Building precision oncology via real-world data standardization, privacy preserving infrastructures, and collaboration among IT and clinical experts: The DIGICORE network experience

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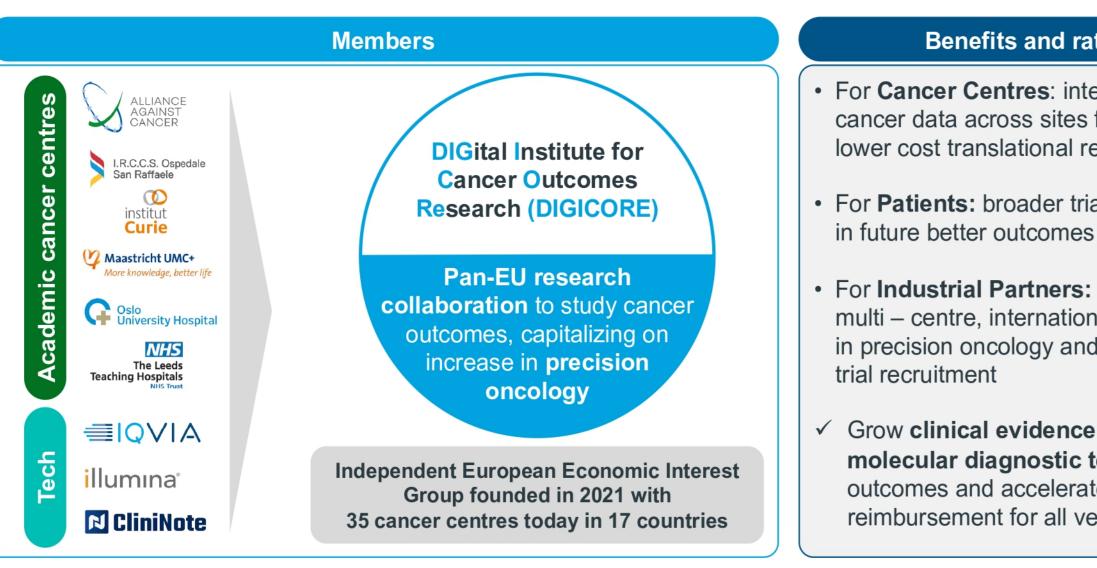
RATIONALE

DIGICORE: Advancing Precision Oncology with Real-World Data

- ☐ Unlocking RWD for Precision Oncology: Real-World Data (RWD) is crucial for personalized cancer treatments, offering insights beyond clinical trials and enabling international comparisons of treatment effectiveness.
- ☐ Addressing RWD Challenges: Significant hurdles exist in using RWD, including data sparsity, unstructured formats, privacy regulations, and varied IT infrastructure.
- ☐ **DIGICORE's Solutions**: The DIGICORE consortium tackles these challenges through initiatives like standardized data elements (MEDOC), Al tools for data digitization, privacy-preserving federated learning, and clinician training, with multiple projects already underway or planned.

THE NETWORK

DIGICORE is an international public private partnership set-up to transform and digitise cancer outcome research, and from there digitise research



Benefits and rationale

- For Cancer Centres: interoperability of cancer data across sites for improved, lower cost translational research
- For Patients: broader trial access and
- For Industrial Partners: Drive commercial multi – centre, international RWE projects in precision oncology and drive precision
- Grow clinical evidence base for molecular diagnostic tests in improving outcomes and accelerate test reimbursement for all vendors

DigiCore

THE MISSION DIGIOCORE has developed an open innovation technology stack to solve this, called DigiONE – a <u>digi</u>tal <u>Oncology Network for Europe</u> 1. Minimal Essential Description Of Cancer (MEDOC) https://doi.org/10.1038/s41591-023-02715-A federated learning system for precision 2. International semantic interoperability from new oncology in Europe: DigiONE **Cancer OMOP standards** 3. Pan-format Cancer data ingestion. Not just ETL Piers Mahon, Ismini Chatzitheofilou, Andre Dekker, Xosé Fernández, Geoff Hall, also NLP, OCR Aslaug Helland, Alberto Traverso, Cedric Van Marcke, Janne Vehreschild. Check for updates 4. GDPR recital 34 privacy conserving solutions for Next Generation Sequencing from every patient, not just those in trials, 5. Full federation with open source Vantage6 to allow through privacy-preserving interrogation of their standardized routine electronic statistical analysis equivalent to centralised data, but without data pooling 5. Modular, protocolized implementation plans to solve for limited data normalisation skills in most hospitals 7. All in open standards and vendor agnostic

THE DATA Those hospital DigiONE databases cover all cancers or >70K new diagnosis a year, typically with cohort start dates of around 2018 Network wide database size (new Dx per year) 73,253 7.489 8.677 7.231 6.150 5.132 4.161 5.125 4.820 6.793 4.277 5.072 5.605 3.416 4.671 2.851 3.774 24.279 20.232 13.488 9.477 6 centres mid 2024 15 centres mid 2025 10 centres end 2024 18 centres end 2025 Lung Breast Prostate Colorectal Haematology Gastrointestinal Gynecological All other cancer diagnoses DigiCore :

THE PROJECTS 10 DIGICORE clinical protocols are in delivery or development, and our first technology research project – we'll hear from 4 of them today 2. Structured data 3. High quality MEDOC 1. Digital Research Basics Level Local database with high data Raw electronic health records • Local database built from structured data, typically rich completeness on all MEDOC Manual curation and data items, likely using NLP for in demographics and activity / extraction possible on small clinical phenotype and cohorts to a protocol specific treatments common data model But weak clinical phenotypes biomarker items 1. Head & Neck 5. Covid19 7. DINASTY mNSCLC (Francesca) Example 8. DINASTY HEr2- mBreast DIGICORE 6. Proposed disease burden and Time-to-treatment study 9. Planned CRC DINASTY 3. Breast – dose variation 4. CRC 10. Planned gender program 11. Impact of different NLP systems on data quality The Digital Institute for Cancer Outcomes Research

NEXT STEPS

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WORKING GROUPS: Performing Effective RWE research

- ☐ Committees within DIGICORE to connect like-minded RWE researchers in hospitals.
- ☐ Aligned to major research themes e.g. a tumour type or topic like health inequalities.
- Open for rectruitment to all European researchers.

TRAINING PROGRAMS: encourage broader study protocol participation

☐ On-going: IDEAL4OMOP, IDEAL4RWE.

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☐ Proposed: Federated learning introduction, OMOP study hackatons, gender medicine, grant writing.

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OMOP: Extending coverage to -omics

- Covering biomarkers from Next Generation Sequencing.
- ☐ Collaborating with companies to directly produce structured data from NGS machines.