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Unleashing the power of Public Health Genomics and Diagnostics for All

AGENDA

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Introduction

Amid the turbulence of early 2024, Can.Heal has persisted in advancing its adventurous agenda of building new links across disciplines, in pursuit of its strategic vision of refining better health opportunities for European citizens. The main goal of CAN.HEAL is to improve access of individuals to prevention, diagnosis, and treatment of cancer through personalized medicine, by upscaling available innovation with the focus on applying ‘Next Generation Sequencing (NGS)’ technology and identifying implementation paths.

The work takes place across the range of specialized working parties set up under the Can.Heal framework, each with its particular specialisation, but all contributing in their own way to the overall goal. The collaborative endeavours of the Can.Heal consortium partners embody a shared commitment to advancing healthcare practices and integrating innovative approaches for the ultimate benefit of cancer patients. As we move firmly into the new year, it is appropriate to provide a snapshot of progress to date across these working groups, which you will find below in section 4.

A turbulent Europe in a turbulent world

The continuing external challenges to Europe – from the global context in terms of climate change, migration, trade and security – find their echoes within Europe too, as its leaders tussle over funding, policies on defence or competitiveness, and the EU's own internal governance.

Health is not immune to the impact of these factors: as recently as February, the EU's much-vaunted enlarged budget for health (including for the Beating Cancer Plan) suffered a 20% cut – principally so as to provide immediate financing to Ukraine. Meanwhile, rival positions on emissions reduction are played out in decisions affecting the car industry and agriculture, demonstrating yet further that strategies are not immutable and everything remains subject to review in light of current circumstances. EU funding, in whichever sphere, and even for projects as evidently meritorious as CAN.HEAL, is a moveable feast, and every aspect of every budget remains subject to intense scrutiny.

A turbulent Europe in a turbulent world

Fortunately, CAN.HEAL is generating a track-record of achievement across its broad range of activity (as this newsletter reports), and so far retains the approval of the public authorities who initiated it. But the world is changing around it, in the broader political and more specific health spheres, as highlighted in this newsletter under “Whither EU health?”, below.

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The logo combines a cross, as a symbol of help, with an object depicting a piece of code, representing the two strands of the initiative – bringing together the power of advanced technology with care and protection.

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“Whither EU health?”

The most obvious aspects of EU health policy at present are the concerns over the sustainability of healthcare systems, the technical capacity of Europe to provide quality health, and the evolution of regulation governing health.

Faced with the – now well-recognised – looming challenge of caring for an increasing population of older patients with a diminishing working-age population, the merits of prevention and early diagnosis come ever more clearly into focus. Here is an area that CAN.HEAL is ideally place to make a real contribution, with its mission of exploiting advanced health technology in pursuit of better public health – and particularly cancer, as detailed in this newsletter.

Europe’s capacity for healthcare has become a hot topic over recent months, with many healthcare companies relocating to other geographies where they find conditions more conducive to their operations – whether it is high-tech firms moving to the United States or lower-tech manufacturing to the Far East for cheaper costs or less exigent regulation. Impelled by phenomena of this sort, the EU has debated at length its so-called “structural autonomy”, without reaching any groundbreaking conclusions. But what has emerged as a working consensus is that the EU must be more effective in promoting and nurturing innovation, and in combining the best of the public and private sectors – and health is one of the key areas identified. Here too, CAN.HEAL has much to offer, both in its specific activities and in its underlying concept of cooperation across sectors, disciplines and partners.

“Whither EU health?”

Healthcare regulation is also centre-stage in Europe at present, with major legislative reforms underway. The discussions on European Health Data Space are reaching a crucial point, as the European Parliament and the member states approach the final straight of their discussions. The reflections of CAN.HEAL on the highly sensitive and contentious issues of secondary use of health data offer a potentially valuable contribution to these negotiations. At the same time, the broad reworking of the EU’s basic rules on pharmaceuticals, still with some probably some years to go before final legislative decisions, touch upon the place of research, the design and management of clinical trials, and the speed and quality of regulatory review. Again, CAN.HEAL’s work has real value in these discussions.

Later this year, the EU will undergo further major change with a new European Commission, a new Council President, and a newly-elected European Parliament. Forecasting the likely impact on health, on research and on funding would be premature, but it is certain that everyone with a stake in Europe – and that includes very evidently those working for the benefit of Europe and, in the case of CAN.HEAL, for European patients and European healthcare – should be alert to the impending changes, and should not neglect any opportunity to make clear in policy circles the merits of the exercise they are engaged in and the need to take it seriously in future decision-making.

CAN.HEAL working parties

Biobanking and the Genome of Europe are the areas of focus for WP4, within the public health arm of Can.Heal, exploring the availability and generation of population-level genetic datasets and their potential uses in cancer-related public health. In collaboration with WP5, it is generating new understanding of an individual's genetic susceptibility to cancer through the use of a Polygenic Risk Score (PRS) that combines information from multiple genetic variants to assess the disease. Understanding PRS variations across populations can inform targeted strategies for screening and prevention, improving public health interventions by identifying high-risk groups for early detection and personalized prevention measures.

A complication of PRS for breast cancer is that different geographic locations have different mixes of genes and environments, so the scores in one country, for instance, may not accurately predict risk in people elsewhere. Scores need to be customized and checked for each population to ensure they can provide valid input for healthcare decisions. The Can.Heal collaboration is testing multiple PRS (for example one generated in a Dutch population and one among Estonians) in predicting breast cancer in population datasets from different countries (for example Latvian and Belgian individuals). The outcome will provide information on how well (or poorly) different breast cancer PRS perform in European populations, and whether additional studies are needed in underrepresented populations to allow for accurate breast cancer risk prediction across the European population.

CAN.HEAL working parties

WP4 also makes connections with the Genome of Europe - part of the 1+MG (One Million Genomes) that aims to sequence the genomes of a million people across Europe. Half of these genomes (500K) will be collected from “normal” individuals across European populations (that is, not selected for any particular disease), forming the "Genome of Europe." The intended outcome will be a comprehensive genetic database representing the diversity of European populations which will facilitate research into genetic factors underlying various diseases and traits. This analysis of vast amounts of genomic data will give researchers insights into population health, disease susceptibility, and personalized medicine. The Genome of Europe promises new understanding of human genetics on a continental scale, and could lead to breakthroughs in healthcare and precision medicine tailored to diverse populations.

One aspect of the Genome of Europe is to elucidate PRS differences between European populations, which will aid in generalizing the PRS for breast cancer generated in one population to others. Genome of Europe has partnered with CanHeal to make possible a selection for cancer cases, so that it will be able to analyse breast cancer genetics (from CanHeal cases) within European populations (through Genome of Europe).

CAN.HEAL working parties

WP 8, on Diagnosis and treatment decision via Molecular Tumour Boards (MTBs), is working in partnership with other elements of CanHeal towards increased harmonization and standardization of guidelines across different healthcare institutions. Precision medicine is generating targeted therapies approved in a tissue-agnostic manner, and MTBs are increasingly used in clinical routine to discuss patients case-by-case and propose potential therapeutic strategies through multidisciplinary discussion. International collaboration has permitted a clear mapping of the different organizations of MTBs across Europe, and further insights are expected from a survey within the Can.Heal clinical arm (with WP8, WP9 and WP10) that highlighted heterogeneous structures of MTBs with common diagnostic and therapeutic objectives.

In addition to the customary involvement of oncologists, molecular biologists and pathologists in MTBs, coordination teams are increasingly included to allow smoother workflows and follow-up of what are typically difficult cases of oatients in therapeutic failure, refractory and/or metastatic, or with rare cancers. But across Europe, patient coverage is still limited, and reimbursement of testing costs is uneven. The integration and structuring of clinical and molecular data is key to provide standardized guidelines for molecular interpretation that utilize reproducible bioinformatics pipelines (including machine learning) to support treatment decision. Recommendations are under development in conjunction with WP3, and training activities addressing MTBs experts is being organized with WP13.

CAN.HEAL working parties

WP9 covers treatment and follow-up, and is exploring how Comprehensive Genomic Profiling (CGP) can be used in real-life situations to offer more treatment options to cancer patients and make precision oncology more accessible. The BALLET study conducted by the Belgian Society of Medical Oncologists has shown the feasibility of a fully standardized CGP workflow across nine collaborating NGS laboratories, with the national Molecular Tumor Board (nMTB) interpreting the CGP results and making treatment recommendations accordingly. Treatment recommendations were not always followed, often because of hurdles in accessing treatments, and the uptake of treatment recommendations varied widely. Analysis of this data should develop guidelines for using CGP, with the aim of optimizing access. Evidence used to support reimbursement decisions by healthcare authorities in Belgium will be shared through CAN.HEAL to healthcare authorities across the EU. A large survey with WP8 and WP10 on NGS and MTB practices across EU countries is in planning, and should result in identifying gaps and challenges that need addressing.

Oncology decision support tools are under study in WP10 to refine critical clinical recommendations derived from next-generation sequencing in cancer diagnosis, prognosis, and treatment planning. The interpretation of sequencing data can be improved by innovative tools for clinicians, but the need for a standardised framework and harmonisation in their application is becoming urgent. An extensive mapping exercise in collaboration with WP8 and WP9 has resulted in the EU-OncDST concept. This modular, transparent, interoperable and evolving tool assists in centralising, interpreting, and visually presenting patient’s data for MTB discussions. Its design includes interoperability with patient follow-up modules, and a connection to clinical trials and previous case databases, further enhancing support for MTBs and promoting uniform treatment approaches.

CAN.HEAL working parties

WP10 is now collaborating with WP13 on training and education to explore the potential of the EU-OncDST concept in patient empowerment, and with WP9 on capacity building centred around the implementation of precision medicine in the EU.

WP12 aims to identify and describe legal and ethical requirements for secondary data use in cancer genomics. Since its use requires safeguards and security measures that are only partially reflected in various laws and regulatory frameworks, and regulatory guidance is still less than totally clear, WP12 encourages discussions among experts and further involvement of citizens and patients. In 2023, WP12 focused on identifying and mapping Can.Heal partners' legal basis for processing genomic data for secondary use for research and development, as well as quality management, policy development, stakeholders' needs, and legal and ethical challenges. A review was conducted of data protection legislation and corresponding case law, data governance legislation, professional and ethics guidelines, and associated literature. In addition, a study of patients', citizens', and stakeholders' perspectives on ethical and legal governance of genomic data in clinical and public health contexts related to cancer was conducted through an extensive literature review, to create an overview of the main values, needs, and concerns. This provided the starting point for interactive discussions with Can.Heal stakeholders during an online workshop in October 2023. Key points here with balancing deidentification of data with the potential benefits of returning results to patients and their relatives, the treatment of incidental findings, and respecting individual rights without overburdening researchers or clinicians.

CAN.HEAL working parties

WP14 is establishing recommendations for the adoption of personalised approaches in the EU health system, with strong stakeholder engagement. It is analyzing the results and evidence from other WPs, and after mapping their activities, a data collection form has been sent to partners for future analysis using the Consolidated framework for Implementation research (CFIR) framework so as to present the facilitators and the barriers of the current personalised approaches. It is also setting up of the Medical and Public Health Cancer Genomics Platform, and a literature overview has identified the best definition of the overall system architecture. Another task is the creation of a modelling tool for forecasting impact of an optimal Cancer Care Model, based on a literature review that identified the Care Process Self-Evaluation Tool (CPSET) as the tool of choice to be tested for breast cancer clinical pathway. The results of surveys in 2023 are now under analysis. WP14 is also producing recommendations on effective and sustainable implementation of personalised medicine approaches – on the use of PRS in breast cancer screening, and on the use of liquid biopsy (LB) in the management of patients with metastatic colorectal cancer. A policy brief on the clinical utility of MTBs is also being drafted.

CAN.HEAL working parties

WP3 launched a self-assessment tool, and prepared use cases for CANHEAL initiatives for equity, cost-benefit analysis, and adoption and scalability. These covered methodology in the public health arm of Can.Heal, and in the clinical/medical arm, and a series of transversal WP activities relating to law, ethics, and citizen engagement and training and education. It also announced an evaluation plan by AQuAS, FISABIO, and NKI proposing a methodology for assessing equity, multi-dimensional impact and adoption and scale-up, and complementary upskilling sessions were conducted. The equity dimension consists of capacity building for equity in cancer genomics, equity in cancer genomics research actions, equity in cancer genomic services, and personalized medicine. The multi-dimensional impact assessment consists of context and study design, value mapping of cancer genomics, and costs related to cancer genomics. Adoption and scale-up assessment consists of Future and Early Adopters Needs desirability Assessment, Innovators' maturity and feasibility Assessment, Future and early adopters feasibility and viability evaluation, and reimbursement approach.

Upcoming events

The CAN.HEAL AGM plenary meeting will take place in Paris on April 16-18 2024.

In connection with this meeting, CAN.HEAL will also organise a public event entitled: 'CAN.HEAL: Stakeholder Session: Propelling Health Care through Public-Private Partnerships'. This will take place from 14.00 - 16.00 on April 18, immediately after the CAN.HEAL AGM.

BEACON project in collaboration with CAN.HEAL is also organising a stakeholder meeting in in Warsaw on May 16-17 to focus on central and eastern Europe. The event is entitled 'Mobilising Collaboration among Stakeholders to Optimise the Growing Potential of Data for Tackling Cancer'

Further details on these meetings and on any aspect of CAN.HEAL or of this newsletter are available, as always from Els Van Valckenborgh PhD, Sciensano: email: Els.VanValckenbrgh@ciensano.be and Denis HORGAN , EAPM: email: denishorgan@eupm.eu

THANK YOU!

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