Access to Personalized Medicine:
linked reimbursement for drug/diagnostic combinations

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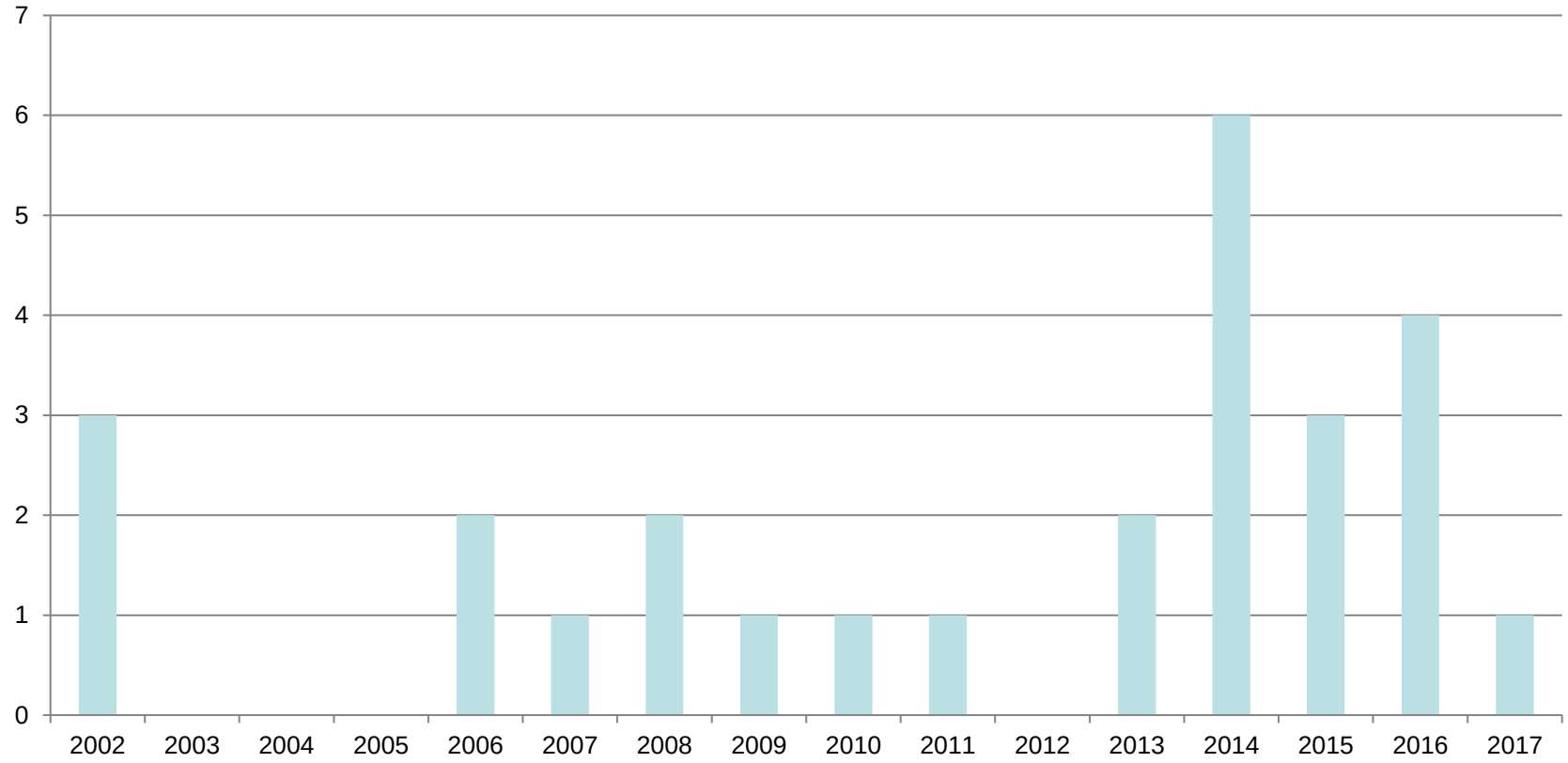
access to personalised medicine in Belgium

“personalised medicines” reimbursed in BE

status March 2017



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→ what is the goal of health care systems?

The primary goal of health care policy =
to m… …CIENCY
pop…
avai…

Challenges

within an ethical framework built on equity and solidarity principles. → EQUITY

Report of the Belgian EU Presidency, endorsed by the EU Council of Ministers of Health in Dec 2010

access to personalised medicine in Belgium

- innovation challenge
  - simple tests…….multimarker tests…….full genome/exome
  - new technologies
  - rapid evolution: complexity increases
- integration challenge
  - different expertise
  - good clinical practice
- infrastructure challenge
  - link patient data from different areas/ fields of specialisation
  - real-world data

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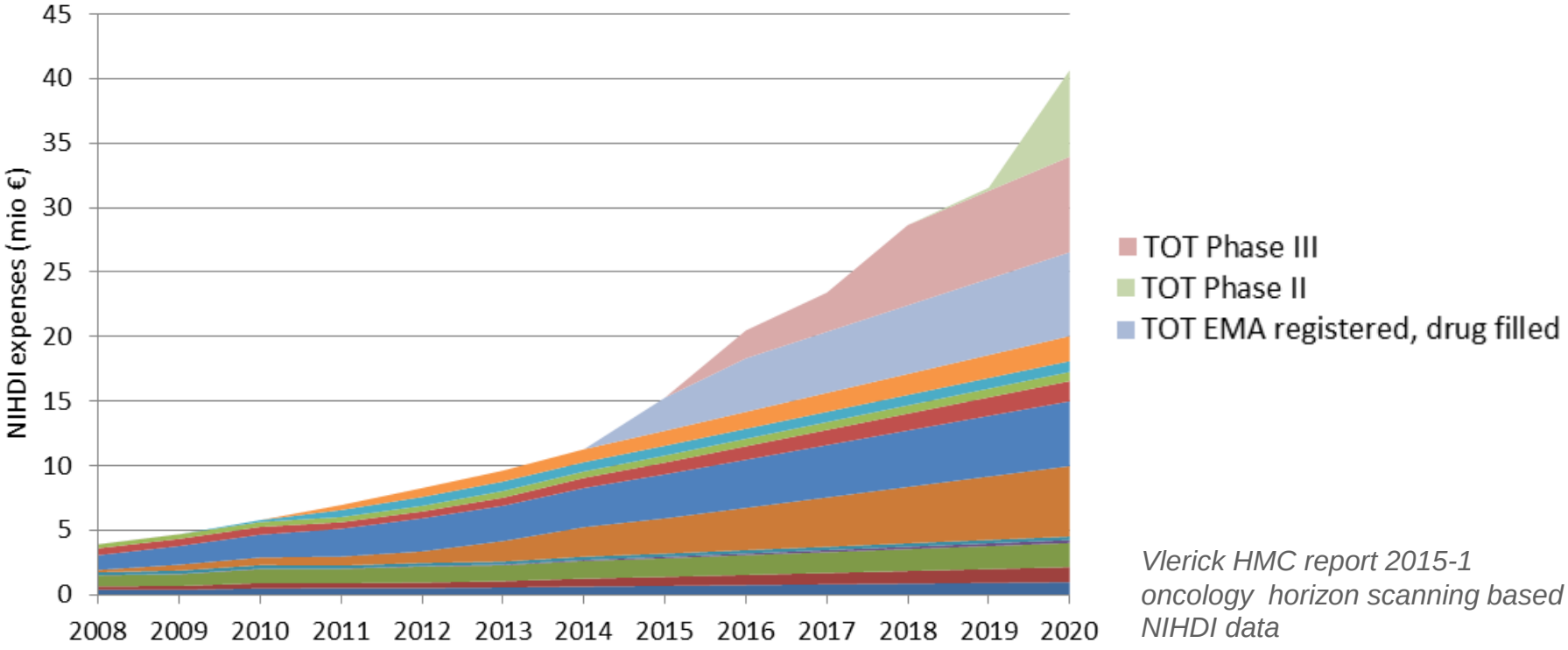
- financial challenge
  - Projection of the budget impact of the Dx from 2008 to 2020



Vlerick HMC report 2015-1 oncology horizon scanning based on NIHDI data

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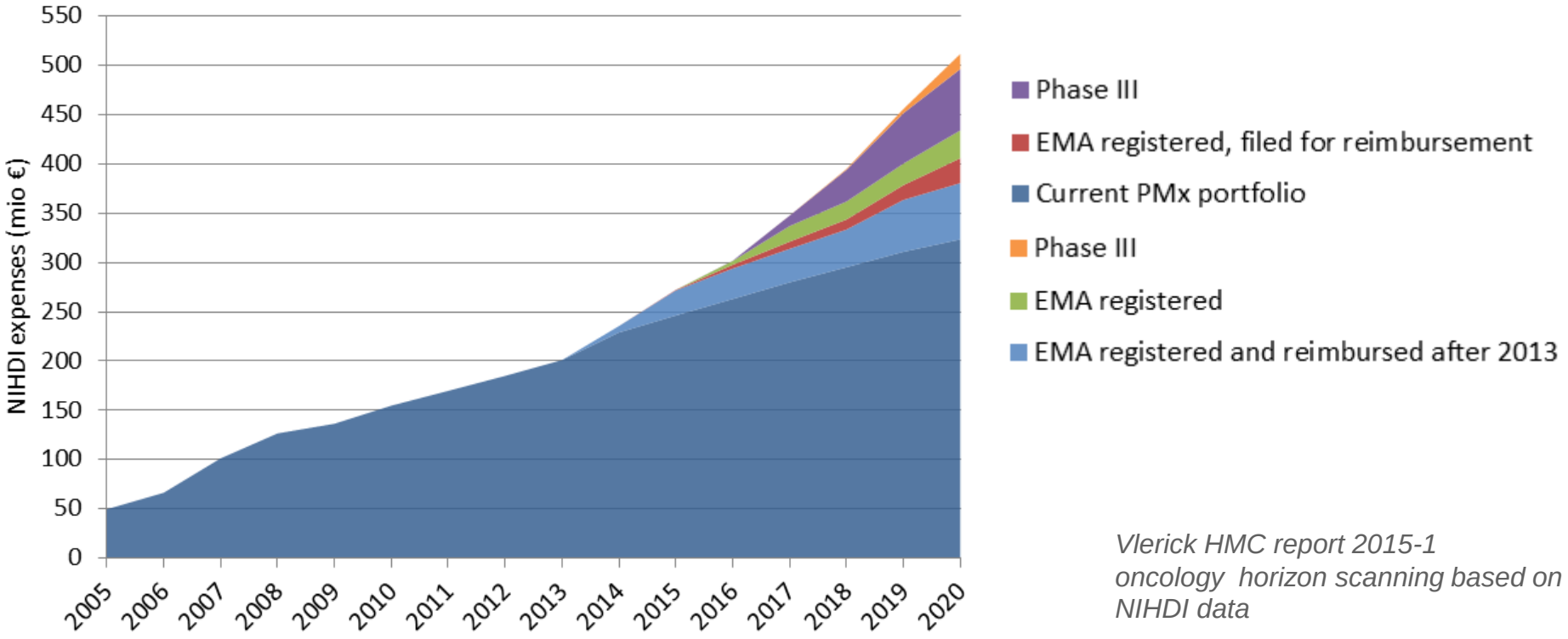
- financial challenge
  - Projection of the budget impact before savings of reimbursed PMx in Belgium from 2005 to 2020



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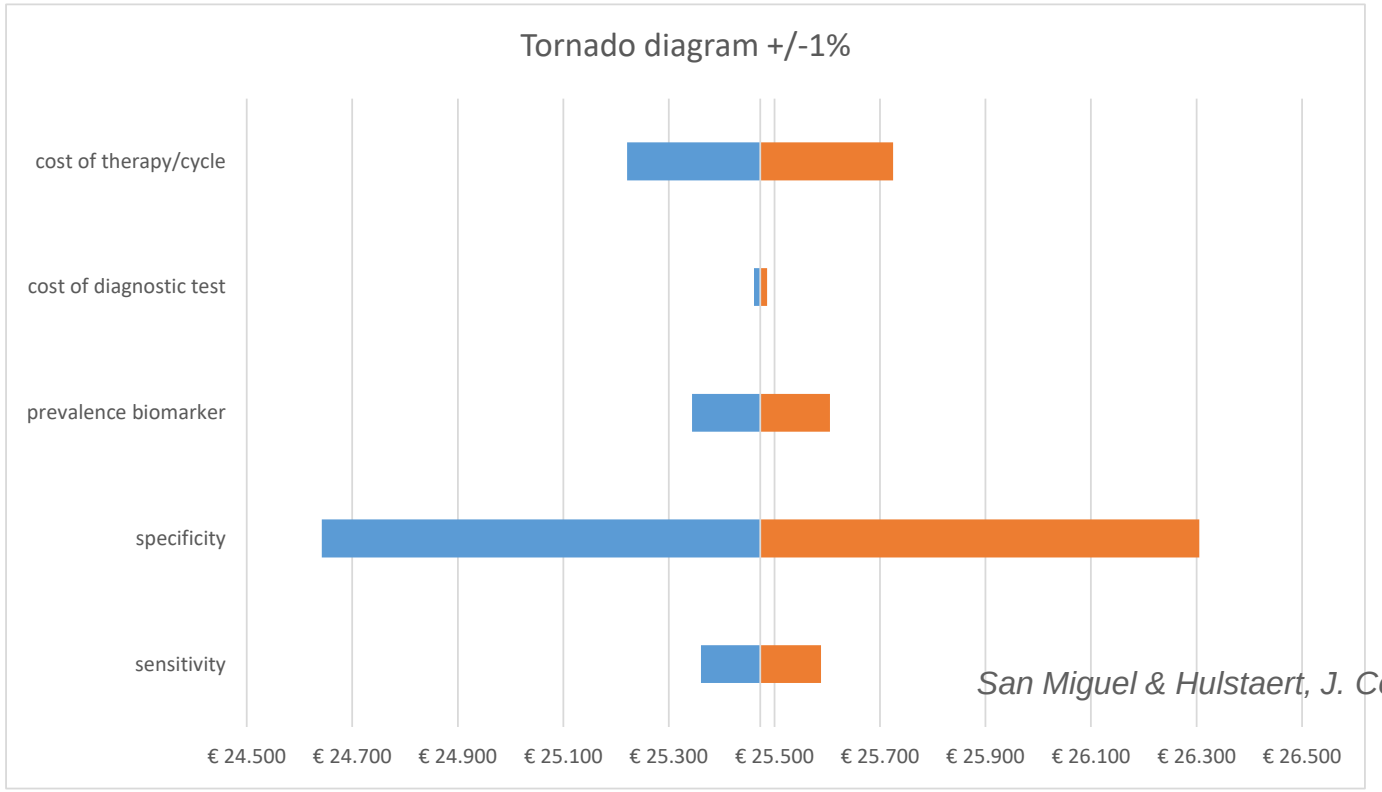
quality impact: influence of different parameters on cost effectiveness (trastuzumab/HER2 example)



San Miguel & Hulstaert, J. Comp. Eff. Res. 2015

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quality impact: influence of **specificity** on cost effectiveness (trastuzumab/HER2 example)

Variable	Gold standard – FISH test	Scenario 1	Scenario 2
		IHC – treat IHC 2+ and 3+	IHC plus FISH for 2+ and 3+ only
Sensitivity of test (%)	100.0	96.2	96.2
Specificity of test (%)	100.0	88.3	100.0
ICER (vs no treatment)	€15,344	€25,473‡	€14,726

San Miguel & Hulstaert, J. Comp. Eff. Res. 2015

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- regulatory challenge

reimbursement of medicines (CRM)

versus

reimbursements of acts/diagnostic tests (TMC)

- different commission
- different timelines
- different budget
- within NIHDI: different departments

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- regulatory challenge

Medicines:

CRM → Minister → MD

6 months + suspensions

Tests: first: WG Clinical Biology, then:

TMC → Medico-mut → CBC → Ins Com → Minister → RD

minimum 18 months

- **2 different technologies/processes/expertise**
- **keep up with quick technological evolution**

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NIHDI vision:

access to personalized medicine:

health care reimbursement procedures
should be adapted to achieve
a simultaneous reimbursement start
for treatment and test

reimbursement of personalised medicine: permanent mixed working group CRM – TMC

Platform Companion Diagnostics (CDX@riziv.fgov.be)

- members:
  - representatives of TMC and CRM (Bureau) (or substitute)
    - Laboratories (Clin Biol., Path, CMG)
    - Clinicians
    - Insurers
    - WIV-ISP
    - KCE
    - NIHDI
    - ComPerMed
    - invitees (HealthData, Cancer Registry,…)
  - conflict of interest, confidentiality

reimbursement of personalised medicine: permanent mixed working group CRM – TMC

- tasks:
  - advise to both CRM and TMC
    - new nomenclature
    - modifications of existing nomenclature (link drug)
    - implementation of new technologies (NGS, GEP)
    - ad hoc expertise dossiers (CRM-TMC)
      - e.g. Tagrisso (CRM)
- communication ComPerMed

Personalised medicine: linked reimbursement procedure

simultaneous reimbursement drug-test

- scope:
  - medicines that have a predictive molecular biology marker in their reimbursement criteria (CRM) + these markers (TMC)
- required characteristics:
  - linked
  - flexible
  - timely
  - transparent
  - package (combined expertise)

  all this taking into account competence

Personalised medicine: linked reimbursement procedure

- concept:
  - **NEW article 33ter:**
    - new “generic” nomenclature codes for predictive tests linked to a drug *(diagnostic/prognostic: article 33bis)*
    - defined by TMC
    - published by royal decree
  - **NEW chapter “VIII”:**
    - list of “personalised” drugs
    - + list with “companion” tests

if the Minister decides to reimburse the drug, the marker will be added to the list by the same Ministerial Decree

Personalised medicine: linked reimbursement procedure

- methodology
  - providers: idem art 33bis
    - Clinical biology
    - Pathology
    - Centre for human genetics
  - content: end-to-end process
  - quality: ISO15189 + control by ISP-WIV + EQA
  - fee: 3 levels of complexity
    - complexity of test
    - complexity of sample
    - prevalence
    - consistent with existing nomenclature 33 and 33bis

Personalised medicine: linked reimbursement procedure

- methodology
  - follow-up: separate codes
  - diagnostic rules:
    - 1/diagnostic phase
    - follow-up: 1/follow-up period
  - cumulative rules:
    - on the list for art33ter = tarification through 33ter
    - no double tarification (with 33bis)
  - registration mandatory
    - start with “light” registry
    - reports for data providers, health insurance and
    - future: link with MOC/COM and outcome data

Belgian Cancer Registry

Personalised medicine: linked reimbursement procedure

nomenclature (TMC): art. 33*ter*

platform CDx

drugs (CRM): chapter VIII

reimbursement possible after testing for an associated predictive marker

Code "A"
marker-indication combo in the list of chapter "VIII" (level 1)

Code "B"
marker-indication combo in the list of chapter "VIII" (level 2)

Code "C"
marker-indication combo in the list of chapter "VIII" (level 3)

registration of result mandatory

§ 123
Reimbursement of specialty drug Herceptin in metastatic breast cancer if amplification of the gene HER2 with a test performed as per article 33ter of the nomenclature + other criteria

list with marker-indication combo:
Pseudocode abc
amplification HER2 in metastatic breast cancer, code C (level 3)

Personalised medicine: linked reimbursement procedure

- impact
  - Article 33ter: drug in chapter VIII (reimbursement conditions)
    - change of fees
    - new tests
  - Article 33bis: prognostic/diagnostic/…
    - cumulative rule: no double tarification with 33ter
    - transfer of purely predictive tests
    - new generic code level 1
    - generic code B-3000: only once
  - Chapter VIII: MOC/COM, electronic if possible
  - budget:
    - redistribution
    - 2 mio EURO from Cancer Plan

Personalised medicine: linked reimbursement procedure

- reimbursement procedure new drug/diagnostic:
  - submission CRM of drug/diagnostic combo
  - the CRM evaluates the package drug-marker
  - the CRM is advised by clinical + technical experts
  - the CRM formulates, timely, a motivated proposal to the Minister, who decides whether or not to reimburse of the drug and to add the marker on the list (transparent)
  - the decision of the Minister on new reimbursements, or on modifications, is published every month (flexible)
  - every addition of a new marker to the list and every change of the list is discussed in the platform CDx and subsequently validated by the TMC (competence)

Personalised medicine: linked reimbursement procedure

- tarification procedure for tests through art 33*ter*:
  - every test can be charged, whatever the result
  - mandatory registration of test + result in the HealthData registry **PITTER**
    → only once
  - PITTER automatically generates a registration ID
  - tarification:
    - nomenclature code
    - pseudocode
    - registration ID

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INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE
HEALTHDATA

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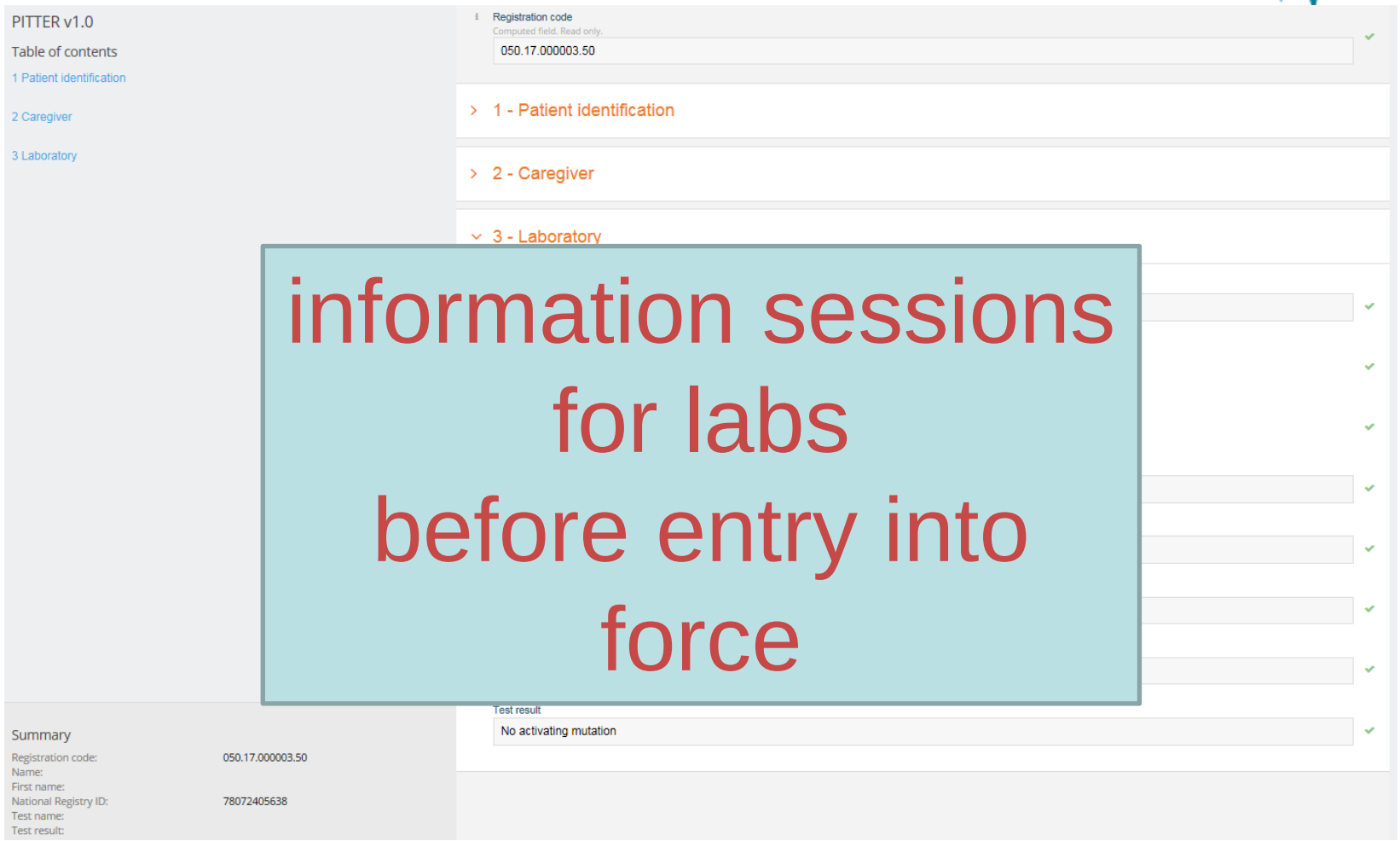
Q1 2018

Personalised medicine: linked reimbursement procedure



information sessions for labs before entry into force

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