DIGICORE announces DigiONE: the Digital Oncology Network for Europe to transform cancer care

DigiCore

DIGICORE, the Digital Institute for Cancer Outcomes Research in Europe is pleased to announce the results from its Platinum Fund. DIGICORE used an open innovation challenge to define a digital infrastructure for precision oncology care management and research appropriate for Europe. This is an important step to solve Europe's digital interoperability challenges in hospital oncology electronic health records from diagnosis to clinical outcome. Such an automation solution has the potential to transform the management of cancer care and reduce the cost of precision oncology research. Both are essential if Europe is to deliver the Beating Cancer Plans and the Cancer Mission.

DIGICORE invited care quality focused hospitals from its own membership and those from OECI to apply for funding in a two-step process. Step 1 developed a clinical consensus on a European minimum data standard to describe cancer. Step 2 asked the hospitals to design a local implementation of that consensus in near real time routine data.

16 comprehensive cancer centres in 13 European countries participated in the clinical consensus to define the minimum data standard. They started from the French OSIRIS data model developed by Institute National Du Cancer. OSIRIS covers both clinical and biomarker information in 65 clinical data items and 67 -omic data items. OSIRIS is approved by Commission Nationale de l'Informatique et des Libertés (CNIL, the French national data regulator) and is highly privacy conserving under GDPR.

Each cancer centre measured the local availability and clinical relevance of OSIRIS data items. From that input, the group reached a consensus on a Minimal Essential Description of Cancer (MEDOC) optimised for cancer care quality management. DIGICORE selected care quality as the primary use case to make MEDOC relevant to all clinicians and cancer centres. Such frontline clinical engagement is essential for high quality primary data. To assist large scale European implementation, MEDOC streamlines OSIRIS down to an essential and achievable 40 clinical data items. This is 25 data items or 39% less than OSIRIS, yet still allows high quality cancer and cachexia outcome research.

In step 2, DIGICORE, with funding from IQVIA and Illumina, set MEDOC as the target specification for an open innovation challenge for the participating hospitals. Hospitals designed and costed a local working prototype for one of six nodes in a federated network. In keeping with DIGICORE's open innovation approach, they could use any IT solutions of their choice, be it open source or commercial. Extensive training was provided on modern technology options such as Optical Character Recognition (OCR) and Natural Language Processing (NLP) to help hospitals integrate state of the art technologies. Combined with primary data capture improvement these solutions promise to deliver high quality and complete data essential for modern research and care quality monitoring.

Entries were judged by an independent expert committee including patient representation for their likelihood to successfully deliver a European network prototype. The prototype must achieve high routine data quality on the target dataset in near real time with appropriate privacy management under GDPR. All proposals included patient participation. After written submission and interview, these 6 teams being awarded funding (in alphabetical order):

- Frankfurt University Hospital, led by Prof. Dr. Christian Brandts, Prof. Dr. Janne Vehreschild, Prof. Holger Storf
- Leeds Teaching Hospitals NHS Trust, led by Prof. Geoff Hall
- Maastricht Comprehensive Cancer Centre represented by Prof. Andre Dekker and Dr. Alberto Traverso
- Oslo University Hospital team, coordinated by Sissel Jor
- Cliniques Universitaires Saint-Luc (UCLouvain, Brussels), led by Prof. Cedric Van Marcke
- Ospedale San Raffaele University and Research Hospital team, led by Prof. Giovanni Tonon

These centres now have the challenge to pilot DigiONE, the **DIGI**tal **O**ncology **N**etwork for **E**urope and to pioneer the digital transformation of precision oncology care management and research in the twenty-first century. Work on the pilot is expected to start in early Q2 2023 after hiring of local delivery staff and be complete by end Q1 2024.

Prof. Vehreschild, speaker of the German National Pandemic Cohort Network (NAPKON) and a haem-oncologist observed, *"We have seen in the Covid pandemic the need for real world digital research infrastructures in NAPKON, ORCHESTRA and LEOSS to transform the speed and quality of insights both for research and policy making. Such digital cohort solutions have immense potential within the European Cancer Mission and Beating Cancer plans."*

"As a practicing oncologist and data scientist, I know there is so much we can learn from real cancer patients and comparing practice across hospitals. We have done that in the Ovarian Real World International Consortium I help coordinate, but the hard way. DigiONE and MEDOC will make care quality benchmarking almost touch of a button". Prof. Hall, Chief Clinical Information Officer for Leeds Teaching Hospital and for Health Data Research UK

"The Personal Health Train has shown that federated real world data can allow sensitive health data to remain where it is with strong privacy controls, and for the research question to travel to the datasource 'stations' rather than data from various sources having to be transported to the research question. Federation within DigiONE still allows complex research questions such 'what predicts survival after lung cancer?' but with the research power of a European network, not a single centre" commented Andre Dekker, Professor of Clinical Data Science at Maastricht University, and head of Academic IT at Maastricht University Medical Center

"In the Norwegian CONNECT public-private consortium one of the key obstacles we have identified in the implementation of precision cancer medicine is mobilising our routine clinical data. Participating in DigiONE allows us to share what we have learnt and learn from others". Sissel Jor, Section lead, Oslo university hospital

"Participating in this process really forced us to stretch what we can do as a hospital with our data. I know as a researcher and clinician the benefits that an infrastructure like DigiONE can have, for instance to study questions that will never be addressed in commercial-led studies, like the impact of treatment discontinuation on cancer outcomes". Prof. Cedric Van Marcke, medical oncologist at Cliniques universitaires Saint-Luc, Brussels

"We know that in precision oncology, every patient is a rare patient. To understand how best to treat cancer in the genomic era will require us to have insights on the molecular pathology and clinical response of every willing cancer patient. Solutions like DigiONE that can be put into every cancer centre everywhere will be essential to getting that understanding and improve cancer outcomes". Prof. Giovanni Tonon, Director of the Center for Omics Sciences at Ospedale San Raffaele University and Research Hospital

Bettina Ryll, Founder of Melanoma Patient Network Europe and former patient representative on the European Cancer Mission and part of the selection committee commented, *"It is fantastic to see the motivation of cancer centres from different countries to work together to improve patient outcomes. There remains a lot to do across Europe in particular on the return of data to patients and the creation of high societal value digital value propositions. All of those will need clean and standardised data to power them, such as in DigiONE".*

"At Illumina, we believe in the power the genome to improve human health. Linking genomic data to clinical data opens up immense opportunities for generating real world evidence. What excited us about the DigiONE project was its focus on high quality, standardised data and the transformational vision of the federated data infrastructure – both of which are crucial for oncology care and high-quality evidence generation. We look forwards to working with the DigiONE community to accelerate our understanding of and ability to treat cancer". Brock Schroeder, VP market access, Illumina

"It has been a pleasure and a privilege to design something like DigiONE with such a talented community. DigiONE has enormous potential to transform cancer care for the better. We know from the epidemiological registries there are at least 250,000 lives to save across Europe from reducing variation in cancer outcomes. But without the clinical insights to be founding in rich linked data like DigiONE we don't know why we have that variation or how to tackle it". Dr Piers Mahon, Senior Principal European Data and Evidence Networks, IQIVA's open innovation do-tank and Commercial Research Manager for DIGICORE

"The DIGICORE community wishes the consortium every success in getting to technology proof of concept as quickly as possible. Care quality focused cancer centres are stuck using manual tools like clinical audit to improve our capability to carry out outcomes research and improve personalized medicine approaches. Solutions like DigiONE that bring the power of IT to health data have to be the future". Prof. Gennaro Cilberto, President of DIGICORE and Scientific Director Instituto Nazionale Tumori Regina Elena

Editors notes

For more information please contact: info@digicore-cancer.eu

DIGICORE, the Digital Institute for Cancer Outcomes Research, is a legally independent public private partnership set up as a Belgian European Economic Interest Grouping. It includes 34 large cancer centres from 14 countries, 2 cancer networks in Unicancer and Alliance Against Cancer and two industrial technology partners in IQVIA and Illumina. It was founded in April 2021 after long term discussions with its strategic partner the OECI (Organisation of European Cancer Institutes, 108 major cancer centres with a care quality improvement mission). DIGICORE's mission is to transform the cost and speed of cancer outcomes research in the era of precision oncology using advanced digital methods, open standards and open innovation. To learn more, visit www.digicore-cancer.eu

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IQVIA (NYSE: IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. With approximately 77,000 employees, IQVIA conducts operations in more than 100 countries.

IQVIA is a global leader in protecting individual patient privacy. The company uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while generating and analyzing information on a scale that helps healthcare stakeholders identify disease patterns and correlate with the precise treatment path and therapy needed for better outcomes. IQVIA's insights and execution capabilities help biotech, medical device and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviors, and scientific advances, in an effort to advance their path toward cures. To learn more, visit www.iqvia.com

NAPKON: The German government initiated the Network University Medicine (NUM) in early 2020 to improve national research activities on the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic. To this end, 36 German Academic Medical Centers started to collaborate on 13 projects, with the largest being the National Pandemic Cohort Network (NAPKON). The NAPKON's goal is creating the most comprehensive Coronavirus Disease 2019 (COVID-19) cohort in Germany. Within NAPKON, adult and pediatric patients are observed in three complementary cohort platforms (Cross-Sectoral, High-Resolution and Population-Based) from the initial infection until up to three years of follow-up. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9336157/

ORCHESTRA (C**O**nnecting eu**R**opean **C**o**H**orts to incr**E**a**S**e common and effec**T**ive **R**esponse to S**A**RS-CoV-2 pandemic) is a multidisciplinary European based international cohort research project that brings together knowledge, resources and patient data to find rigorous scientific evidence of treatment and prevention measures on COVID-19. 37 partners from 15 countries have established a research infrastructure to collaborate according to defined common standards. Research objectives include identifying predictors of COVID-19 presentation, sequalae by virus variants and immunity function status, markers of disease severity, vaccination efficacy and long-term consequences of COVID.

Led and initiated by Prof. Evelina Tacconelli and her team from the University of Verona, ORCHESTRA is part of HORIZON2020, the EU innovation and funding programme and started in December 2020 with the goal to create a clear understanding of the clinical expression of the SARS-CoV-2-Pandemic and to deliver recommendations for future health crises (e.g. on the topic of data sharing "Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response - ScienceDirect").

The Lean European Open Survey on SARS-CoV-2 infected patients (LEOSS) represents a prospective European multi-centre cohort study that has been created to get more in-depth knowledge about the epidemiology and clinical course of patients infected with the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Mandated by the German Society for Infectious Diseases (DGI) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and funded by the DZIF (German Centre for Infection Research), LEOSS was initiated mid of March 2020 and has developed into a comprehensive registry. It follows a collaborative and integrative research approach with an anonymous recruitment of SARS-CoV-2 infected patients, which have been treated at university or non-university hospitals or at medical practices. Routine data of the acute phase of COVID-19 has been collected retrospectively and provided in an Open Science context to researchers. So far, more than 135 international sites have documented over 12.950 completed cases and more than 25 research manuscripts have already been published. https://leoss.net/publications/

CONNECT, the Norwegian Precision Cancer Medicine Implementation Consortium, is a novel public-private partnership driving the implementation of precision cancer medicine across Norway in routine care. https://oslocancercluster.no/connect/

OSIRIS (Gr**O**upe inter-**SI**RIC sur le pa**R**tage et l'**I**ntégration des donnée**S** clinico biologiques en cancérologie) is the new French national standard for precision oncology real world data formed under the auspices of Institute Nationale Du Cancer (INCa) DOI: 10.1200/CCI.20.00094