Valentine's Agreement

Advancing Personalized Healthcare in Belgium

February 2020

BSMO's Precision Group and Roche partner to launch the GeNeo Pilot Project dedicated to establishing a nationwide Personalized Healthcare Framework in the Belgian healthcare system to transform cancer care through a personalized approach to diagnosis and treatment, driven by genomic profiling and real world data.

The aim is to enable broad patient access by securing reimbursement of comprehensive genomic profiling and demonstrate the value of a PHC framework for all patients living with cancer in Belgium through better patient outcomes.

Transforming the health system

We are at a pivotal moment in health care history. On the one hand, health systems are facing major challenges: rising healthcare costs, ageing populations, the increasing prevalence of chronic diseases and growing health inequities. On the other hand, an unprecedented convergence of medical knowledge, technology and data science is revolutionizing patient care and shifting the way we define healthcare.

The science of medicine has allowed us to make incredible advances in diagnosing and treating diseases. Nevertheless, the complexity of human biology is staggering. Every person is unique and in many ways, so are diseases. A unique understanding of human biology combined with new ways to analyze health data is unlocking enormous potential and redirecting focus on the individual profile of each patient in health and disease.

Thanks to the medical and technological advancements and the growing ability to collect, integrate and analyze health data, we are finally at a stage where we can address these challenges by establishing a personalized healthcare (PHC) ecosystem and unlocking the promise of personalized healthcare for patients, physicians and society.

For patients this could translate to an improved quality of life or a longer life; fewer unnecessary treatments, side effects and associated costs through smarter decisions on whether, when and how to treat; and greater peace of mind with higher probability of success.

For physicians, personalized healthcare can bring clarity in an increasingly complex landscape of treatment options; increased confidence in their treatment decisions; and potentially improved outcomes for their patients.

For society, it means better and efficient use of resources in the healthcare system, higher cure rates, and lower burden of disease all which will positively benefit a patient's and caregiver's life quality and contribution to society. Personalized healthcare will be a key component of sustainable health systems, where data will empower tailored care and improved outcomes for patients.

Personalized healthcare can help solve problems and bridge gaps across the healthcare ecosystem: from drug discovery, development and approval to diagnosis, disease monitoring and access. The goal is to transform the health system and drive towards more sustainable, data-driven, learning health

systems that work better for patients, helping to deliver the right treatment to the right person at the right time.

This paradigm shift is especially true for cancer care. Our understanding of oncology has dramatically changed over recent decades. Improved characterization of tumors, combined with the accelerated availability of targeted treatments and immunotherapies, has led to the rise of precision medicine. It has transformed the treatment model from a traditional one-size-fits-all standard of care, based on the primary location of the cancer, to a more targeted treatment approach driven by a deeper understanding of the tumor profile.

Being at the forefront of medical innovation, Belgium has recognized and incrementally implemented these necessary building blocks for precision medicine in recent decades[1]. Thanks to these initiatives, Belgian healthcare has gradually evolved from a traditional, location-driven system to one driven by profiling and targeting, and hence improving patient care.

For Belgium to embrace this advantage and continue its scientific leadership, it must have the ambition and courage to go beyond today's practice and knowledge. The ambition to transition to a personalized healthcare approach requires the integration and implementation of different elements: state of the art tumor characterization via comprehensive genomic profiling; availability of molecular guided therapeutic options based on extensive tumor profiling; and optimal treatment decisions integrating the power of Real World Data (RWD).

The main challenge for the nationwide implementation of a consistent and functional personalized healthcare framework is the lack of available data on the impact of such an approach on patient outcomes, which in turn makes it difficult to predict the cost efficiency of the model. This lack of data is the result of the difficulties and inconsistencies faced by health systems as they roll out precision medicine elements.

Joining forces

With the opportunities and challenges healthcare is currently facing, strong collaborations are more critical than ever before. No single individual or organization can change anything as sophisticated and complex as healthcare. Stakeholders across the healthcare ecosystem must take ownership and responsibility, and work together to advance healthcare policy for the benefit of the patient and the society.

The Precision Steering Committee of the Belgian Society of Medical Oncology ('Precision Group') and Roche Pharmaceuticals Belgium ('Roche') are joining forces in a unique collaboration to co-create a pilot project, GeNeo, to establish a Personalized Healthcare Framework in the Belgian healthcare system, nationwide. At the core of this pilot project collaboration is an Investigator Initiated Study (IIS) constructed on the solid foundation of the existing 'Precision' infrastructure[2]. In the IIS, one thousand patients will receive comprehensive genomic profiling – across different oncology indications – in parallel to routine diagnostic practice. Comprehensive genomic profiling unlocks more treatment options, supports better treatment decisions and improves patient outcomes. The objective of the IIS is to demonstrate the value of comprehensive genomic profiling over routine next generation sequencing and enable us to construct a comprehensive genomic database of all profiled patients.

The aim of the ISS study is ultimately to:

- ensure a standardized nationwide approached;
- secure reimbursement of comprehensive genomic profiling to enable broad patient access; and
- demonstrate the value of a PHC framework for all patients living with cancer in Belgium through better patient outcomes.

To achieve this, each partner has a key role in making this vision a success.

The Precision Group will:

- run the dedicated study to generate data on comprehensive genomic profiling (CGP);
- update testing guidelines based on the generated data;
- expand the capability of the Clinical Genomic Database (CGDB) to routine care.

1 CDx convention, Cancer Immuno Therapy Framework, MOC reimbursement, 'Next Generation Sequencing' convention, 1st submission of targeted therapy (NTRK) in agnostic setting
2 Clinico genomic database and innovative clinical trial infrastructure

Roche will:
- provide an innovative cancer profiling tool through Foundation Medicine services;
- support and provide expertise for the development of Clinical Decision Support Tool;
- sponsor the study through dedicated funding.

Building on a mature infrastructure and innovation-friendly healthcare environment, we strive to establish a true personalized healthcare model that provides optimal patient management in oncology and brings the benefits of personalized medicine to people living with cancer in Belgium. In this respect, both partners commit to engage with other relevant stakeholder to raise awareness and secure support to progress the evolution of PHC in Belgium.

This public-private collaboration incorporates the advancements in scientific knowledge, data analytics and digital technology, and connects all the 'Precision Medicine'[3] elements together in an integrated approach. It aspires to transform cancer care through a personalized approach to diagnosis and treatment, driven by genomic profiling and real world data. By efficiently managing health system resources and providing each individual patient the best possible care, the success of this project would strengthen Belgium's position as a leader in personalized healthcare.

Better patient profiling

Matching the right treatment to the right patient starts with efficient and effective diagnostics. By using comprehensive genomic profiling, it is possible to map an individual's unique genomic profile across all four types of alteration, spanning several hundred different types of mutations. These in-depth insights provide invaluable information to physicians, helping them to make the best possible treatment choice for each patient, and map their treatment journey to identify future courses of action should a disease progress.

In addition, a *strong patient screening infrastructure is the foundation for strengthening the Belgian clinical trial footprint. The attractiveness of Belgium for clinical trials will positively affect Belgian patient access to the most innovative medicines, increasing the potential to receive the most optimal and advanced therapeutic care based on specific cancer profiling. This will ultimately improve patient outcomes and benefit the health system and society.*

Better treatment decisions

Healthcare professionals (HCPs) face enormous pressure to rapidly recommend the best possible therapy for a diagnosed cancer patient. As the amount of data available from various sources exponentially grows, the complexity in decision-making and the need to integrate different data sources will also increase.

Based on comprehensive genomic profiling, the pilot empowers molecular guided therapeutic options for patients at the local level, with a central registration using the Precision infrastructure, in combination with a National Molecular Tumor Board to ensure that all genomic alterations found in the patient are interpreted in a similar manner across Belgian. To provide more clarity and improve confidence in decision-making, a clinical workflow and a decision support software tool will support the experts in considering personalized therapy options for patients.

The treatment decisions of the National Molecular Tumor Board are registered in a clinical genomic database[4], together with the result of the CGP and the clinical data outcomes. Combining genomic and clinical data enables a more accurate measure of the precision medicine model, and increases our understanding of disease pathology and potential improvements in patient outcomes.

To maximize the value of the Personalized Healthcare Framework and truly improve routine care, the use of the clinical genomic database from the study setup is scaled up by expanding the optimal decision support to the broader medical-oncology community (clinical decision tool).

3 Patient identification, Molecular Guided Therapeutic Options, Clinical Decision Tool, Clinical Genomic Database
4 Precision 1

GeNeo PRECISION ONCOLOGY

Offering more options to patients

Groundbreaking advances in healthcare are only meaningful when they reach the people who need them. To be able to translate the tumor profile into an actionable treatment journey and provide optimal care, broad access to treatment options is essential.

Belgium is a clinical trials hub and is recognized as an 'innovation adopter', providing patients access to new treatment options. Embracing this reputation and implementing the infrastructure to facilitate patient recruitment (CGP) will attract more clinical trials to Belgium. A *strong patient screening infrastructure is the foundation for strengthening the Belgian clinical trial footprint* and in turn increase available treatment options for patients. Together with appropriate regulatory and access pathways for precision medicines, access to molecular guided therapeutic options can be maximized.

We remain committed to advancing healthcare in Belgium and proudly launch the GeNeo pilot project as a first step in establishing a personalized healthcare framework for the benefit of patients nationwide.

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