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FOR ACTION AGAINST CANCER

WP6: Genomics and Cancer

Marc Van den Bulcke - Cancer Centre - Sciensano

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WP6 GENOMICS AND CANCER

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Scope: Develop practical guidance for Member States on:

- 1) the **societal debate** on ethical, legal and privacy issues on the use of genome information in healthcare
- 2) stratified screening by **genetic testing** of high-risk cancer patients
- 3) implementing **precision genomics** in medical care
- 4) how to deal with **'Direct to Consumer'** testing
- 5) **education and training** on genomics of health professionals, policy makers and the citizens

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Deliverable linked to this work package

D 6: Roadmap on Implementation and Sustainability of Cancer Control Actions in the field of genomics (M 34)

Milestones to be reached by this WP

M 6.1. Launch of expert working groups (M 6)

M 6.2. Symposium on Genomics in Cancer Control and Care (M 30)

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WP6 ‘Genomics and Cancer

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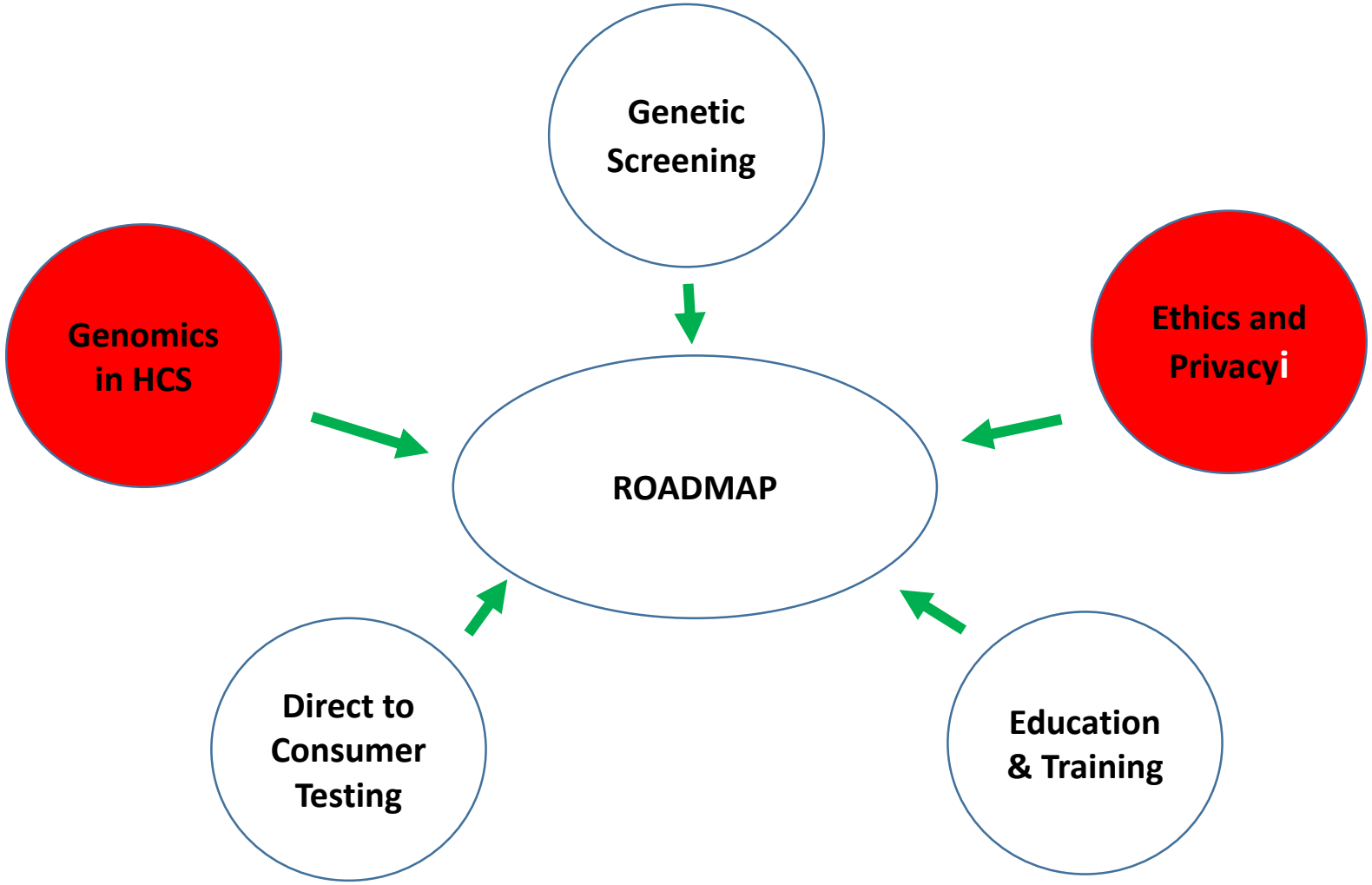

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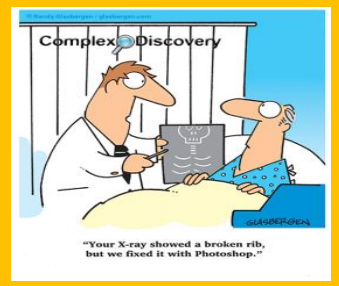
Task 6.3: Introducing ‘omics’ in the healthcare system

INTAKE



CANCER?

Imaging

Surgery
BIOPSY

Immuno
Q & RT-PCR
digPCR
Micro-array
FISH/ISH
Sanger seq
‘omics’
…

Molecular diagnostics

Test dbase
(auth.bron)

Cancer register
Incidence date

CYTOLOGY
HISTOLOGY
Cyto-Histo Reg

Pathology

MDC

Treatment
CLINICIAN

sciensano

healthy all life long

ROADBOOK FOR THE IMPLEMENTATION OF NEXT-GENERATION SEQUENCING IN CLINICAL PRACTICE IN ONCOLOGY AND HEMATO-ONCOLOGY IN BELGIUM

Cancer Centre
Sciensano

.be

PUBLICATION

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Archives of Public Health

COMMENTARY Open Access

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

Els Van Valckenborgh[1*], Aline Hébrant[1], Aline Antoniou[2], Wannes Van Hoof[1], Johan Van Bussel[3], Patrick Pauwels[4], Roberto Salgado[5,6,7], Waltruda Van Doren[8], Anouk Waeytens[8] and Marc Van den Bulcke[1]

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A MULTISTEP PROCESS

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Step 1
- Feasibility/HSE/HTA/Horizonscanning (**March 2015**)

Step 2
- Intervention plan/Roadbook (**April 2016**)

Step 3
- Pilot phase (**2018-2020**)

Step 4
- Structural integration (2021-2023)

Step 5
- Monitoring/surveillance (continuous)

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ROADBOOK – 10 ACTIONS

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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

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ACTION 2: DEVELOPMENT OF GUIDELINES FOR NGS USE

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The Belgian next generation sequencing guidelines for haematology-oncology

A. Hébrant, Ir, PhD[1], G. Froyen, PhD[2], B. Maes, MD, PhD[2], R. Salgado, MD[3], M. Le Mercier, PhD[4], N. D'Haene, MD, PhD[4], S. De Keersmaecker, PhD[5], K. Claes, PhD[6], J. Van der Meulen, PhD[6], P. Aftimos, MD[7], J. Van Houdt, PhD[8], K. Cuppens, MD[9], K. Vanneste, PhD[5], E. Dequeker, PhD[8], S. Van Dooren, PhD[10], J. Van Huysse, MD[11], F. Nollet, PhD[12], S. van Laere, PhD[13], B. Denys, MD[12], V. Ghislain, PhD[14], C. Van Campenhout, PhD[14], M. Van den Bulcke, PhD[1]

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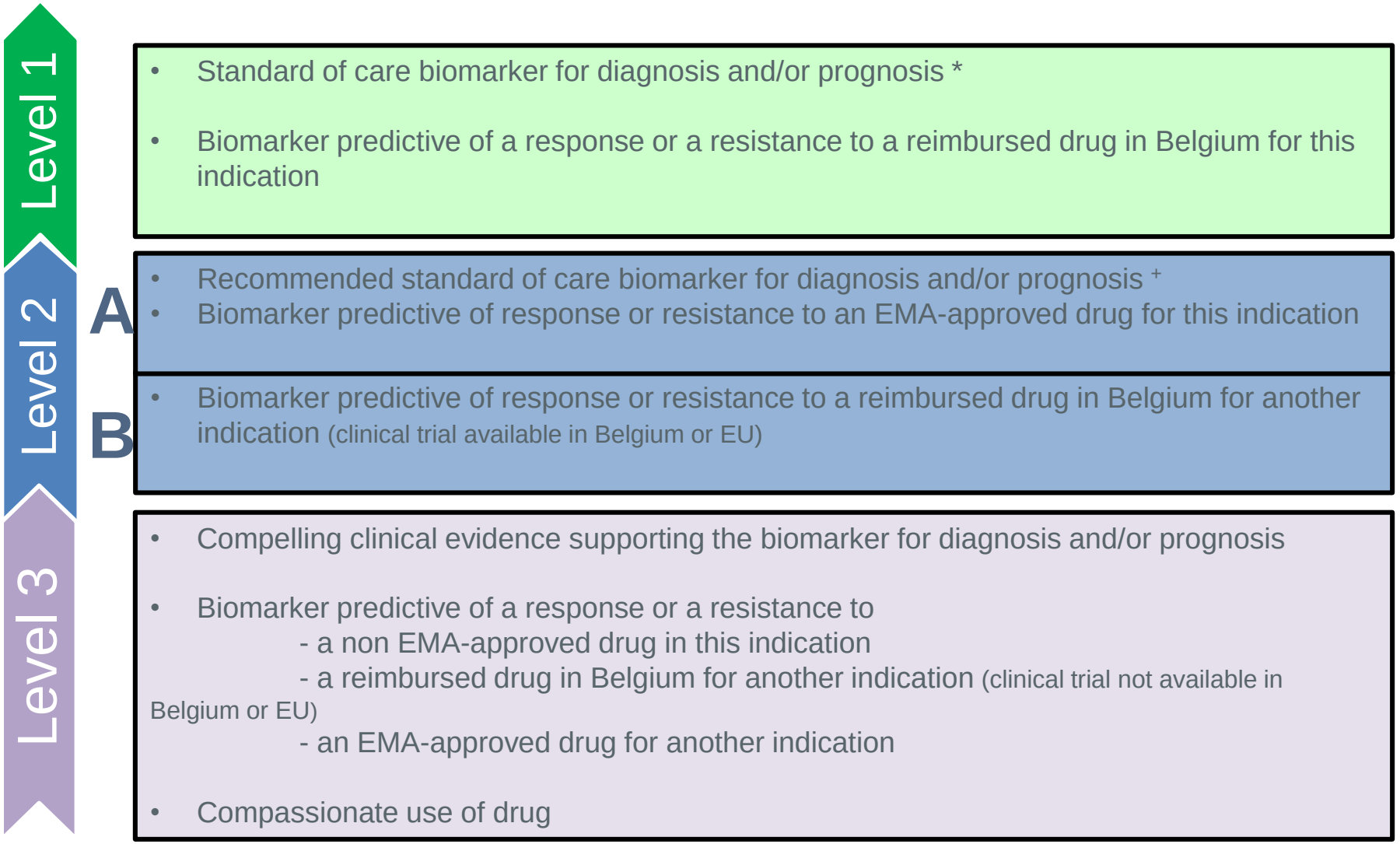
Test levels



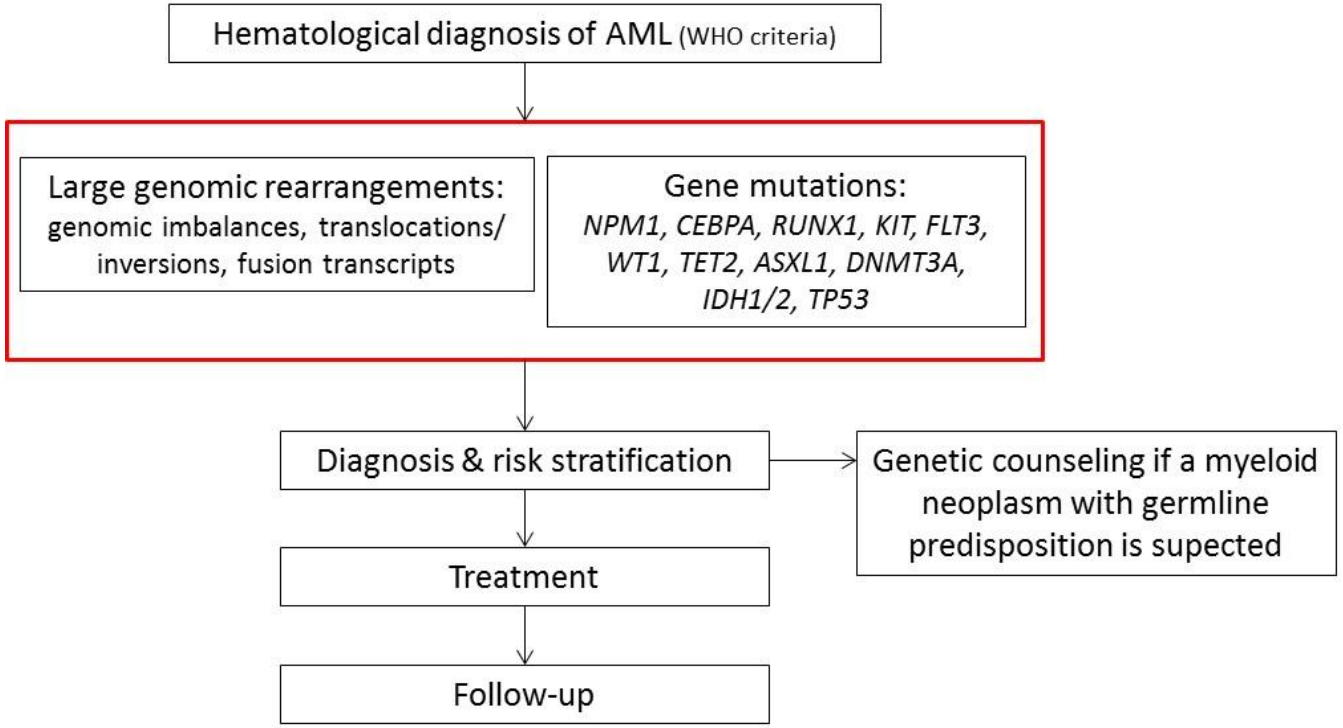
* Standard of care: Included in guidelines (WHO) AND consensus from experts ComPerMed

+ Recommended standard of care: Clinical evidence AND consensus from experts ComPerMed

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



ACTION 6: IMPLEMENT NGS REGISTRATION, STORAGE AND DATA MANAGEMENT

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NGS comes with the generation of large amounts of data and the management of such information can represent an important added value for quality, outcome analysis and reimbursement reallocation as well as for clinical and public health research.

- → develop a technical platform for central collection and storage of NGS data
- → Healthdata.be

- Ultimate goal: a **central molecular registry** with the results of all molecular tests
- → improving access to data for clinical research
- → facilitating evaluation and decision making for policy makers

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ACTION 7: PROVIDE NGS EDUCATION AND TRAINING

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Education and training on the use of NGS is necessary due to the various challenges

- Defining the concrete needs: in concert with the healthcare sector, more specifically the College of Oncology, the College of Genetics, the Commission of Clinical Biology and the Commission of anatomic pathology

- Cover different aspects:
  - technical, legal and ethical aspects
  - clinical applications
  - new evolutions towards third-generation long-range DNA sequencing, whole genome/exome sequencing, RNA sequencing

- A first initiative by the Molecular Pathology Working Group: a two-day course → mandatory for all residents in pathology

LINK TO TASK 4 & 5 OF WP6

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ACTION 8: INFORMED CONSENT, LEGAL AND ETHICAL IMPLICATIONS OF NGS USE

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AIM: to map the attitudes and information needs of cancer patients whom NGS testing is offered

Develop guidance for informed consent on use of NGS data

→ **Focus group** study:

→ **Citizen** labs

Link to task 1 of WP6

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ACTION 9: PILOT STUDY 'NGS USE IN ROUTINE DIAGNOSTICS'

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AIM:

- To assess the effectiveness of NGS in molecular diagnostics in oncology and hemato-oncology
- To assess how this multi-testing approach can be positioned in the current reimbursement system taking into account:
  - clinical utility
  - alternatives
  - therapeutic and societal need
  - quality and costs
- To evaluate how a molecular data registration system can be best organized for quality control, output analysis and public health research.

Aim: OPTIMAL GENOMICS-DRIVEN PATIENT CARE!!

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