

Roadbook for the implementation of Next-Generation-Sequencing (NGS) in Routine diagnostics in (hemato) oncology in Belgium



STATUS

Implementation completed
Program ongoing

LAST UPDATE

Select a date

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Diagnostic & Treatment

PROBLEM & OBJECTIVE

PROBLEM Next-generation sequencing (NGS) has become a key technology in cancer diagnosis, prognosis and prediction. Large variation in how this novel technology is being implemented and utilized may impact the quality of care of patients.

OBJECTIVE The Belgian NGS Roadbook was developed including

- (1) centralized governance,
- (2) integrated technical and logistic actions with allocated budgets, and
- (3) standardization across multiple program elements (data interpretation, reporting storage, reimbursement, ethics/legal requirements, societal issues)

REFERENCES & DOCUMENTATION

- [Roadbook](#)
- [Guidelines](#)
- [Compermed website](#)
- [DNA debate](#)
- [Article Roadbook](#)
- [Article eval Roadbook implementation \(coming soon\)](#)

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KEY COMPONENTS / STEPS

In 2015, a Health Service Evaluation (HSE) study was performed together with the Cancer Centre of Sciensano and the national health technology assessment agency (KCE). Based on the recommendations of the HSE, the NGS Roadbook 2016–2020 was prepared together with all stakeholders (see list above) and approved by the Minister of Health in 2016. Most actions ran in parallel under the coordination of the Cancer Centre of Sciensano, the National Institute of Public Health. Key component are:

- Creation of a national commission for personalized Medicine (ComPerMed)
- NGS Guidelines and an external quality assessment (EQA) structure (2016–2017) were developed;
- Reimbursement system (nomenclature) has been adapted to cover NGS testing (2017–2019)
- Centralized data registration at HealthData.be (2016–2019) was established with a link to the national cancer registry, which opens the possibility to create patient-matching applications (e.g., optimize diagnosis, match with clinical trials)
- Broad consultation with patients/citizens on ethical, legal, social implications of the use of genomics information
- Creation of ten networks (including hospitals and laboratories) allowed to use, analyze and be reimbursed for NGS testing
- Laboratories performing NGS tests in oncology are obliged to participate in the EQA of NGS testing organized by Sciensano
- Initiation of a 3 year pilot study (dates) on the introduction of the NGS Roadbooks actions in Belgium

KEY CONTEXTUAL FACTORS

In Belgium, the reimbursement of NGS tests is covered by the sickness insurance funds managed by the National Institute for Health and Disability Insurance (NIHDI). Moreover:

- Key stakeholders involved in the development of the Roadbook were: the Ministry of Health, the NIHDI, the College of Oncology, The Commission Clinical Biology, the Commission of Pathology, the College of Genetics, The Cancer Registry, the FAGG, Belac and the Cancer Center of Sciensano.
- Belac is the national mandatory accreditation body
- HealthData.be is a big health data platform which hosts and links over 50 datasets and registries in Belgium
- A 2003 law obliges all hospitals and laboratories to send exams results to the Cancer Registry

MAIN IMPACTS / ADDED VALUE

- The Roadbook format coordinates the effective implementation of multi-stakeholders actions
- The preparation of the Roadbook has brought all field experts together to share their expertise and experience with NGS resulting in compliance to NGS testing guidelines in routine practice
- Consensus on NGS test scope and content increases standardization and facilitates common cost-effective purchasing of test devices
- Having a participatory approach with all key stakeholders (clinicians, pathology, clinical biology, genetics, oncology, bioinformatics and patients/citizen increases the likelihood of commitment and acceptance of the Roadbook
- The Roadbook allows the monitoring of the introduction of an intervention in the healthcare system

LESSONS LEARNED

- Sufficient time needs to be planned for discussion among stakeholders to facilitate consensus on practical implementation
- Centralized data registration requires major information technology investments by all key parties – continuous helpdesk function/support is essential
- Standardized technical and clinical approach is essential for retrospective evaluation of the effectiveness of the diagnostic testing
- Adaptation of nomenclature (for reimbursement system) is a complex and tedious exercise and therefore payers need to be involved from the beginning
- Consensus on the scope of testing requires integration of budget reallocation process
- The development of roadbooks facilitates implementation of multi-stakeholders interventions