in cancer care.

Section 1: The Power of Data

Getting the Balance Right

The Covid-19 pandemic has shed fresh light on the power of data for improving outcomes in cancer care, from real-time observation of the impacts of the pandemic to optimisation of care. The insights we can gain from comprehensive and quality data have the potential to bring enormous benefits to patients, health systems and society, guiding decisions for care, research, and regulatory issues. But the pandemic has also revealed long-standing barriers in our health systems that limit the optimal collection, use and sharing of data: with data systems that are not interoperable, regulations lagging behind technical advances and poor integration of data into clinical practice.

1. Health Data – Definition & Importance

Health data are a very specific type of data, which are defined by the European Data Protection Supervisor as follows:

“Health data refers to personal information that relates to the health status of a person. This includes both medical data (doctor referrals and prescriptions, medical examination reports, laboratory tests, radiographs, etc.), but also administrative and financial information about health (the scheduling of medical appointments, invoices for healthcare services and medical certificates for sick leave management, etc.). Health data is considered sensitive data and is subject to particularly strict rules and can only be processed by health professionals who are bound by the obligation of medical secrecy.”⁵

Health data can either be created directly by healthcare professionals through electronic health records and national healthcare databases (such as cancer registries, laboratory diseases, hospital registries) or by patients themselves, through health mobile phone applications, wearable devices, screening tests, social media posts, and regular paper surveys.

With the progressive digitalisation of our daily lives, and especially the digitalisation of the healthcare environment, more and more health data are created. Just in 2018, worldwide, healthcare organisations saw an explosive health data growth rate of 878% since 2016.⁶

1.1. The benefits of health data

The Digital Health Network has identified several benefits of health data, for patients, healthcare systems and the cancer research ecosystem.⁷

- » **For patients**, having access to their health data and being able to share it with the healthcare professional of their choice is an empowerment tool. Indeed, it allows patients to gain insights on their health status, which may ultimately have an impact on their quality of life and allow them to have an active role in their care pathway. Moreover, allowing healthcare professionals to have timely access to up-to-date health data favours more efficient and safe personalised timely care.
- » **For healthcare care systems and providers**, being able to access huge data sets may improve the quality of research and treatments, by supporting the identification of risk factors, speeding up diagnosis and predicting outcomes of treatments. Moreover, health data supports the development of better targeted public health strategies as data helps to gain insights for strategic planning and redesigning better care pathways.
- » **For the research ecosystem**, health data supports clinical research and may speed up the development of new treatments and therapy strategies.

1.2. The uses of health data – data for care & for research, innovation, policy-making and regulatory decision

Health data, coming from different sources, can be used to support healthcare delivery (**primary use of data**), and can also be used for health research, health policy making or regulatory purposes (**secondary use of data**).

Data for healthcare delivery:

Data drives all decisions at every step of the cancer care pathway. It supports research, early detection for screening, efficient and timely diagnostic, precise and effective treatment, and timely, sustained and personalised follow-up.

Data has the ability to drive quality, innovation, and efficiency in cancer care. This brings value to individual patients through more accurate diagnosis, personalised treatment, and follow-up care. It also helps healthcare professionals better understand their patients' needs and adapt care accordingly. In addition, it has the potential to ensure a greater continuity of care: considerable

knowledge can be gained from combining different data sources and the depth of insights we could draw from systematic collection of data is considerable to achieve personalised care. At a system level, large-scale data collection can lead to improvements in care and provide insights into which aspects of care offer the greatest impact on patients and health system efficiency.⁸

Additionally, the European Commission's Expert Panel on Investing in Health has identified a strong role for digital transformation in healthcare to **better support the needs of patient safety**, including in respect to barcode-based administration and automated dispensing of medication.

Genomic Data

The last decade has seen an exponential growth in genomic data, which refers to the genome and the DNA data of the organism. Genomics data are changing the way we treat patients, making each cancer unique by providing detailed characterisation of the unique genetic mutations that aid cancer development.⁹ These data are therefore advancing scientists and healthcare professionals' understanding of the causes of each person's cancer and are providing insights into how a cancer might progress and respond to treatment.

Similarly, genomic data can improve screening by better defining and stratifying high-risk populations, and support diagnostic, enabling a more precise and earlier diagnosis through linkage with other data sets.

Genomic data can also accelerate the development of new medicines and data-driven innovations. Indeed, each new genomic data added/discovered is a potential target for treatment development. Healthcare systems will ultimately also benefit from the use of genomic data, by avoiding unnecessary treatment, and reducing inefficiencies.

In this respect, genomic data can help foster **more individualised and effective treatment**.

Supporting this agenda, the European Commission has launched the **1+ Million Genomes Initiative**, aiming at building a common database with at least 1 million genomes in the EU by 2022. Part of the EU's agenda for the Digital Transformation of Health and Care, it has already been signed by 21 Member States and it aims at setting up a collaboration mechanism with the potential to improve disease prevention, allow for more personalised treatments and provide a sufficient scale for innovative, clinically impactful research. This shall be done through an interoperable, cross-border network of national genome databases associated with other relevant data, like electronic health records.

Data for research, innovation, policy-making and regulatory purposes:

Secondary use of health data refers to the processing of personal data for purposes other than those for which the personal data were initially collected. This might include supporting

the improvement of care planning, treatment development, safety monitoring, research, and policymaking. Achieving reliable data reuse is a worthy challenge: a lot of efforts are currently being conducted to develop the most suitable regulatory framework to allow health data reuse, ensuring that the necessary safeguards are in place.

Real Time Data – Data for Better Informed Decision-Making in Time of Pandemic

The exchange of health data across borders can contribute to the better optimisation of patient care. Indeed, the Covid-19 pandemic has highlighted the benefit of exchange of data to fight public health threats. The value of such exchange does not only lie in clinical patient data, but also in data related to medical devices, treatment, and healthcare professional availability. In this respect, the demand for a platform on which data comes together is great.

Practical examples include the concept of real time data. Real-time data is information that is delivered immediately after collection, there is no delay in the timeliness of the information provided. Real-time (or near real-time), openly shared quality data has demonstrated its enormous value during the Covid-19 crisis, and its absence in some cases, as a serious deficiency.

DATA-CAN: Real time data in time of pandemic¹⁰

Covid-19 has brought into sharp focus the need for timely intelligence to inform urgent decision-making, when dealing with a virus that spreads rapidly, placing huge demands on health services. The UK has a long-established tradition of disease registries and health data reporting, especially related to cancer. However, with the pandemic, it became apparent that the system was unable to determine the direct and indirect impacts of Covid-19 on cancer patients in a timeframe to underpin rapid action, due to the time between health data collection, curation and being made available. DATA-CAN identified this gap and provided real-time data from National Health Services to demonstrate to physicians, policy makers and governments the significant impact that Covid-19 was having on cancer services UK-wide.

Real World Data to Inform Regulatory Decision-Making

Real-world data, which are any data that was created outside the strictly controlled circumstances of clinical trials, are gaining increasing attention for their potential use in regulatory decision-making processes. Indeed, real-world data, which are data relating to patient health status and/or the delivery of health care routine, are important for understanding how cancer treatments perform in routine clinical practice. Collected beyond the clinical trial settings, and coming from various sources, such as patient registries, electronic health records, insurance databases, social media, and patient research networks, they are increasingly used to monitor post-market safety and adverse events and to support coverage decision and develop guidelines, but also to support clinical trial designs. As highlighted by the European Medicines Agency's DARWIN platform, delivering real-world evidence around the lifecycle of medicinal product, real world data can be helpful in closing the gap between experimental studies and clinical realities.

However, real world data should not be considered as a gold standard as their collection process is not standardised and the quality of data is very uneven. Since data in secondary real-world data sources were collected or generated for purposes other than research, they will include gaps and biases. Therefore, given a specific research question or study, it is important to assess whether the real-world data source is relevant and can reliably represent the research question or study. It is very likely that data from clinical trials will remain the best available standard, but they can be positively complemented by other processes, such as real-world data, when traditional clinical trials are not feasible or when they can have an added value.

In this respect, the Digital Health Network highlights the need for clear guidance on how to incorporate Real-World Data into decision making processes.

2. Infrastructures and Tools to Harness the Potential of Health Data

As part of the European Union's Digital Strategy, the European Commission is increasingly developing new tools to support the digitalisation of healthcare across Member States.

2.1. Cancer Registries – the way forward

The Digital Health Network is pleased to witness the increasing development and use of population-based cancer registration across the European Union. Cancer registries aim at collecting, storing, and managing information on all cases of cancer occurring in a defined population and geographic area. Data collection is done in a systematic way from several sources, including hospitals, death certificates and laboratory services.

Population-based registries in cancer play an important role in research and epidemiology by offering key indicators on incidence and prevalence of cancer. They are also used for planning and evaluation of cancer control programmes and policies. This may include monitoring cancer occurrence and future needs or examining the

efficiency and performance of screening and treatment, by way of some examples.

The first population-based cancer registries were established in the 1930s. Since then, there has been an increasing development, with now over 200 registries in Europe, benefiting from a continuous facilitation of processes of collection, storage, and analysis of data over the years.

Almost all the European population-based cancer registries are members of the European Network of Cancer Registries (ENCR)¹¹, which was established by the European Commission thirty years ago, with the aim of promoting collaboration between registries and defining data collection standards. This network feeds into the European Cancer Information System (ECIS)¹² which provides quality and timely indicators on cancer burden across Europe.

However, while cancer registries are promising for better understanding cancer trends, significant disparities remain with only 60% of the European population covered.¹³ The Digital Health Network has identified several factors challenging cancer registration in Europe:

- **Heterogeneity of healthcare systems and legal landscapes**

At the European level, cancer registration is subject to the regulatory parameters of the General Data Protection Regulation (GDPR). The differences in the interpretation and implementation of GDPR across Member States are barriers to cancer registration in European countries. GDPR Recital 157 acknowledges that in order to provide an accurate and complete data to objectively inform about cancer incidence and trends, population-based registries need to collect data from an entire population and therefore should work under the no-consent principle, ie. the consent of a patient is not necessarily due to substantial public interest. Meanwhile, GDPR also includes specific provisions ensuring that cancer registries' settings, procedures and responsibilities are regulated, with the aim to fully protect patients' data, while not jeopardising the cancer research ecosystem. However, some European countries have not translated this no-consent principle into national guidelines, therefore threatening the quality of these registries.¹⁴

- **Fragmentation and dispersion of information**

Most cancer registries are local, regional, or national. While platforms such as the ENCR try to centralise and standardise data from several countries, some cancer registries remain unincorporated and in the national language. European cancer registries differ in various ways, including, their design, their processing methods, definitions, their language, or data sources. The issue of inter operability of data sets and databases remains unresolved: "Enabling full interoperability within and between population-based patient-registry domains would open up access to a rich and unique source of health data for secondary data usage".¹⁵

- **Validity and completeness of cancer registries' data**

It is very rare that a registry, within a certain geographic area, succeeds to register every single case of cancer: some cases are double registered, and some cases remain outside the catchment population.

Similarly, because data comes from various sources, their quality remain very uneven. Moreover, as cancer registration is impacted by the expansion of medical knowledge, many data fields are being added over time, making complete data collection very challenging. For example, in the last twenty years, registries have expanded from approximately 25 required data elements to more than 200 required data elements.¹⁶ While this is very positive in terms of data quality, this also means that cancer registries are mostly never complete. Indeed, within most cancer registries, information on care details (type of first treatment, type of surgery), information on potential cancer recurrence, relapse or metastasis, and information on after-care (late effects and comorbidities) remain very low.¹⁷

In the course of developing this paper, the issue of coding errors has been highlighted as hampering the functioning of cancer registration.

While cancer registries have progressively become important elements of cancer policies across Europe, there is still room to improve the potential of cancer registries and to strengthen their support to comprehensive cancer control. In this context, the Digital Health Network recommends to:

- » **Establish targets for cancer registry interoperability and establish common rules, definitions and standards** to make data comparable and increase the linkages between epidemiological, administrative and clinical data sources.
- » **Expand the recommendations developed by ENCR on minimal data sets for collection by cancer registries** through linkage with current health data flows (further integrating administrative databases).
- » **Validate and disseminate European best practices and recommendations on common standards and procedures for cancer registries**, notably the harmonisation of legal requirements and provisions included in the GDPR.

- » **Increase the prominence of cancer registration within national political agendas**, including by further including stakeholders at the national level, such as healthcare professionals, patient organisations, and research communities.
- » **Clarify the scope of population-based cancer registries**: the terminology of cancer registration can only apply to registration covering all the cases of a defined territory, and not to non-exhaustive cohorts to avoid lack of representativeness issues.

The Digital Health network believes that these recommendations are crucial as cancer registries have the potential to become even more impactful as tools in the fight against cancer. In this respect, the European Cancer Organisation supports the current draft recommendation of the European Parliament's Committee on Beating Cancer to "create at least one cancer registry in each EU region, including remote and outermost regions and to support the strengthening of the capacity of national cancer registries to collect data and to support Member States in ensuring the comparability of data sources and the interoperability of regional and national cancer registries".¹⁸

2.2 The European eHealth Digital Service Infrastructure, supporting the exchange of patients' health data across borders

The European Union is increasingly committed to offering all European citizens a safe and easy continuity of care when travelling abroad, by accelerating and facilitating cross-border access to electronic health records. Such a digital health service aims at enabling an easy sharing of health data across borders, through the exchange of electronic patient records or e-prescriptions. This pan-European process is supported by the very recent **European eHealth Digital Service Infrastructure** (eHDSI). The eHDSI, is a platform developed in 2018, which uses information and communication technologies and is planned to be accessible to all EU citizens.

- The eHDSI aims at being the basis for exchange of **ePrescriptions**, allowing EU citizens to obtain their medication in a pharmacy located in another EU country, thanks to the online transfer of their electronic prescription from their country of residence to another country.

- Similarly, the eHDSI aims at supporting the exchange of **Patient Summaries** (reduced form of Electronic Health Records), including information on important health-related aspects. This is meant to provide healthcare professionals with essential information in their own language concerning the patient when the patient comes from another EU country.

The eHDSI will ultimately **widen the scope of choices for European patients and empower them in choosing where they wish to be treated.**

More to do to reach the 2025 goal on patient data interoperability

The exchange of ePrescriptions and Patient Summaries is theoretically open to all Member States and the objective is that **by 2025 all European patients will be able to share their data with the healthcare professional of their choice abroad.**

However, only very few countries benefit from these services: the first exchange only took place in January 2019 between Estonia and Finland. In 2021, only Croatia, Luxembourg, Malta, Portugal, Czech Republic, Estonia, and Finland are using this infrastructure.

In fact, most European countries are still not presently well prepared to accommodate such systems of ePrescription exchange. Indeed, **due to important interoperability and literacy challenges, a significant amount of work remains to be done to achieve this objective by 2025.** On the one hand, the uptake of digital health solutions remains slow and varies across regions. A lot of prescriptions and health records are still not in digital format. Even when the latter is preferred, data is often scattered in different places, and incompatible standards and formats in electronic health records are still an unfortunate reality. On the other hand, a pivotal question remains to convince some reluctant Member States of the benefits that could be achieved with such a system.

The European Cancer Organisation hopes that the **upcoming European Health Data Space will ensure that different Health systems can exchange information seamlessly between countries by further promoting the use of existing EU standards and fostering the adoption of interoperable solutions.**

In this respect, **the Digital Health Network recommends to:**

- » **Improve and extend the clinical Patient Management System (CPMS) used for the European Reference Networks (ERNs), to be used outside of ERNs in the future.** Indeed, the CPMS could be a very interesting tool and software to exchange health data and could be further developed and support the eHDSI, if improved. The National Comprehensive Cancer Centres promoted by Europe's Beating Cancer Plan could be identified as pioneers in further developing the CPMS and using the eHDSI.
- » **Foster patient-centricity within the eHDSI** to ensure that sharing of data is conditioned by patients' consent.
- » **The European Commission's recommendations on a European Electronic Health Record exchange format¹⁹** should be further implemented with the view of supporting the eHDSI development.

In addition, the Digital Health Network believes that the European Health Data Space could offer promising opportunities for the exchange of data and control of patients over their health data, if it takes precedence over other digital regulations, such as the GDPR and Data Governance Act.

Finally, the Digital Health Network sees the upcoming roll-out of the **Cancer Survivor Smart Card**, proposed in Europe's Beating Cancer Plan, and the **Health passport**, proposed in the EU Cancer Mission, as important initiatives to allow all European cancer survivors to have a summary of their clinical history to facilitate and monitor follow-up care. In this respect, oncology could be considered as a pilot project for a future widening of electronic health records across Europe.

3. Upcoming Policy Initiatives to Deliver the Promise of Data for Cancer Care

"A Europe fit for the digital age" is one of the political priorities of the European Commission, including the healthcare ecosystem, as highlighted by the European Commission's Communication on the Transformation of Digital Health and Care,²⁰ aiming at enhancing the digitalisation of the health sector.

Building on this general impetus, the European Commission is very active in developing new initiatives, with the objective of harnessing the power of data for healthcare.

While developing the paper, some policy initiatives, including those that are part of Europe's Beating Cancer Plan or of the Cancer Mission, have been highlighted by the Digital Health Network as potential milestones in delivering the promise of data for cancer care.

European Health Data Space: Getting the Balance Right and Reaching Interoperability Milestones

The European Cancer Organisation supports the concept of a common framework for data sharing, envisaging the initiative to achieve many benefits for healthcare, research, and policy. Indeed, an interoperable European Health Data Space is a prerequisite to fully harness the potential of health data in the EU.

In the course of developing this paper, the Digital Health Network has highlighted the need to:

- Ensure the **right balance is struck between good governance and protecting data safety whilst not overburdening the cancer research environment**.
- Seek **European level processes** and guidelines to prevent further divergence in national approaches.

The European Cancer Organisation further recommends that the European Union and its Member States agree and pursue **firm targets and indicators for the interoperability of health data**, including such matters as registry interoperability and the deployment of health interoperability standards. The definition of **common European health data standardisation** to support the categorisation of identifiable, anonymised and pseudonymised is a repeated ask from the cancer community. Federated data models should also be promoted to enhance interoperability.

Wherever possible, **patients and healthcare professionals should be closely involved and consulted** as they have an important role to play in the achievement of improved regulations and standards, providing real life practice experience and perspective.

The Digital Health Network hopes that the European Health Data Space will include **specific provisions on the harmonisation of the mechanisms by which personal health information can be shared in the EU**, building on already existing initiatives not to overburden the healthcare professionals. There is also a strong support within the European Cancer community for the European Health Data Space to enhance interoperability with a federated data model.

Whether the European Health Data Space is going to be a success in enabling a secure sharing of data across Europe, at least two conditions should be met:

- » The European Health Data Space should develop **the same common framework for the primary use of data** and the secondary use of data. Both uses should be considered in the same perspective, to avoid creating more complexity.
- » The European Health Data Space should consider the specificities of health data and allow for regulatory simplification by **taking precedence over other data frameworks** and regulations, such as GDPR or Data Act. Considering the importance of a harmonised legal framework which could be achieved by clear rules on the interplay of those Regulations, the European Cancer Organisation would welcome the European Health Data Space to function as a *lex specialis* and serve as a stand-alone legal basis to process personal health data, subject to certain conditions.

Cancer Inequalities Registry

As a flagship initiative of the Beating Cancer Plan, the European Commission is planning to establish a Cancer Inequalities Registry, aiming at identifying trends, disparities, and inequalities between Member States. With these qualitative assessments of the country-specific situation, the Cancer Inequalities Registry will identify key challenges and specific areas of actions to guide investment and interventions at the EU level, but also at the national level.

The European Cancer Organisation believes that such a Registry has the potential to be an important step to address the discrepancies in prevention, screening but also gaps in survival and access to treatments in Europe. To take the most out of the initiative, the Digital Health Network would like to emphasise that:

- » Enough resources should support this initiative to allow the development of a **lively and interactive platform**, and not limit this Registry to a mere report.
- » This registry **should not be limited to a country comparison perspective**, but analysis across regions and within countries.
- » It should include aspects such as **socio-economic inequalities and marginalised groups**.
- » **Criteria** to include in this mapping exercise should be as follows: healthcare infrastructure and equipment, waiting times, medication treatment capacity, medical devices and drugs availability and capacity, workforce shortages and patient safety (adverse events).
- » **A public-facing system displaying key indicators would empower patients and policymakers with the information required to drive change.**

European Cancer Patient Digital Centre

As part of the EU Mission on Cancer, the European Commission is planning to establish a European Cancer Patient Digital Centre (ECPDC) by 2023.

The plan is that patients and survivors will be able to access their own clinical data, to deposit clinical and patient-reported health data in a standardised, ethical, and interoperable manner, and share their data with healthcare professionals and researchers in a secure way. The ECPDC will ultimately become a huge cancer database in Europe and will facilitate cross-border healthcare for cancer patients. Data within the ECPDC has the potential to be a valuable resource for research to improve the understanding of cancer.

The ECPDC will allow patient access to their own clinical data and collection of patient-reported outcome data, therefore **empowering patients by co-decision around care or participation in scientific research.**

The Digital Health Network recognises the value of such a Centre, as it will allow patients and researchers better and safer access to health data.

- » Ultimately, if ECPDC is going to be a success, it must **report back benefits that are meaningful to patients**: in this respect, solutions to support patient navigation through national healthcare systems and cross border healthcare should be included.
- » **The ECPDC should build on, rather than duplicate, pre-existing initiatives and projects.** This could include further mapping of the cancer data landscape.
- » Before launching such a project, a feasibility study should be concluded, including attention to the interoperability issue. While the project seems very beneficial, it is hard to understand how it will work if data interoperability standards are not established. Within the virtual network, all national infrastructure should have the same features and should be connected to national cancer registries.

4. Challenges: Technical Barriers, Governance Issues & Digital Uptake

Overall, these policy initiatives testify that the European health data environment is undergoing improvement in order to fully harness the potential of data in healthcare. However, these activities are often felt to be developed in silos and many further actions are still required to support the full digitalisation of healthcare. Many challenges persist, mainly concerning the way we use and collect data:

Technological challenges

- » Firstly, the Digital Health Network has identified an important **technological challenge**, that needs to be resolved to allow the adoption of digital health care solutions.
- Inherent to data, the **quality and content of data remain a key concern**. The data quality is very uneven and varies across databases, mainly due to insufficient quality control schemes, sometimes making data untrustworthy and unusable. Similarly, most data sets do not include all necessary information for oncology, while completeness of databases is a crucial requirement. Furthermore, the issue of data bias should be highlighted. Indeed, depending on the way data are collected and available, there is a risk that biases are included about certain populations and about certain types of cancer. Building data sets that are representative of an entire population is a continuous ask of the cancer community.
- Moreover, in oncology, data sources struggle to keep up with the pace of innovation and new treatments.
- The way healthcare systems are fit to accommodate health data is also a criterion to assess. The **interoperability and standardisation issues** have been identified

by our Digital Health Network as the most important challenges to tackle. Health data is collected in such a way, that the format is different everywhere, making it highly challenging to understand the meaning of health data in different contexts. Indeed, while integrating and linking various health data is fundamental, the cancer community is challenged by limited interoperability between data sources and registries, using different standards and software. Therefore, this lack of interoperability and standardisation leads to fewer links between data sets across the care pathway.

- The **health data environment is still very much fragmented** and while much data is collected, it is still often retained in disconnected silos.

Indeed, while health data is increasingly available, the European data landscape remains very complex and fragmented, particularly for oncology, with over 1100 oncology data sources across Europe.²¹

- Although more and more digital health solutions for accessing data are deployed across Europe, and although the Covid-19 pandemic gave a fresh push, a large number of European citizens and healthcare professionals do not have access to health data in a digital format. Data are often available in paper, or only a limited set of data are available in a digital format. Moreover, software and platforms are rarely user-friendly, limiting the ability to collect enough data.

The Importance of Data Standardisation

Interoperability refers to the ability of devices and systems to exchange and use/read information from other devices and systems without specific efforts. For the healthcare sector perspective, it means that patient data can be shared from an organisation/a healthcare professional to another, without difficulty.

To achieve this, **systems should be able to talk to each other and understand each other and data should be collected and classified according to defined and common standards.** The format/coding of data should therefore be similar, the design and types of data shared should also be similar, as well as the language.

Similarly, the interpretation of methods for anonymisation and pseudonymisation of health data vary significantly across Europe, creating interoperability issues and hindering data sharing.

To achieve interoperability, we must adopt and optimise electronic health records (EHRs) and health information exchange (HIE) services. To ensure that data will be readable anywhere across Europe, data standards should be established and deployed across every European healthcare infrastructure.

Data standards are created to ensure that all parties use the same language and adopt the same approach to sharing, storing, and interpreting data, therefore being the backbone of interoperability:

- **Terminology standards:** the absence of a unified vocabulary for diseases and procedures might lead to miscommunication. To avoid ambiguity and enhance the clarity of content, healthcare systems rely on code sets and classification systems representing health concepts. Such sets should be uniform at the EU level to ensure full interoperability.
- **Content standards** refer to the structure of electronic documents and the types of data they must contain, to ensure that the data is presented in a clear and understandable format.
- **Transport standards** precisely define the data exchange, including the format, the technical architecture, the methods, software and application programming interfaces.

If we aim to accelerate health data interoperability in Europe, the embedding of such European standards is a prerequisite.

Governance challenges

- » Challenges pertaining to **data governance** might also be identified, mainly highlighting the inconsistent data governance framework across the European Union.
 - Fragmented implementation and interpretation of the GDPR at a national level are creating additional hurdles to the cancer research environment, especially in terms of cross-border collaboration and data sharing. Stakeholders engaged in cancer research have frequently raised the concerns of negative unintended effects of GDPR. It impacts clinical research, diagnosis, and care, and limits the potential utility of cancer registries by creating barriers on the conduct of secondary analysis due to the interpretation of the regulation's patient consent requirements. The Digital Health Network urges for the right balance to be striven for, ensuring too that regulation does not make the European Union an unattractive research environment, or hinder international research cooperation, which is essential for cancer care.
 - Moreover, while health data governance frameworks are essential for a safe and coordinated approach to health data, **most European countries are still at the very early stages of setting such data governance strategies.** Some champions with well advanced policy might be identified such as Austria, Finland, Norway, or Estonia. But most European countries still lag behind.²² Indeed, few cancer plans, and country policies explicitly target health data. At both European and national levels, at country and at regional level, the lack of common open standards and data models is a key barrier to the primary and secondary use of data.

GDPR – Unlocking Health Data Sharing with a Better Implementation²³

While the General Data Protection Regulation (GDPR) is a much-appreciated piece of legislation, variations in the implementation of the law have led to a fragmentation of approach which makes cross-border cooperation for care provision, and research difficult.

The inclusion of the principle of a “one-time consent” for retrospective research, as well as the principle of “no-consent” for population-based registries within GDPR was an important milestone for the cancer community. Such principles should allow, in theory, to fully protect the privacy of patients while not threatening research in Europe.

- **Informed patient consent.** Indeed, in the case of observational retrospective research which allow clinicians and researchers to look back at previous patient cases for research purposes, the patient has the right in theory to be informed about the future use of his data and to retain the right to consent or not. However, this is highly difficult to foresee for which purpose the data will be used in the future: this means, while ensuring the highest level of data privacy and the possibility to withdraw consent there is no need for consent to be specific on the nature of the research and to ask patients to re-consent at a later stage. Such a system would allow physicians to easily collect useful data for research purposes.
- **No-consent.** While patient consent is of utmost importance, population-based cancer registries provide extremely useful information about incidence and survival of cancer, and improve the understanding of cancer. For cancer registries to be efficient, they need to collect the data of the entire population. A single dissent would mean that the data would not be representative of an entire population. In this respect, the GDPR highlights the possibility for population-based registries to work under the no-consent rule as they have a high public health interest.

While these specific provisions had the potential to greatly influence European research oncology and solve some of the most pressing issues when it comes to the reuse of data, the potential of GDPR is hampered by the challenge of interpretation and implementation of GDPR across Europe. There are several provisions in the GDPR that leave it open to Member States to introduce additional rules and interpretations. As a result, it is to be expected that the different Member States implement certain provisions differently, and consequently, become an obstacle for collaborative research in Europe.²⁴

The ambiguous guidance on implementation, especially on aspects related to consent and health research, established by the European Data Protection Board indeed resulted in an uneven implementation, with either differencing national guidelines or no national guidelines at all, making the exchange of health data for secondary use harder. Indeed, Member States have the possibility to establish derogations under the GDPR, especially with regards to the choice of legal basis for processing under the GDPR. Over the course of developing this paper, the below challenges were highlighted:

- Cross-border research consortia are hampered by the different national rules which create conflicts as data subjects may exercise their rights against one controller but not a joint controller in the same consortium, with unclear impact on big data collection.
- Due to the different preferences of legal basis, data are collected or made available using consent in one country and using public interest or legitimate interest in another country.
- Lack of a common European interpretation of what constitutes anonymisation to transform personal data to non-personal data, of what constitutes pseudonymisation, and of what is secondary use of data hamper cross-border collaboration.²⁵

Ensuring that the aforementioned principles are harmonised across Europe is therefore of the utmost importance in order to allow oncology research and care to function effectively. The Digital Health Network trusts that the upcoming European Health Data Space, as long as it provides a high level of legal and operational governance, will support health data access and sharing for the research community. A Code of Conduct is considered desirable to explain concepts from the GDPR and to ensure a consistent approach to health data exchange at a more practical level.

Integration and implementation challenges

- » Last but not least, challenges related to **digital literacy and use of data in clinical practice** have been identified by the Digital Health Network relate to the way patients and healthcare professionals perceive and use data. Indeed, lack of awareness and skills as well as misconceptions undermine the full potential of health data.
- While they recognise the high benefits of the use of health data, numerous healthcare professionals have indicated the **high burden represented by data collection in their daily professional routine**. In addition, healthcare professionals have indicated that they **do not have the necessary skills and training to fully harness the power of data in healthcare and integrate data insights into clinical decision-making**. Indeed, the use of data in supporting cancer care remains limited due to some technical barriers, that could be removed through better training and better optimisation of data collection processes. In addition, having good and optimised data displays and data dashboards can support the healthcare professionals in bringing actionable data insights.
 - This should be put in parallel with the **low patient trust related to the use of their health data**. On the one hand, patients are not fully aware of the benefits that might be achieved by health data. On the other hand, they are very concerned with data privacy.
 - An important **digital divide** exists and contributes to inequalities in access to care. Only a clear value for the user will encourage the use of digital tools, and a shift from existing practices. In this respect, **digital literacy both for patients and healthcare professionals** is a pre-requisite to the full integration of health data into clinical settings.

The Irish National Cancer Information System – NCIS: Case of Success to Overcome Barriers²⁶

The Irish NCIS project is led by the Irish National Cancer Control Programme in response to requirements identified by health professionals delivering cancer care services. Some of the key concerns noted included a lack of information sharing systems between hospitals, difficulties in obtaining patient records and the absence of a centralised IT system.

The NCIS is a computerised system that records information about a patient's cancer case, diagnosis and treatment. NCIS aims at being introduced to all Irish public hospitals providing cancer services.

This project is making a significant difference for all patients receiving systemic anti-cancer therapy across Ireland enabling digital support for prescribing and administering chemotherapy.

The goal of the NCIS is to deliver a clinical information system to support the care of oncology and haemato-oncology patients. Access to the patient's cancer treatment record is available through the NCIS, thanks to a thorough work to make health data more interoperable across Ireland and thanks to the establishment of dedicated platforms for patients, healthcare professionals and researchers. This ensures that all relevant healthcare providers will have access to the patient's data in an appropriate and timely manner.

In addition, NCIS has several key functionalities which can be used by various health care professionals including prescribing, electronic medication administration records, support for aseptic compounding, multidisciplinary team meetings and medication management.

The architecture behind the NCIS and the data repositories built, is a perfect success case since it overcomes many of the aforementioned barriers. **With everything under the same architecture thanks to a single system gathering all cancer data (tests, treatments, diagnostics), data are generated in one standardised way and are available for healthcare professionals and researchers.**

Key Policy Recommendations:

Addressing data governance

- **Better implementation and harmonisation between the various European data governance legislations** are to be welcomed to facilitate health data linking and sharing between providers and patients. The European Cancer Organisation urges any such model to be based on core principles such as **openness, transparency and wide stakeholder involvement**. Such data framework should encompass all other provisions included in other relevant legislation to ensure complementary between initiatives and facilitate an easy understanding.
- Achieving greater harmonisation of interpretation of GDPR requirements across Europe is a repeated request to harness the full potential of data in health care: while fully protecting the privacy of patient data, the GDPR should not jeopardise clinical and epidemiological research in the EU. **The European Cancer Organisation would therefore welcome a harmonisation of GDPR implementation across the European Union through new dedicated provisions, specific codes of conduct and certification schemes.**

Ensuring interoperability and data quality

- True potential of data can only be reached if authorities and organisations collaborate on **creating standards for the governance and exchange of data**. To avoid any technical difficulties, the European Cancer Organisation suggests the **establishment of targets and benchmarks for data interoperability**. **To fully harness the potential of digital health, improving the interoperability of data systems remains a high priority**
 - The European Union should facilitate the adoption of the robust data standards already available to improve the national and international interoperability of data sets.
 - Existing national and international initiatives on data standardisation and interoperability should also be scaled up at the European level.
- The European Cancer Organisation supports the establishment of **cancer data quality standards** and protocols in order to ensure that all data sets are complete, representative and of high quality.

Ensuring uptake of data in cancer care

- Relevant European funding schemes should be activated to provide appropriate **funding and resourcing to train and upskill the healthcare workforce** so that they keep pace with innovations in data collection and use.

Similarly, toolkits and education programmes should be established to foster digital education and digital health literacy for patients.

- Data governance legislation should be continuously adapted to ensure that:
 - Patients have appropriate control over their own health data and to ensure that consent is flexible and progressive.
 - Electronic health records are developed in a standardised way, with safeguards.
 - A systematic and standardised collection of patient-generated health data is supported as these data are crucial but not currently consistently used and collected.

Patients first

- Overall, the European Cancer Organisation supports a roadmap on patient-driven governance, ensuring that patients can be assured of the safety of sharing data in new ways, and that their needs are fully accounted for.
- Patients should be involved in all initiatives developed related to health data: They should be seen as active participants rather than passive recipients.
- A key principle should govern any initiative: No citizen should have their data shared unless they give their consent. Such consent should not threaten public health and should be regarded as the understanding of how their data will be used.

Section 2: Telemedicine

Harnessing Digital Potential for Quality Care and Better Access to Cancer Care

According to the European Commission, telemedicine can be defined as “the provision of healthcare services, through the use of Information and Communication Technologies, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients”.²⁷

Telemedicine uses telecommunication technology as a tool to deliver health care, initially to populations with limited access to care. Since the early developments of telemedicine as we know it in the 70s, access to telemedicine has expanded with greater portability, improved usability, lower costs, and higher quality.²⁸ One positive area that has emerged during the pandemic is the increased deployment of telemedicine to support cancer care across Europe: “**We’ve had five years of innovation in five weeks**”.²⁹

1. Telemedicine: Applications, Benefits, and Specific Considerations

Telemedicine provides promising opportunities in solving the challenges of access to care and workforce shortages by redistributing the oncology workforce where needed³⁰. If wisely deployed in cancer care, telemedicine might result in improved access to clinical cancer services. Minimising the disruption caused by the disease to patients, increasing patient satisfaction and increasing cost efficacy³¹ also provide specific rationales for the implementation and expansion of telemedicine. Indeed, telemedicine contributes to an increase of the number of cases managed daily by healthcare professionals, helping to ensure continuity of care, and facilitating the connection between large and small cancer centres. The current Covid-19 pandemic has also revealed another property of telemedicine, where routine health care had to be provided remotely to protect the patient

and healthcare professionals from unnecessary exposure to the virus. Telemedicine also supports patients in rural areas and difficult-to-reach areas of countries that are disadvantaged in comparison with other territorial settings, or with limited capacity to travel to acute care settings to receive their medication.

Examples of successful applications of telemedicine to cancer care include cancer telegenetics, remote chemotherapy supervision, administration and remote monitoring of oncology medication, symptom management, survivorship care, palliative care, and approaches to increase access to cancer clinical trials.³²

Most studies on telemedicine demonstrate **at least equivalency to in-person care and high levels of patient and health professional satisfaction.**³³ Some studies even demonstrate improved outcomes compared with in-person care.³⁴

Telemedicine should be understood within the whole framework of primary care. Indeed, developing and evaluating integrated health care models, including primary care professionals, for cancer patients may combine an approach based both on telemedicine and outpatient appointments/home visits as appropriate covering all patients’ health needs. Including primary care professionals in cancer patients’ care model may support patients without internet access. Telemedicine with cancer experts may be implemented in primary care offices for these patients, enhancing collaborative care as well.

European Reference Networks and Virtual Tumour Boards: A Success to Take Inspiration From

European Reference Networks (ERNs), established in 2017 by the European Commission, are a telling example of success in digitalisation in cancer care. As virtual networks of healthcare professionals, they allow a concentration of resources in one virtual room to discuss complex and rare cancer cases. These Networks are much praised in the cancer community as a mean of successfully deploying digital tools to the benefit of cancer patients across Europe.

The ERNs are connected through a highly secured web-based platform in the form of an online hospital, called the Clinical Patient Management System (CPMS), through which 'virtual' advisory boards, composed of high-level medical specialists, can be convened, to review a patient's condition. These virtual tumour boards are tangible examples of the benefits and achievements that telemedicine can bring in respect to improving access and quality of care. With a virtual tumour board, the expertise is brought directly to the patient and experts from various care centres can easily team up, leading to new synergies. **Virtual Tumour Boards facilitate movement of information and knowledge, as opposed to requiring patients themselves to move and also support healthcare cooperation by resolving expert fragmentation.** Indeed, as the care of patients with cancer becomes increasingly complex and therapeutic options become more nuanced, virtual Tumour Boards allow multidisciplinary dialogue about complex therapeutic decisions throughout the vast array of geographic settings.

***The EuroBloodNet Cutaneous Lymphoma Virtual Board** is using the CPMS to bring experts together in the field of cutaneous lymphoma, a rare cancer for which the small patient population did not have before a dedicated place to consult and receive treatment plans. This virtual board pools the expertise of 18 experts from EuroBloodNet network centres from 11 countries, producing a personalised report within two days, therefore allowing better outcomes for patients, improved cost-efficacy and removing geographical barriers to cancer care for this very rare cancer³⁵.*

Such a tool has already provided invaluable wide-ranging benefits to improve patient care. These include the possibilities for health professionals to:

- Consult their peers and seek a second opinion from a panel of experts.
- Securely share medical information and high-resolution images, in accordance with the latest EU data protection legislative framework.
- Build repositories of cases, which can subsequently be used as a large bank of data for further research.³⁶

The Digital Health Network calls on all European decision-makers to work together to ensure the provision of continued support to the ERNs when reviewing the CPMS and to take inspiration from their successes for the achievement of the EU's ambitions on the digitalisation of healthcare more widely.

However, special attention should be taken when implementing telemedicine in order to ensure equity of access for patients, their safety and their engagement. Telemedicine should be a complement and not a substitute to in-person care.

Indeed, while enhanced accessibility of cancer services for patients is to be welcomed, more consideration is required as to how telemedicine

is best deployed in routine cancer care over the longer term. In particular, the potential detrimental impacts of telemedicine on diagnosis and access to multidisciplinary and multi-professional care, including on supportive interventions typically provided in conjunction with an outpatient appointment, need more attention. **It is the view of many healthcare professionals and patients that high level of medical care is only achievable through direct physical interaction**

with patients. Disadvantages mentioned include errors in at-home measurements, lack of emotional connection and inability to perform a complete physical examination. Administration of oncology medication at home should be performed in a safety way for the patient and for the family, avoiding contamination of chemotherapy drugs at patient's home. The Digital Health Network recognises these concerns. Interestingly, some members of the Network have expressed the views that new digital tools such as Virtual Reality or Telepresence robots have the potential to address some of those problems.

In the course of developing this paper, it was regularly mentioned that the **situation of underserved or marginalised populations**, notably due to lower access to, or familiarity with, technological tools, as well as connections and shortages, must be addressed, to ensure that the implementation of telemedicine does not widen existing disparities.

Considering the different views on telemedicine amongst physicians and patients, the **individual patients' preference for virtual or in-person consultation should be respected.**

In this respect, the European Cancer Organisation welcomes the European Union's commitment to facilitate the uptake of telemedicine. Initiatives and best practices aiming at turning telemedicine into a standard medical procedure, to which every European citizen may have access are of the highest importance and have already contributed to an increase in the use and quality of telemedicine.³⁷

2. Challenges to Implement Telemedicine in Clinical Practice

However, despite the above benefits and European initiatives, telemedicine is still far from being widely used in Europe. Difficulties include the costs of implementing a telemedicine service, hindrances with the interoperability of technical infrastructures, concerns about confidentiality and privacy of health data, lack of ethical rules specifically applicable to telemedicine, hesitations from health professionals regarding their liability exposures, the ambivalence regarding the legal framework of telemedicine in Europe, as well as some patients' preferences for in-person visits.³⁸

A global eHealth survey by the World Health Organization reported that lack of funding, infrastructure, prioritisation and legislation were the most commonly cited barriers to implementing telemedicine programmes.³⁹

Cultural conditions: fear of depersonalisation of healthcare

Cultural conditions such as the lack of acceptance by healthcare professionals and patients (and their family), as well as the fear of data security breaches and the importance of the healthcare professional-patient relationship are a first explanation to the difficulties to deploy telemedicine further.

Relevant training, digital literacy needs and required tools

The Digital Health Network would like to highlight, that the development of new tools and programmes to support the deployment of telemedicine, should be firmly based upon the realities of clinical practice.

- When developing such tools, there is a general assumption that everyone, including healthcare professionals and patients, know how they work. However, many healthcare professionals and patients do not have the necessary digital skills to use these tools. This is often mentioned to be the case for older citizens and for socially marginalised groups.

Despite the positive effects of eHealth technology, telemedicine and its great promise, a vast majority of healthcare professionals feel insufficiently trained to deal with the digital revolution: technology adoption is limited by the **absence of a dedicated set of knowledge and skills among healthcare professionals regarding the use of such tools.**

A survey conducted by the European Health Parliament on the digital skills for health professionals highlighted that for **more than 80% of participants report that the currently available eHealth/mHealth training is inadequate.**⁴⁰

In this respect, implementation of telemedicine schemes need to be supported by **Health Professionals' training in skills, and communication approaches to interact with**

patients through telemedicine. In addition, health professionals need to be aware of advantages and limitations for each process. A surveillance system may help record potential safety issues and alert telemedicine community to work on future improvements.

- Conversations with the healthcare professionals and patients in the development of this paper brought forward report of healthcare infrastructures using **obsolete hardware and software.** For instance, many healthcare professionals have indicated that they are using their personal smartphone for video consultation with their patients, as their professional equipment is not fast enough for this purpose. On the other hand, some European citizens do not have a smartphone to access video consultation. Access and affordability to connection tools are therefore pre requisites to the full deployment of telemedicine.

Policy conditions

- **The absence of national strategies related to telemedicine** and of legal frameworks in some Member States create important barriers. While some governments and healthcare agencies all over the world are funding telehealth programmes⁴¹ and while the Covid-19 pandemic brought new impetus to all the Member States on the development of these telehealth programmes, **the lack of widely accepted standards and procedures results in limits to the trust in the quality and reliability of telemedicine solutions.** Likewise, solving this issue of interoperability between telemedicine solutions is fundamental to avoid legal, operational, and language obstacles. Guidelines and protocols on how to ensure robust identification and handle privacy concerns were regularly mentioned in correspondence with the Network.

- **Reimbursement schemes** are also an important obstacle to the full deployment of telemedicine. Generally, within the EU, reimbursement schemes of telemedicine services remain vague, heterogeneous, or even non-existent. While some telemedicine services are eligible for reimbursement, patients still bear the cost in most cases. As a result, non-transparent and complex reimbursement models lead to confusion – patients are not able to understand which services are reimbursable and often choose to avoid telemedicine services altogether, despite their cost efficiency.

France decided to reimburse teleconsultation exactly as if it were a face-to-face consultation, starting from September 2018. In 2020, 5.4% of medical consultations in France were performed remotely. Telemedicine only accounted to 0.1% of procedures in 2019.⁴²

These barriers can only be overcome by the implementation of comprehensive regulatory guidelines, driven by governmental and professional medical organisations, and the involvement of all stakeholders in designing, implementing and evaluating telemedicine applications.

Key Policy Recommendations:

To ensure an optimal and efficient use of telemedicine to support cancer patients, all health systems should set up coordinated strategies for the appropriate and proportional use of telemedicine in cancer care:

- » Appropriate **training opportunities for relevant healthcare professionals and expert guidance on the best use of telemedicine** in cancer settings is a crucial milestone in the further deployment of telemedicine. As such, within the framework of the Beating Cancer Plan, telemedicine should be included in the **Inter-Specialty cancer training Programme**, allowing all healthcare professionals to update their skills and be granted the opportunity to develop high-quality expertise in telemedicine.
- » **Patient first**: Telemedicine interventions should follow the **principle of co-creation, including the patients from the start**. Importantly, specific measures must be in place to ensure that the **individual status and preferences of the patient are considered**. **Hybrid systems** combining the offer of telemedicine in specifically relevant situations with the provision of in-person appointments must be set in place, as well as **digital literacy programmes and measures** to allow all patients, no matter their digital skills, to benefit from this hybrid system.
- » **Relevant guidelines** in the field of telemedicine should also be urgently defined **at national level**, as, in some countries, uncertainties at the legal and practice level have hampered the deployment of telemedicine. In this respect, the European Commission should promote **guidance and exchange of best practices**, especially in relation to **reimbursement practices, safety regulation and quality assurance**. The French example has highlighted the positive correlation between full reimbursement of telemedicine consultation and the increased use of telemedicine by patients. Successful examples should serve as a basis for the European Commission to issue recommendations to lift barriers to telemedicine deployment.
- » At the EU level, the final objective is to turn telemedicine into a **standard medical service**, secure and accessible to every European patient and fully covered by their respective social security systems. A **harmonised European framework** for telemedicine would entail bringing the full **responsibility of telemedicine services into DG SANTE** and not fragmenting telemedicine rules and measures into several regulations, falling under various authorities.
- » Via instruments such as the Horizon Europe and EU4Health programmes and others (i.e., EU structural funds), the EU should support the deployment of telemedicine.
 - A first funding scheme would stimulate the deployment of telemedicine in Member States with lower access rates, by investing in the necessary equipment.
 - A second stream would promote independent research to generate robust evidence on the appropriate use and benefits of telemedicine in cancer care, as well as to inform implementation and future strategies, including on:
 - Mobile technologies to support communication between patients and healthcare providers and treatment of patients at home.
 - Qualitative studies to understand how physicians' and patients' experience telemedicine in cancer care, exploring their perspectives on the adoption of a new service model, particularly in issues such as communication and relational closeness.
- » To ensure **equal access to telemedicine** within the European Union, access to telemedicine should be included in the **Cancer Inequalities Registry** – using telemedicine as an indicator will help to foster its deployment. Likewise, in respect to the Beating Cancer Plan that aims to ensure that 90% of eligible patients have access to the Comprehensive Cancer Centres by 2030, including telemedicine practices in such facilities, will foster the achievement of the above objective.

Section 3: Artificial Intelligence

The Potential of Artificial Intelligence to Enhance Cancer Care: Reality or Illusion?

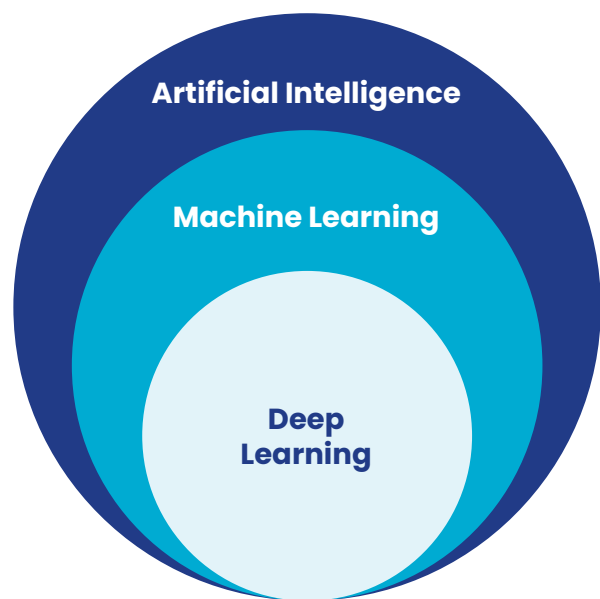
In oncology, health data can be analysed with the help of Artificial Intelligence (AI) to accelerate the processing of these vast amounts of data with one of the aims being to facilitate precision and personalised medicine. Indeed, the clinical potential for an AI informed approach lies in its ability to analyse and integrate large amounts of data coming from diverse sources in order to generate clinical decision support and facilitate diagnostic and care.

The European Commission defines AI as “systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals”.⁴³ AI can therefore be defined as a machine simulation of human intelligence processes including learning, reasoning, and self-correction.

In this respect, **AI has the potential to help transform cancer care with the promise of more automation, accuracy, optimisation, and efficiency for cancer patients, for those at risk of developing cancer as well as for healthcare systems.** As a result, investment in AI in healthcare has dramatically increased in the past decade;⁴⁴ and discussion of AI are now frequent and common among healthcare decision makers, governments, investors, innovators, and the EU institutions. The recent Artificial Intelligence Regulation⁴⁵ published by the European Commission in 2021, the world’s first concrete proposal for regulating AI, is likely to become a blueprint for the safety and fundamental rights of people and businesses, while strengthening AI uptake, investment and innovation across the EU.

The ultimate objective of AI is to build systems that “can perceive the world and make decision in the same way as humans do”.⁴⁶

To achieve this, AI systems are built on a broad range of computational methods that mimic humans. **Machine Learning**, a subfield of AI, relies on statistical methods to detect hidden patterns within a data set. Similarly, **Deep Learning**, another subfield of AI uses artificial neural networks in which multiple layers of processing are used to extract progressively higher-level features from data.



AI is promising to **transform health systems from being reactive to proactive, predictive, and even preventive.** In this respect, **leveraging AI algorithms** and related subfields can help us tackle many challenges, such as support **in removing inefficiencies and inequalities in the access to healthcare** and enabling equal and timely access for all patients.

However, **numerous challenges, including scientific, technical, and ethical challenges and questions remain to be solved before assessing whether AI will keep its promises for cancer care.** While promises and potentials are promising, we need to clearly assess where and when AI can support cancer care.

1. Applications of Artificial Intelligence in Cancer Care: The Vision.

AI is not a panacea but the possibilities and applications of AI can play an important role in enhancing the quality of cancer detection, treatment, and overall cancer care particularly at a time when Covid-19 is impacting upon diagnosis and treatment of cancer. Indeed, AI can play an important role in improving the quality and timeliness of cancer detection and in facilitating the appropriate selection of treatment for different cancer subtypes, leading to an enhanced overall delivery of cancer care. In the course of developing this paper, it was regularly mentioned that this might create efficiencies which might help the long-term sustainability of healthcare systems.

It is believed that the interaction of AI with other advances such as the electronic health records will help to create a **more data-driven reality** in which medical practice would be based on the more precise curation of information and its management, ensuring better intelligence (high-precision results), error reduction (limiting uncertainty), **increased efficiency** (ensuring a more optimal deployment of workforce time and expertise) and **potentially cost reduction**.⁴⁷

In this respect, AI could therefore have the potential to help bridge the transition of current medical practice to the “4 Ps” of medicine: prevention, participative, personalised, and predictive medicine.⁴⁹

Additionally, AI has the **potential to help free clinicians from more routine tasks**, so that they can apply their expertise where it is most needed and interpret the results from AI analysis in the clinical context so as to engage with patients in a more precise and personalised way, with the potential to increase value over time. The underlying idea being that **the human-machine interaction can augment human performance and clinical decision-making, ending with better care for patients while having an efficient use of healthcare resources**.

Overview of Applications of AI in Cancer Care

- Improve accuracy of screening techniques based on the analysis of imaging data.
- Help specialists to diagnose with greater speed and accuracy by identifying previously unrecognised imaging or genomic patterns associated with cancer.⁴⁸
- Predict the likely best treatment response and the best way to steer it:
 - » Gaining efficiency thereby avoiding wasting money in non-appropriate treatments.
 - » Protecting patients from side effects and adverse events of treatments that would not have any positive effects on them.
- Optimise cancer care processes by supporting treatment planning, scheduling and other day-to-day administrative tasks.²
- Empower health democracy, with patients better informed and able to have a meaningful dialogue regarding their treatment options.

AI in cancer prognosis

When considering the high accuracy of Machine Learning, that the Digital Health Network often considers even higher than that of a statistical expert, it was said that AI can be applied to cancer prognosis.

Prognosis prediction of cancer is essential to enhance the patient's survival rate. Developments in computer engineering based statistics over the last years have seen an increasing application of computational methods to analyse the prognosis of cancer: as a result, it has been shown that the accuracy of such analyses is significantly higher than that of empirical predictions. In this respect, and thanks to machine learning, cancer prediction performance has never been so high.⁵⁰

AI in cancer treatment and research⁵²

- With medical imaging, it is possible to combine large data sets and use open data, meaning that the images can not only be objectively analysed and quantified but also combined with genetic and environmental data and related to clinical outcomes to determine the optimal therapy for a particular patient.
- AI might have a role in how cancer therapy is administered: some AI dose reduction algorithms have been developed to find the most appropriate dose for each patient.
- AI might help **accelerate drug discovery**. Research is being conducted to show how AI can be used to detect and interpret the characteristics of certain molecules that play a role in cancer growth, but also to make predictions about new drugs that will target these molecules and help assess the effectiveness of these drugs. Research is also being conducted to identify new approaches to create new drugs more efficiently with the use of AI.
- Finally, AI can **improve cancer surveillance**, through the analysis of patient data via deep learning methods. Algorithms can be developed to automatically extract tumour characteristics from patient reports, saving many hours of manual processing. This will help us better understand how new diagnostic methods, treatments and other factors affect patient outcomes.

AI in cancer diagnostics

AI, in the form of deep learning technology, can be used for the detection and classification of different tumours.

AI can support staging a disease, with less invasive techniques. For example, in low-grade glioma, an AI image classifier could mean a patient could avoid having a biopsy.

Indeed, while developing this paper, it has been highlighted by the Digital Health Network that AI can help support clinicians in the interpretation of cancer imaging data, by distinguishing different types of cancer from normal tissues, identifying stages of cancer and evaluating the tumour (and the patient) response to anti-cancer treatment.

In the case of breast cancer screening, traditionally there is a need for two radiologists to look at hundreds of images per screening and perform repetitive tasks, analysing images with use of pattern recognition by the radiologist. In this respect, the American Food and Drug Administration has approved in 2020 an AI-based software to assist radiologists in detecting breast cancer in screening mammographs.

With the growth in development of AI algorithms in radiological imaging, much of the routine analysis can be performed by Machine Learning, sparing the radiologists time and experience for more complex cases. In this respect, AI should not be seen as a replacement for the radiologist, rather it complements, supports and enhances the radiologist's proficiency in achieving an accurate timely diagnosis.⁵¹

AI in cancer clinical trials

AI could also have positive impacts on cancer clinical trials, for example by improving study recruitment. Indeed, clinical trials are often challenged by suboptimal patient selection and recruiting techniques as well as by the difficulty to monitor patients effectively during clinical trials, explaining the high trial failure rates.⁵³ It is believed that AI has the potential to transform key steps of clinical trial design from study preparation to execution: for instance, AI-based systems can facilitate the identification of patient eligibility for participation in clinical trials based on biomarkers.⁵⁴

More specifically, AI theories and methods are used to support Big Data, which refers to large data sets that may be analysed computationally to reveal patterns, trends, and associations. Big Data is a step forward when it comes to the **development of personalised medicine**, supporting the research for the most appropriate treatment for each patient.

The Harmony Alliance: Big Data for Blood Cancer ⁵⁵

The Harmony Alliance consists of over 80 public and private organisations working together on Big Data for Blood Cancer. Developing a life changing treatment for these diseases, mainly rare, can be a very complicated process.

Collecting and harmonising high-quality data on outcomes of existing treatments is crucial but often hampered by lack of data as well as variations in health care practice throughout Europe presenting a challenge to clinicians, researchers, and regulators.

In this respect, all members of the Harmony Alliance are working together to collect data from all over Europe on as many patients with blood cancer as possible. They anonymised these data and reassembled them in one harmonised Big Data platform by building the harmony Big Data platform, where they can undertake Big Data analysis, improving the understanding of these rare conditions and shortening the development of new drugs and treatments.

Such a project allows the streamlining of processes for data flow within Europe and the development of best practices related to computational patterns and can be extended to other cancer types.

2. Challenges: AI in Oncology, an Illusion?

91% of healthcare insiders see artificial intelligence boosting access to care, but 75% believe it could threaten the security and privacy of patient data.⁵⁶

While cancer care can benefit greatly from AI, several potential barriers have been identified. Indeed, while the promise of AI applications in oncology remains great, the clear benefits still seem far away and important challenges remain to be tackled.

Indeed, **the Covid-19 pandemic has highlighted the pitfalls of AI.** While the pandemic increased both the funding and demand to use AI in hospitals and while AI was believed to be a useful tool to fight the pandemic, over the course of developing this paper, it has been highlighted by the cancer research community that AI did not make a significant difference and has even had potentially harmful impacts with missed diagnoses.⁵⁷ Unfortunately, AI did not pass the test of the pandemic. This might be explained by the poor quality of data that was used to develop relevant tools. Data being collected in the middle of a pandemic, not in the most standardised way led to AI systems built on mislabelled data or data from unknown sources. With data sets which are a mixture of multiple sources and potentially contain duplicates, some AI systems were used on the same data they were trained on, misleading any reader on their accuracy.

Such failure highlights the fact that reliable AI solutions depend on the access to a significant amount of high-quality and representative data: a critical component of the AI landscape is the need to have the potential to access data sets in a safe, responsible and effective way to perform analysis that can deliver distinct clinical insights.

The Digital Health Network believes that this experience will help AI systems to mature.

Taking advantage of the many opportunities of AI in cancer care will therefore require increased investment and some challenges to be overcome. Oncology is a challenging area to develop AI tools because of the vast amounts of data coming from different sources and the heterogeneity of the disease. Barriers to implementation are numerous and the effort needed to overcome these barriers in education, training, standards, and structures are huge, as highlighted in the table below: the Digital Health Network has identified the several challenges when it comes to AI integration into the clinical practice in the following chart.

Ethical challenges	
Algorithmic fairness and biases	<ul style="list-style-type: none"> • Opacity of algorithm, also called the “black box issue”, meaning that no explanation is given on how the algorithm arrived at its final output, which is an additional hurdle when it comes to human interpretation of AI for decision-making. Currently, algorithms do not provide the reasoning it used to come to its result. More efforts are needed to provide the necessary explanation on algorithms functioning to ensure more transparency towards health care professionals. • Because AI is mainly based on pattern recognition, the AI algorithm might replicate existing inequities within the data set (socioeconomic status, race, ethnic background, religion, gender, disability), and ultimately might amplify inequities in health systems. In this respect, poor training of AI systems and low-quality data sets potentially result in significant errors. Indeed, any pattern embedded within the data used to develop a model will be propagated to all results. Increased inclusion of underrepresented groups in the training data is necessary to ensure prediction accuracy, but this will take time as most of available current data sets include such inequalities.
Data privacy, safety	AI systems being trained on data sets, this raises some concerns about data privacy and safety. In this respect, strong protections on data such as pseudonymisation and anonymisation techniques and specific provisions on transparency are necessary.
Application and acceptability of AI	<ul style="list-style-type: none"> • While the Digital Health Network believes that all AI systems should be supervised by a human, the fear of a potential competitive relationship between AI systems and medical staff is very much embedded in the representations of healthcare professionals. In this respect, the issue of acceptability of AI systems, both for healthcare professionals and the patients, is an important hurdle: ensuring that they see the benefits of AI is a prerequisite to any full implementation of AI in clinical settings. • The potential risk of AI to widen the gap between the patient and healthcare professional has also been highlighted by patients and healthcare professionals as an issue that limits the acceptability of AI.
Legal challenges ⁵⁸	
Liability	New AI-based technologies also raise challenges for current liability regimes. Indeed, healthcare professionals are concerned about their legal responsibility when it comes to errors made by AI systems. While the EU has already taken several steps to address liability in AI, the absence of legal framework in this respect is a significant barrier for medical staff to adopt AI in their practice. ⁵⁹
Cybersecurity	Cybersecurity is another important issue that needs to be considered when addressing legal challenges of the use of AI in healthcare. Most of the underlying infrastructure for AI is vulnerable to both cyber and physical threats and hazards.

Structural challenges	
Interoperability	Interoperability challenges slow down machine learning in healthcare. While there are large amounts of data in electronic medical record systems, we are still unable in many cases to derive clinical meaning from that data. When researchers and physicians want to employ AI systems to gain clinical insight into a large data set, collected from multiple institutions, interoperability is really key. Solving interoperability issues is one of the first steps in harnessing the full potential of AI.
Technical issues and data quality	<ul style="list-style-type: none"> • With regards to the exponential growth in cancer research, new data are emerging every day: any AI algorithm should therefore be able to consider this dynamic data and take into account the changes in source data.⁶⁰ • The lack of large, well-annotated and publicly available cancer data sets is a significant barrier to AI research and algorithm development. Indeed, the lack of reference data sets in cancer research hinders reproducibility and validation. Supporting the annotation, harmonisation and sharing of standardised cancer data sets is essential to drive AI innovation and support training and validation of AI models.⁶¹ • To ensure long-term sustainability of AI systems, the algorithm should be reproducible. However, as AI algorithms are sensitive to any very subtle changes in the data sets, that cannot really be identified in advance, the lack of reproducibility is really an issue and could limit the implementation of AI systems. The implementation of AI reporting standards could help in this respect but are very difficult to establish.⁶²
Infrastructure	AI requires managing large amounts of data and therefore large servers and high connectivity tools, that are not available in most of European hospitals. In this respect, the lack of proper data infrastructure is the main barrier in fully deploying AI.
Integration challenges	
Benefits of AI	Very few published studies in oncology have compared the effects of AI interventions with the standard of care on patient outcomes in oncology. The extent to which AI will impact patient outcomes and cost therefore remains uncertain. To gain a better understanding on this, Randomised Controlled Trials are necessary, and this would be very expansive and complex to design. In the meantime, without concrete evidence of the benefits of AI, integration in clinical practice remains limited.
AI literacy	<ul style="list-style-type: none"> • Whether healthcare professionals integrate AI systems in their daily routines depends on how smoothly those systems integrate into their workflow. If an AI system is designed as a separate application that adds extra steps to a clinical procedure, it will be less likely to be integrated. • Understanding how AI works and what are the potential benefits is the first step for a full implementation of AI. Lack of relevant knowledge on training on AI among practitioners is therefore a problem. Without the relevant expertise, medical staff is not able to trust the evidence on which the algorithm is based. Likewise, understanding AI contributions and integrating AI into clinical decision-making requires specific knowledge. • AI management and interpretation is resource-intensive and very costly, it requires skilled bio-informaticians, which are generally not part of any hospital staff. Therefore, implementing AI in clinical settings also requires developing new job opportunities.
Research	Currently, the use of AI in cancer research and treatment is in its infancy. Most of the research is focused on method development, rather than on the implementation of these methods in clinical practice. ⁶³

Considering all these challenges, it is crucial that the European Union, in cooperation with relevant stakeholders, work on tackling the above challenges to ensure that AI is effectively and responsibly implemented in an ethical and legal way, that takes on board the concerns of patients and citizens. In this respect, public and political discussions should be held to rethink current frameworks and adapt them to the constantly evolving rhythm of AI innovation.

In respect to the increasing recognition of necessity for a strong pan European framework to ensure the trustworthiness of AI in healthcare, the European Cancer Organisation welcomes the European institutions' commitment to have an open dialogue to regulate AI applications through implementable strategies, but also expert groups, sharing of best practices and White Papers. We hope that the new regulation currently being debated will guarantee the safety and fundamental rights of people, while strengthening AI uptake, investment and innovation across the EU.

Key Policy Recommendations:

In the context of current political discussions within European institutions around the new AI regulation⁶⁴, the European Cancer Organisation calls for this new regulation to ensure an optimal, efficient and responsible use of AI to help support cancer patients and improve their outcomes. In that respect, all health systems should establish strategies for the appropriate and proportional use of AI in cancer care, including:

- » **A trustworthy AI system based on public trust which should ensure: informed consent, high levels of data protection and privacy, cyber resilience, algorithmic fairness, an adequate level of transparency and regulatory oversight, high standards of safety and effectiveness, and an optimal liability regime for AI systems.**
- » As the lack of large, publicly available, well-annotated cancer data sets has been a significant barrier for AI research, support for harmonisation and sharing of standardised cancer data sets is essential.

In this respect, achieving interoperability of data and harmonisation of data sharing through the European Health Data Space will help foster the deployment of AI. **Agreed protocols and appropriate standards to encourage cross-border collaboration should be established by the EU:** comprehensive databases should be established through standardised collection and processing of data in order to test and compare algorithms and results.

- » **Patients first:** all decisions and applications around AI must consider the benefits for the patients.

AI applications in healthcare should not be market-driven, but patient-driven instead. In this respect, wherever possible, patients (and citizens) should be closely involved and consulted. It is fundamentally important to adequately inform patients about the processing of their data and foster an open dialogue to promote trust.

Considering EU ambitions in this area, the European Cancer Organisation recommends that **the EU's digital programme, EU4health and other relevant funding streams include support for patients' organisations in contributing their time and expertise to support AI initiatives.**

- » EU funding schemes should also incentivise the involvement of data science and AI communities which should be critical partners in realising the promise of AI in cancer research. This would ultimately support the **development of an AI in cancer research community**, bringing the AI research community and the cancer research community together.

Appropriate funding opportunities and exchange platforms should be established to support innovative research on the use of AI in cancer. The Digital Health Network **calls for studies on:**

- The appropriate principles for responsible and ethical use of AI.
 - The assessment of AI benefits and costs in terms of clinical outcomes.
 - Patient and healthcare professionals' experiences with AI in cancer care.
 - Appropriate ways to close the gap between research and clinical integration.
- » **Better application of European regulations** is needed to guarantee the privacy of patients and the trustworthy handling of data, focusing on better implementation of:
- Ethical requirements and guidelines.
 - Prohibition of excessive reliance on AI in isolation.
 - Framework for high-quality data, infrastructures, and interoperability.
- » As AI systems require **high-quality data to operate effectively**, new European measures should ensure that:
- The **implementation of oncology computerised systems at Member State level** that records information about a patient's cancer case, diagnosis, treatment and outcomes in one structured format to train AI algorithms while minimising potential biases. EU's digital program, EU4health and other relevant funding streams should provide funding to Member States to implement such a computerised system.
 - Data sets used for AI are adequate and equitable and the analytics used are standardised, transparent, and subject to rigorous evaluations of clinical safety and effectiveness. Similarly, the insights drawn from data analysis are of high quality and always submitted to human analysis⁵⁵.
- » **Public and professional awareness of the possibilities of AI should be promoted**, e.g. through tailored education. Making training on AI widely and freely available at medical schools across the EU is a necessity: it is of the utmost importance to educate medical staff on the strengths and weaknesses of this technology. Incentives and guidance from the EU are important to achieve these goals; and the Europe's Beating Cancer Plan should take the necessary steps in this regard.

Section 4: Other Digital Solutions

Blockchains, Virtual Reality and Robotics: The New Digital Frontier in Cancer Care

As the Artificial Intelligence technology and digital transformation mature, there are great expectations of their potential to further promote the advancement of medicine through a wide range of new applications, such as virtual reality, robotics and blockchain.

These new technologies are the new digital frontier in medical innovation and hold promises if guiding principles are well implemented. Relying on the availability and quality of vast amounts of robust unbiased data, the Digital Network believes that they can bring several benefits both for patients and healthcare systems, when placing the patient at the centre.

However, to fully reach this new frontier, a **cultural transformation** is needed: it is important that healthcare professionals are aware of the existence of these new tools, know their potential and their shortcomings, and are knowledgeable enough to understand when and how they can be applied. The infrastructure could even be already there but if there is no cultural transformation, there is no implementation of digital tools and services.

Moreover, not **every healthcare system across the European Union is able to accommodate and afford such innovation**. While developing this paper, the inequalities issue when it comes to digitalisation and new technological tools in healthcare has been highlighted: inequalities in terms of equipment and infrastructure remain very important and limit a common implementation of these digital solutions.

In this respect, the Digital Health Network believes that the current **Europe's Beating Cancer Plan** could offer some solutions to allow for the uptake of blockchain, Virtual Reality and Robotics in healthcare, and especially in cancer care.

1. Blockchains in Healthcare: Resolving the Privacy and Security Hurdles?

Blockchain is an emerging technology, for storing and transmitting information, that has the potential to revolutionise the way we share data and support the establishment of a citizen-centric digital society.

This technology offers high standards of transparency and security because it operates without a central control body. Blockchain allows its users – connected in a network – to share data without intermediaries. In practice, a blockchain is a database that contains the history of all exchanges made between its users since its creation.

In this respect, blockchain can support the management and authorisation of health data exchange and access, providing full traceability of data exchange. Integrity of data is the principal characteristic of blockchain.

While we are witnessing an increasing interest in digital health and personalised medicine and an explosion of patient-generated data, blockchain technology appears as a great solution to the previously mentioned data challenges. Indeed, blockchain offers **new ways to data mobilisation and allow a trusted usage, as well as new ways to manage consent and data access and control**.

To avoid any confusion with blockchain systems used for the trending cryptocurrencies, we need to distinguish between public and private blockchains. Indeed, while cryptocurrency uses public (anyone can join) on-chain blockchains (complete transaction records on the blockchains), the healthcare sector is using permissioned (only pre-authorized authentication), off-chain (only aggregate parts on the blockchains, actual records remain in clients' systems) blockchains.

1.1. Potential applications of blockchain technology in healthcare

Blockchain technology contributes to harnessing the full potential of the digital transformation of health systems, particularly in the areas of identity verification, informed patient consent, data sharing and access permissions, as well as pharmaceutical supply chain management.⁶⁶

Indeed, several benefits can be identified for patients, as well as for healthcare organisations:⁶⁷

- For hospitals, it can be a way to **solve data insecurity and interoperability**.
- For doctors, it helps to ensure transparent **virtual identification**. Blockchain can contribute to secure identification, via secure encryption key. This is becoming increasingly important as data coming from medical devices need to be matched with electronic medical records.
- For the pharmaceutical industry, blockchain can be a way to **better manage supply chain and inventory management**.
- For patients, this is an opportunity to **foster control and ownership of their data, via advanced informed consent mechanisms**. Indeed, blockchain is used for managing electronic medical record data. Ultimately, blockchain empowers the patients to control the data and decide who can access and use their data.
- Blockchain provides a **secure way to share patient information** with healthcare professionals, contributing to personalised healthcare.
- Blockchain is also a **useful solution to foster patient awareness about the use of the health data for research and other purposes and protect the uncontrolled dissemination**. Indeed, in traditional settings, electronic data can be used and reused, outside of the scope of patient consent. With blockchain, if a patient decides to change their consent, the change can immediately impact the permission on the whole chain.
- **Confidentiality and security**: Participants do not need to trust each other or some other third party that guarantees confidentiality. In addition, the data and its transactions are secure; they cannot be modified or deleted by some third party.

The below table summarises the key potential applications of blockchain technology in healthcare:⁶⁸

Improved service management	<ul style="list-style-type: none"> • Improve control and transparency over health services • Certification of medical professionals • Compliance
Clinical trials	<ul style="list-style-type: none"> • Improve transparency • Improve relationship management among stakeholders • Facilitate recruitment, protocol, and consent management • Improve confidentiality • Enable data automatic share and visibility among institutions and independent scientist
Public health	<ul style="list-style-type: none"> • Improve data flow on the spread of contagious diseases
Data access and exchange	<ul style="list-style-type: none"> • Improve access to data • Facilitate privacy management and consent management • Identity management tools • Management of health records
Drugs authenticity	<ul style="list-style-type: none"> • Supply chain transparency • Provenance tracking • Reduce drugs counterfeiting
Non-clinical benefit	<ul style="list-style-type: none"> • Management of medical insurances

Estonia Using Blockchain to Manage Patients' Data

Estonia, home to one of the world's most digital governments, has become the first country to use blockchain for healthcare on a national scale. Indeed in 2016, the Estonian eHealth Foundation launched a project aimed at safeguarding patient health records using blockchain technology.

"We are using blockchain as an additional layer of security to help us ensure the integrity of health records. Privacy and integrity of healthcare information are a top priority for the government, and we are happy to work with innovative technologies like the Blockchain to make sure our records are kept safe," said Artur Novek, in charge of the implementation of the system.⁶⁹

1.2 Challenges

- » **Technological challenges:** While blockchain technology is very promising, important technical challenges remain to be solved.
 - Blockchain technology is not currently fit for high-volume data due to capacity constraints and to the limited rate of processing transactions executed per second⁷⁰. However, with regards to the current race to create the fastest blockchain and recent developments, this is very likely that in the coming years, blockchains will be able to accommodate high-volume data. Moreover, despite the current limitation of blockchains, the storage of large records such as full electronic medical records through blockchain technology is still more efficient and less costly than the current way of storage.
 - This new data management tool does not remove traditional challenges, such as **interoperability and the need for high-quality data**.
- » **Governance issue:** Blockchain is a completely new way of managing data and approaching central authority, it therefore requires discussions on how to handle governance of this technology. Because of the sensitivity of health data, **blockchain technology should be overseen by relevant authorities and subject to regulation and protocols**.⁷¹ Being far from a European governance model, authorities are struggling to uptake and implement the blockchain reality: the lack of regulations and guidelines prevent blockchain implementation.
- » In terms of **regulatory constraints**, there is an **inherent tension between the rationale of the blockchain technology and some structural elements of the GDPR**: data minimisation, the right to amendment and the right to be forgotten are deeply in contradiction with blockchain immutability⁷² and require that personal data be stored off-chain in order to make them modifiable. The off-chain health data storage solution could also be advisable on technological grounds with regards to the present blockchain scalability limitation.⁷³
- » **Trust and literacy challenges:** Finally, as blockchain represents a significant change from traditional data management method, training and education of healthcare professionals is therefore more than welcome to ensure efficient use. **Whether blockchain enables patients to have great control over their data also depends on their ability to access and understand this technology**. The lack of professional awareness on vendors and solutions is also an issue.
- » Despite the blockchain secure environment, **security challenges** remain obvious vulnerabilities of blockchain applications in healthcare.

Key Policy Recommendations:

While the European Union is already committed to becoming a global leader in blockchain and is engaged in various actions and partnerships,⁷⁴ the European Cancer Organisation, would like to remind the importance of the following specific provisions:

- » **Patient first:** Develop education and awareness programmes on new ways of thinking around data and data management.
- » Ensure compliance with current regulations and data governance framework.
- » Support further research on the benefits, challenges and applications of blockchain in healthcare through European funding schemes.

2. The Potential of Virtual Reality in Healthcare: Supporting the Whole Care Pathway and Empowering Patients

Virtual Reality (VR) refers to a computer-generated simulation of a real environment, including virtual world, immersion sensory feedback and interaction.⁷⁵ In the medical environment, VR allows visual interaction with 3D anatomy reproduction and is mainly applied to practice medical skills, nursing skills, surgical planning, symptom management,⁷⁶ anxiety disorders and rehabilitation.⁷⁷

While VR is not yet widely used in all healthcare settings across Europe, this is very likely that, in the coming years, VR will be used more and more to improve the effectiveness of medical procedures and enhance human capabilities.

2.1. Applications of Virtual Reality in healthcare

VR has already multiple applications for health, including:

- **Training of healthcare professionals:** VR may support **training scenarios** especially for surgeons and **3D reconstruction of the human body**, with the replication of common surgical procedures. This technology is becoming a valuable tool in training aspiring surgeons but also for surgeons to **practice complex operations beforehand**.

Indeed, it has been shown that VR is useful to overcome the training challenges pertaining to surgery (i.e., the lack of standardised assessment for surgical skills, the lack of adequate opportunities to consistently practice new skills – especially related to new technologies). By avoiding unnecessary risks with refreshing knowledge directly in the operating room, VR addresses this skills gap through immersive training, that can be used anytime and anywhere. In this respect, **a recent study highlighted that VR training improved overall surgical performance by 230% compared to more traditional training methods.**⁷⁸

- **Intervention and distant intervention:** VR has the potential to **facilitate anamnesis and diagnosis**.
- VR serves as a new way for medical

professionals to observe, communicate and collaborate in real time. Using specific cameras and a VR headset, a highly skilled professional can watch and advise any consultation, and even surgery, taking place anywhere else. Such technology has the potential to **decentralise medical specialisation**.

- Concrete examples of the use of VR in treatment also include the 3D mapping of organs for pre-op diagnosis as an alternative to opening the patient.
- VR can also be used to treat phobias and neurodegenerative diseases by exposure to an augmented environment.
- **Patients' engagement and management:** VR is also very much used to improve **patients' satisfaction** along the disease pathway. VR offers the possibility to:
 - **walk the patient through their surgical plan** by virtually entering a patient-specific reconstruction.
 - **be used as an empathy tool for doctors:** VR offers the possibility to healthcare professionals to virtually experience the diseases, helping them in better empathising with their patients.
 - **support pain/stress management and rehabilitation.** In fact, VR immersion in a relaxing environment, before or after a surgical act, reduces stress and pain levels for patients by keeping patients focused and relaxed. Likewise, VR has shown to be effective in speeding up recovery time and facilitating coordination and dexterity through games technology.⁷⁹

As well, VR helps create an immersive teleconsultation when patients are not able to travel to a consultation, facilitating access to experts and high-quality services. In this respect, VR is empowering patients in their care pathway.

The Digital Health Network believes that VR in healthcare should be considered from a **patient perspective**. While patients often express concerns about VR, mainly on the reimbursement of VR as a therapeutic option, but also on society's reliance on technology, they are eager to witness an increasing development of VR as it provides new solutions to reduce physical pain and improve mental distress.⁸⁰

2.2. Challenges

While recognising the huge potential of VR in the healthcare sector, the Digital Health Network would like to remind that **VR is not an alternative to more traditional procedures, but a useful complementary tool**. Similarly, VR cannot be used in every situation, nor with every patient: patient age, health status, and cultural conditions, as well as digital literacy are key factors in VR appropriateness.

Despite the important potential benefits of VR, a recent survey highlighted that in 2020, the use of VR among medical professionals is very limited across Europe, with **only 5% of the responding European clinicians using Virtual Reality**.⁸¹

Having said that, important hurdles remain to fully harness the potential of VR in healthcare: structural, financial and regulatory challenges might be highlighted, including:

How to make clinical settings fit for VR?

- VR is an ever-evolving field that requires **very specific programming skills**, that are currently not included in most medical schools' curriculum across Europe. If VR is to become a reality, healthcare professionals need to be aware of the potential of VR and how to use it whenever suitable.
- **Adequate infrastructures to accommodate VR** are expensive and include high-quality hardware, high-speed computers, accurate tracking systems, high-resolution displays and highly-specialised accessories.⁸² In this respect, the Digital Health Network acknowledges that traditional clinical settings do not necessarily have the necessary resources and tools to implement VR: huge inequalities in VR uptake across Europe can mainly be explained by the lack of necessary infrastructures and resources to implement such infrastructures.
- **Patients are still very reluctant to experience VR**: the apprehensiveness towards modern technology and the lack of face-to-face communication are major concerns.

How to make innovation reach the patients?

- The Digital Health Network is concerned with the **huge inequalities that persist across Europe when it comes to the availability of VR tools**.
- In addition to a very fragmented VR market, there are very **weak links between research and the market**. A considerable amount of public money goes into research institutions and universities across Europe, which are developing incredible technologies. These, however, often do not make it to the market: while some hospitals are equipped with the necessary material, they are still missing a diverse software library.⁸³ "Just as we cannot treat all patients with only one or two medicines, there is a need for a variety of software available, for each pathology treated with VR and each category of patients."⁸⁴

How to adapt the regulatory framework to VR?

- VR brings numerous questions on the collection, storage, and **use of data**. Indeed, the training, diagnosis and treatment through VR allow the creation and storage of patient data. Issues around secure data storage and legitimate data access need to be tackled.
- In case of dysfunction of the VR tool, such as a defect or misuse leading VR to be a hindrance rather than a help, the Digital Health Network would like to remind the legal vacuum that currently exists: **who is liable in case of defect** remains a question to be answered. Will it be the manufacturer or the end user, i.e., the healthcare professional?
- As VR is an expensive innovation, reimbursement schemes should be redefined considering the balance cost-benefit and cost-effectiveness of these procedures.

Key Policy Recommendations:

VR solutions are attractive and potentially game-changing: they can offer alternatives to drugs and surgeries and can therefore, if implemented properly, limit risks, be more cost-effective and less time consuming both for patients and healthcare professionals. In this respect, action is needed to address the above-mentioned issues and to release the full potential of VR. The European Cancer Organisation would therefore suggest the following:

- » The European Commission, across various Directorates-General (DGs), should **seize the moment and make Europe fit for digitalisation in healthcare by investing in digital literacy. The overall community, across EU countries and regions, need to be empowered and informed of the potential as well as the shortcomings of the use of VR.**
- » **The regulatory framework needs some overhauling to accommodate the new challenges brought by VR: the new Medical Device Regulation, the Data Act Regulation as well as the upcoming European Health Data Space should be complementary in considering VR in a holistic way.**
- » DG SANTE and DG CONNECT should, in coordination, develop standards and protocols for an effective application of VR in healthcare settings.
- » **The various European fundings schemes should support:**
 - educational and training programmes, with practical orientation, on VR for healthcare professionals.
 - knowledge sharing and sharing of best practices to facilitate the development and standardisation of VR across Europe.
 - applied research, close to market introduction to create a strong bridge between research and innovation.
 - Generation of more evidence on VR use, the effect on clinical meaningful outcomes in oncology and the cost effectiveness of its use.
 - actual introduction of existing VR tools in the clinical setting, across the European Union to allow digital inclusion.

3. Robotics in Healthcare: Opportunities and Risks

Considering the ageing population and the workforce shortage, robotics development in healthcare appears as an opportunity. Benefiting from the power of Big Data, robotics could lead to improvements all along the disease pathway: prevention, medical diagnosis, surgical interventions, treatment and long-term care.

3.1 Applications of robotics in healthcare

While robotics in healthcare is still in its early stages, numerous applications may be identified, including:

- **Robotics in surgery:** Robotic surgery is a recent innovation in which surgery is performed using a robotic device, e.g. **robotic arm which is controlled by a human surgeon**, generally meaning fewer risks of complications and a faster procedure. The robotic device is accurate, allowing smaller incision and therefore reducing blood loss and faster recovery. Using Artificial Intelligence, surgical robotics is benefiting from computer vision, allowing to distinguish types of tissues and avoiding nerves and vessels during procedures. Robots are already able to perform on their own minor sub-procedures, such as suturing.
- **Robotics for clinical settings operations/ management:** Robots are also used in clinical settings to support health workers and enhance patient care. For example, during the Covid-19 pandemic, hospitals deployed robots to reduce exposure to pathogens. Robots can clean patient rooms, track supply and equipment but also distribute medicines to patients, allowing healthcare professionals to focus on more empathy-related tasks. In most cases, health robotics reduces risk, increases efficiency for standardised tasks and improves the working environment.
- **Robotics and automation for medication management:** Robots are also used to automate medication storage and dispensing in hospital pharmacies. These robots allow hospital pharmacists to be focused on clinical activities and not in logistics ones, reduce inventory of medicines in hospitals and therefore, the costs associated to it, improve the purchasing processes in hospital pharmacies minimising the losses coming from expired medication and finally reduce medication errors, the first adverse events for patients in healthcare settings.
Another important benefit is the improvement on stock visibility in hospitals, critical to prevent and improve medicine stocks-outs and shortages. The Pharmaceutical Strategy for Europe includes the settlement of one EU telematic infrastructure to monitor real-time medicine stock in the supply chain: Europe hospitals will require investments in Robotics and informatics to be able to report real-time medicine stocks.
- **Robotics for automation of microbiology laboratories:** Robots offer standardised and scalable automated solutions for inoculation, incubation, plate imaging, culture reading and result reporting. These robots can position microbiology laboratories to achieve more accurate, timely and cost-effective testing, enhancing laboratory operations, maximising financial efficiencies and advancing laboratory operations. They improve laboratory productivity by improving efficiency and turnaround time, increasing testing volume and achieving staff efficiency by reducing rework.

EU-funded disinfection robots during the Covid-19 pandemic

During the Covid-19 pandemic, the European Commission donated over 200 disinfection robots to help sanitise Covid-19 patient rooms and therefore support EU hospitals to cope with the effects of the pandemic. It disinfects a patient room in 15 minutes, and therefore reduces the burden on healthcare professionals while offering them and patients a greater protection against infection.

Such an initiative should be fostered and continued in non-crisis times.

- **High-quality patient care:** Care and socially assistive robots allow social engagement, rehabilitation, and monitoring for patients with chronic and debilitating diseases.
- **Telemedicine:** Moreover, the Digital Health Network highlights that robotics could foster telemedicine. Robotics-assisted telemedicine can bring medical expertise to remote areas. Telemedicine robots can in fact transform physical exams and clinical care as well as monitoring patients. Such telepresence robotics can be controlled remotely and allow clinicians to connect with patients and proceed to examination. The wide adoption of such robots could reduce the medical gaps between rural and urban areas and could also be used in crisis settings, such as the Covid-19 pandemic.⁸⁵

3.2. Challenges

- » **Funding challenges:** robotics required significant investments in capital by European healthcare settings. Despite robotics being cost-effective, the high investments required limit a lot the capacity of healthcare institutions and member states to deploy them. This is one of the main barriers for the adoption of robotics in areas like medication management and microbiology.
- » **Ethical challenges:** The use of robotics raises questions about the **transformation of care and repercussions this might have for human dignity**. Several risks might be identified: would care and nursing robots lead to worse outcomes because the human consideration of care is left out? Whether robots develop more autonomy and become able to make autonomous decisions, who would be responsible for potential harm caused by robots? It appears very clear that **any automated system should be balanced with human presence**.⁸⁶
- » **Trust challenge:** Negative stereotypes concerning robots are a reality. In this respect, gaining the trust and acceptance of patients and healthcare providers is an important issue that can be tackled by making use of reliable sources of information to disseminate and share the pros and cons of robots.
- » **Regulatory and legal challenges:** With the use of robotics in healthcare, many questions arise concerning **privacy, data protection and data sharing**, justifying the need to clarify measures concerning ownership of data, informed consent, and cybersecurity.
Regulatory approval for new generations of medical devices in healthcare has been considered within the revision of the EU Regulation on medical devices, which includes specific provisions on software medical devices. However, whether this regulation fits the future needs of robotics in healthcare remains to be seen.
- » **Technical challenges:** Robotics require high investment and state of the art equipment and technologies. **Integrating robotics within a healthcare system requires high performance computing, 5G connectivity and nanotech**.⁸⁷ Not every healthcare system across the European Union is able to accommodate and afford such innovation, meaning that robotics might worsen existing inequalities.
- » **Workforce challenge:** While there are concerns for robotics replacing healthcare professionals, the Digital Health Network would like to remind that no robots perform a task without the supervision of a healthcare professional – **the human element and supervision should remain a core principle of robotics in healthcare**.⁸⁸ Moreover, the Network believes that some advantages might be identified with robots undertaking some administrative and monotonous tasks: healthcare professionals could focus on patient care and empathy activities.

Further studies and discussions should be held to really assess the potential of robotics in healthcare. **Robots can be a useful and efficient complementary tool but cannot substitute the human presence, decision, and supervision.**

Healthcare has been identified as one of the key areas for robotics by European institutions. The European Parliament led a worldwide debate about the need to establish civil law rules applicable for robotics and calling for further action by the European Commission in this area. In response, the European Commission published a communication

on liability and safety rules applicable to AI and robotics. The European Commission aims to present a revision of the machinery directive in the second quarter of 2021, and it has recently been revealed that there are plans to tackle issues related to ‘human-robot’ collaboration.

Key Policy Recommendations:

» **Regulatory framework needs to be reviewed to accommodate these new challenges, including:**

- Any review of the **Machinery Directive**⁸⁹ should include specific provisions on robot safety and ensuring human oversight.
- Complementarity should be ensured between the **Artificial Intelligence Regulation and the European Health Data Space** to guarantee data privacy and a transparent governance model.
- In addition to developing specific new liability rules for AI systems to face the challenges originating from such a system, a review of the Product Liability Directive⁹⁰ would be welcomed to adapt it to the next-generation robotics and resolve the important liability challenge.
- A review of the **EU’s Radio equipment Directive**⁹¹ should be envisaged to provide great attention to the automatic transmission of data in the use of robotics devices.

» **The various European funding schemes should support:**

- Educational and training programmes, with practical orientation, on robotics.
- Studies on ethical implications and socio-economic impacts of the applications of robotics in healthcare.
- **Patient first:** Information and awareness programmes targeted to patients, on the human-robot interaction.

» DG GROW should develop, in coordination with DG SANTE, but also with international entities such as the World Health Organisation, **validation and certification requirements, including ethical principles, for robotics in healthcare.**

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Participants in the Digital Health Network

Member Organisations Part of this Network



Patient Organisations Part of this Network



To view the latest list of the participants to the Digital Health Network, visit our [website](#).

If you would like to find out more about the Digital Health Network, please contact us at: info@europeancancer.org

As the not-for-profit federation of member organisations working in cancer at a European level, the European Cancer Organisation convenes oncology professionals and patients to agree policy, advocate for positive change and speak up for the European cancer community.

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