Abstract

Over the last decades we have made major progress in diagnosing and treating cancer, however, this disease remains one of the leading causes of morbidity and mortality worldwide, responsible for millions of death each year. A ‘moonshot to cure cancer’ is being called for, which could translate this enormous progress into tangible outcomes for patients.

Every patient is unique. No individual tumour has ever been observed before, or will ever be observed again, due to the enormous genetic/epigenetic heterogeneity between and within tumours and patients, causing each patient (and even cells within the same tumor) to react differently to drugs. While biomarkers can sometimes be used to stratify patients into groups more or less likely to respond to a specific drug, this is still far from the goal of true personalisation, with every patient receiving the drug/drug combination optimal for them.

ITFoC will focus on (short term / 36 months):

1. The construction of one demonstrator for breast cancer to be tested in hospitals after 36 months (HEGP, Nantes Hospitals), comparing i) European medical standards of care and ii) the use of probabilistic mechanistic and systemic models to guide clinical decisions.
2. The proposition of a benchmark test of high quality anonymized curated data to compare the performance of the models in terms of sensitivity and specificity. In consultation with ethicists, a global challenge will be initiated to select the best simulation approaches to predict drug response.
3. The development of a joint platform with access to different modelling methodologies and different business models addressing issues such as data standards, privacy, cybersecurity and data integration strategies.
4. The evaluation of the benefit/risks, the ethical, regulatory, financial and societal impacts at the European level, acceptability and country-specific market access potential.
5. The proposal of policy and guidelines for implementation of digital medicine at the European level.
6. The dissemination of outcomes and analyses to key stakeholders including policy makers, patients groups, health professionals and the scientific community.
7. The preparation of a scale-up phase, comprising lobbying actions, communications, and training activities to extend the project after the 3-year period to include more countries and partners, to incorporate additional sources of ‘deep’ patient data (e.g. sensor data in collaboration with the CONVERGENCE proposal, plus others), and to extend the scope to other tumour types and therapeutic areas, to prevention and ultimately wellness and health.

Overall, ITFoC will showcase federated activities on breast cancer to propose an advanced TRL demonstrator (TRL 5-6) in digital medicine together with a risk/benefit analysis of regulatory, ethical and economic issues, and a proposal of policy and guidelines.
Nora Benhabiles – CEA – France – Funded by: INCa (Coordinator)
Hans Lehrach, Marie-Laure Yaspo – Dahlem Centre for Genome Research and Medical Systems Biology/Max Planck Institute for Molecular Genetics – Germany – Partner not requesting funding
Claudio Luchinat – Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine – CIRMMP – Italy – Funded by: MIUR
Lilia Alberghina – SYSBIO Centre of Systems Biology – Italy – Funded by: MIUR
Marie de Tayrac – Université de Rennes 1
For the French Bioinformatics Network for NGS Cancer Diagnosis – France – Funded by: INCa
Marc Cuglia – Inserm for the French Medical Informatics Network for Clinical Data Integration and Analysis – France – Funded by: INCa
Gilles Wainrib – ENS – France – Funded by: INCa
Alain Livartowski – Institut Curie – France – Funded by: INCa
Marc Cuglia – CHU Rennes for the French western Clinical Data Center Network – GIRCI-GO HUGO federation – France – Funded by: INCa
Aude Sirven – UNICANCER – France – Funded by: INCa
Tommaso Martelli – Giotto Biotech srl – Italy – Funded by: MIUR
Ugur Sezerman – Department of Biostatistics and Medical Informatics, School of Medicine, Acibadem University – Turkey – TÜBITAK
Suveyda Yeniterzi – Epigenetiks Inc. – Turkey – Funded by: TÜBITAK
Marius Geanta – Centre for Innovation in Medicine – Romania – Funded by: UEFISCDI
Lucian Itu – Department of Automation and Information Technology, Universitatea Transilvania din Brasov – Romania – Funded by: UEFISCDI
Edvīns Miklaševičs – Oncology Institute, Riga Stradins University – Latvia – Funded by: LZA
Patrice Denêfle – Institut ROCHE – France – Partner not requesting funding