INNOVATIVE DIAGNOSTICS IN CANCER
A EUROPEAN PERSPECTIVE

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No conflict of interest

Opinions are sole responsibility of the speaker
‘Omics’ in Health Care System of Belgium

- ‘Omics’ in the clinic
- Genomic citizenship: ethics, legal and privacy
- EC Pre-Commercial Procurement (Horizon 2020)
- EC 1 Million genomes project
‘omics and healthcare’: Life course perspective

- SCREENING
- DIAGNOSIS
- TREATMENT
- PREVENTION
- NEONATAL
- PRENATAL
- PRECONCEPTION
- CARE
- ENVIRONMENT
- SOCIO_PROFESSIONAL REINTEGRATION
- POST MORTEM

Genome
Omics in the clinic
Life course perspective

ENVIRONMENT

Genome

PRENATAL

PRECONCEPTION

DIAGNOSIS

TREATMENT

SCREENING

PREVENTION

NEONATAL

SOCIO_PROFESSIONAL

REINTEGRATION

CARE

POST MORTEM

Prenatal

Preconception

Diagnosis

Treatment

Screening

Prevention

Neonatal

Socio_professional

Reintegration

Care

Post mortem

Genome

Environment
ROADBOOK « NGS in oncology »

Roadbook for the implementation of next-generation sequencing in clinical practice in oncology and hemato-oncology

| ACTION 1 | Establish a commission: Commission Personalized Medicine (ComPerMed) |
| ACTION 2 | Development of guidelines for NGS use in (hemato)-oncology |
| ACTION 3 | Development of criteria for NGS use in (hemato)-oncology |
| ACTION 4&5 | Develop and organize a benchmarking trial and EQA for NGS use in (hemato)-oncology |
| ACTION 6 | Implement NGS registration, storage and data management |
| ACTION 7 | Provide NGS education and training |
| ACTION 8 | Informed consent, legal and ethical implications of NGS use in (hemato)-oncology molecular diagnostics |
| ACTION 9 | Pilot study ‘NGS use in routine diagnostics’ |
| ACTION 10 | Build on hospital networks for NGS use in (hemato)-oncology |
Action 1: Establish a commission: Commission Personalized Medicine (ComPerMed)

Website: [https://www.compermed.be](https://www.compermed.be)
Action 2: Development of national guidelines for NGS use in oncology

The Belgian next generation sequencing guidelines for haematology-oncology

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Action 3: TEST LEVELS

Level 1
• Standard of care biomarker for diagnosis and/or prognosis *
• Biomarker predictive of a response or a resistance to a reimbursed drug in Belgium for this indication

Level 2
• Recommended standard of care biomarker for diagnosis and/or prognosis *
• Biomarker predictive of response or resistance to an EMA-approved drug for this indication

A
• Biomarker predictive of response or resistance to a reimbursed drug in Belgium for another indication (clinical trial available in Belgium or EU)

B

Level 3
• Compelling clinical evidence supporting the biomarker for diagnosis and/or prognosis
• Biomarker predictive of a response or a resistance to
  - a non EMA-approved drug in this indication
  - a reimbursed drug in Belgium for another indication (clinical trial not available in Belgium or EU)
  - an EMA-approved drug for another indication
• Compassionate use of drug

* Standard of care: Included in guidelines (WHO) AND consensus from experts ComPerMed
+ Recommended standard of care: Clinical evidence AND consensus from experts ComPerMed
Test Algorithms represent a sequential of molecular tests to be performed for a particular cancer, documented in addition with the clinical utility (diagnosis, prognosis or therapy), test level and a brief description of the molecular test.

- To define the specific conditions for NGS testing
Benchmarking trials

1. SOLID tumours
2. Haematological tumours
3. Genetic testing (e.g. BRCA trial)

- Participants and Public Reports (link to legal licence and ISO accreditation 15189)
PITTER - NGS VIA HEALTHDATA

Central data registration with a link to the national cancer register

support.healthdata@sciensano.be
HEALTHDATA AT A GLANCE

Secure Data Transfer & encoding of IDs
Data Validation
Annotation & Correction Request
Data Storage
BI-Reporting
Registration in Primary System
HD4DP
HD4RES
DATAWAREHOUSE
HEALTHSTAT

Technical description of each data collection

Trusted Third Party for encryption and pseudonymization

Data Captation
Secure Data Transfer & encoding of IDs
Data Monitoring
Data Validation
Data Storage
Analysis
B1-Reporting
1. Standardization of data sets

2. Centralized database of federated databases with common practices

3. Research workspace with integrated analytical tools


EC PCP oncNGS

1 Million genomes project
Reimbursement of NGS

MARKER: art. 33ter

MEDICINE: Chaper VIII

scope: ‘Marker’ and ‘Medicine’ linked by a molecular test

Also prognostic & diagnostic markers
GENOMIC CITIZENSHIP
“Genomic citizenship” in Belgian

Focus group study
• Involving patients in implementation of genomics in the clinic

Citizens forum
• Gaining insight in citizens’ perspectives on ELSI regarding genomics
CITIZENS FORUM

With King Baudoin Foundation
Internationally validated method: wicked societal problems

32 informed citizens share their views

• Dialogue, no need for consensus
• Help from a support team
• Information provided by experts
• Working towards balanced policy recommendations
Information brochure

Citizen Engagement Evolution Roadmap

EC Perspective:

Joint Action CanCon Policy paper on ‘Public Health Genomics in cancer »

Joint Action IPAAC Work package on Genomics

AIM: ROADMAP on sustainable implementation of recommendations made on cancer control and care
WP6 “Genomics and Cancer“

Belgian Cancer Centre, Sciensano
WP6 ‘Genomics and Cancer’

ROADMAP

- Genetic Screening
- Genomics in HCS
- Ethics and Privacy
- Direct to Consumer Testing
- Education & Training
10 topics:

1. Experience of EU MS in implementing CanCon recommendations
   1. Cancer screening
   2. Integrated cancer care
   3. Community-level cancer care
   4. Survivorship and rehabilitation

2. Results from iPAAC WPs 5–10
   1. Cancer prevention (CanCon policy paper)
   2. Genomics in cancer control and care (CanCon policy paper)
   3. Cancer Information system (Transversal in CanCon – JA INFACT)
   4. Challenges in cancer care (CanCon policy paper – EUNetHA)
   5. Innovative therapies (NEW)
   6. Integrated and comprehensive cancer care (EU ERNs)
Sustainability of the final JA IPAAC deliverable:

- General agreement on the need for maintaining the outputs up-to-date after the JA

Options/Opportunities:

- EC Joint Research Centre (link with CReg, ICBSC/ICCCS initiatives, ERNs)
PCP: Next-Generation-Sequencing in Healthcare applications (acronym: Onco-NGS)
Scope: develop integrated solution for testing, analysing, reporting and storage of Next-Generation-Sequencing medical data within routine healthcare diagnostics

4 target domains:
- Metastatic cancers
- Immunotherapies
- Genetics
- Hospital-borne infections
Impact of EC-PCP NGS in Healthcare

Expected Impact:

- New NGS platforms and use of *NGS tests in routine diagnostics* for personalised medicine.
- Accepted new European *standards* and quality assurance schemes with respect to NGS.
- Strengthening of implementation of personalised medicine and *improved clinical decisions and health outcomes* for the benefits of patients.
- Contribution to the *sustainability* of healthcare systems.
- Growth and benefit to *the European industry, in particular SMEs*
PCP partnership

EU Member States (MS)

✓ PCP requirement: at least 3 EU MS
✓ Proposal: 5 countries: Be, Fr, It, Sp and Ger

MS stakeholders (= Test payers)

✓ Be: NIHDI; France: INCA, Aviesan, …
✓ It, Sp, GER: FED+REG

Procures (= Test buyers)

✓ At least two local hospitals or private licensed medical labs
✓ oncNGS: 8 hospitals
- open market consultation with the industry, including on technical and service readiness
- analysis of the suitable testing environments
- analysis of differences in legal public procurement framework for the participating procurers in health and social care,
- market analysis and analysis of potential barriers (standardisation, certification, regulatory requirements, intellectual property rights, contracting models, payment schemes)
- consultations with relevant stakeholders, end-users (consumer organisations, reimbursement bodies) to prepare for a future market uptake of the solutions

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**PCP partnership**
2nd Meeting of the Representatives of the Signatory Member States of the Declaration of Cooperation "Towards access to at least 1 million sequenced genomes in the European Union by 2022"

- Slides produced during the Meeting -

11 December 2018, Brussels
WORKING GROUPS

SCOPE (use cases, pop/disease, KPI

Technological Framework (linking ongoing initiatives, platforms, distr. Query, Interoperability, federation)

DATA (metadata standards, clinical, genomic practices)

STAKEHOLDERS - benefits, incentives for sharing

Bottom up

Communication

GDPR

Short Term
SCOPE / BENEFITS
Governance LEG/ETHI

MId Term
SCOPE / BENEFITS
TAKE-AWAY MESSAGES
LESSONS LEARNED - CHALLENGES

- Need for an open plan (Roadbook) with budget for implementation
- Endorsement by politicians, professionals and public support
- Long-term perspective – patient-centred approach
- « Expect the unexpected »
- (little) Step-by-(litte) step
- « Money should be the solution not the problem »
- Internationalization – clinical trials
- « Pay for Performance » schedules (or alike)
Genomics colleagues

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**Ministry of Health:** S. Van den Bogaert

**Belgian Cancer Register:** H Poirel, N. Van damme, L. Van Eycken

**KCE:** F. Hulstaert, L. San Miguel

**ComPermed partners:** College Oncology, College Genetics, Com. Pathology, Com. Clin. Biol., Sickness insurances, patient organisations,…
THANK YOU