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Improving Cancer Care through Broader Access to Quality Biomarker Testing – An IQN Path, ECPC and EFPIA Initiative

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DECLARATION OF INTERESTS

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- **Personal financial interests (speaker's fee and/or advisory boards):** MSD, Qiagen, Bayer, Biocartis, Illumina, Incyte, Roche, BMS, MERCK, Thermofisher, Astrazeneca, Sanofi, Eli Lilly; Novartis
- **Institutional financial interests (financial support to research projects):** MERCK, Thermofisher, QIAGEN, Roche, Astrazeneca, Biocartis, Illumina, Blueprint
- **Non-financial interests:** President, International Quality Network for Pathology (IQN Path); President, Italian Cancer Society (SIC)

Background

- Predictive biomarkers are essential for selecting the best therapeutic strategy in cancer patients[1]
- The number of predictive biomarkers is increasing: it has been estimated that >25% of patients with advanced cancer may receive a treatment based on genomic profiling[2]
- The availability of high quality biomarker testing is a major limit for the possibility of patients to access to genomic-driven target therapies
- ESMO recently recommended the use of next generation sequencing (NGS) in selected tumor types in routine clinical diagnostics[3]
- The International Quality Network for Pathology (IQN Path ASBL), the European Cancer Patient Coalition (ECPC) and the European Federation of Pharmaceuticals Industries and Associations (EFPIA) launched an initiative to evaluate the access to and quality of biomarker testing across Europe

1. Normanno Sem Cancer Biol 2021; 2. Haslam Ann Oncol 2021; 3. Mosele Ann Oncol 2020

Access to and quality of 12 biomarker tests plus liquid biopsy

Tier 1
Single biomarker IHC / FISH
PD-L1
Single biomarker molecular
BRCA
EGFR
NTRK
Complex genomic signatures
NGS hotspot (up to 50 genes) / targeted panel
NGS comprehensive panel

Tier 2
Single biomarker IHC / FISH
HER2
ALK
MMR / MSI
ROS1
Single biomarker molecular
BRAF
KRAS / NRAS
Other
Liquid biopsy (ctDNA / plasma)

Covered for EU27 and UK

Germany, France, Italy, Spain, UK, Belgium, Netherlands, Sweden, Poland, Greece

Methodology

- Data sources included:
  - ✓ surveys of 141 laboratory managers and of 1.665 cancer patients;
  - ✓ 58 in-depth interviews with laboratory managers, physicians, and payers;
  - ✓ academic papers and documents from government bodies, quality assurance bodies, cancer networks and institutes, other sources
- Access metrics (medicine availability, laboratory access, test availability, test reimbursement, test order rate) and quality metrics (quality scheme participation, laboratory accreditation, test turnaround time) were applied
- The findings were reviewed over a series of meetings by IQNPath, ECPC, EFPIA and key opinion leaders, in order to develop an unbiased view of existing test access barriers and to establish a consensus on critical policy recommendations for immediate, concerted action

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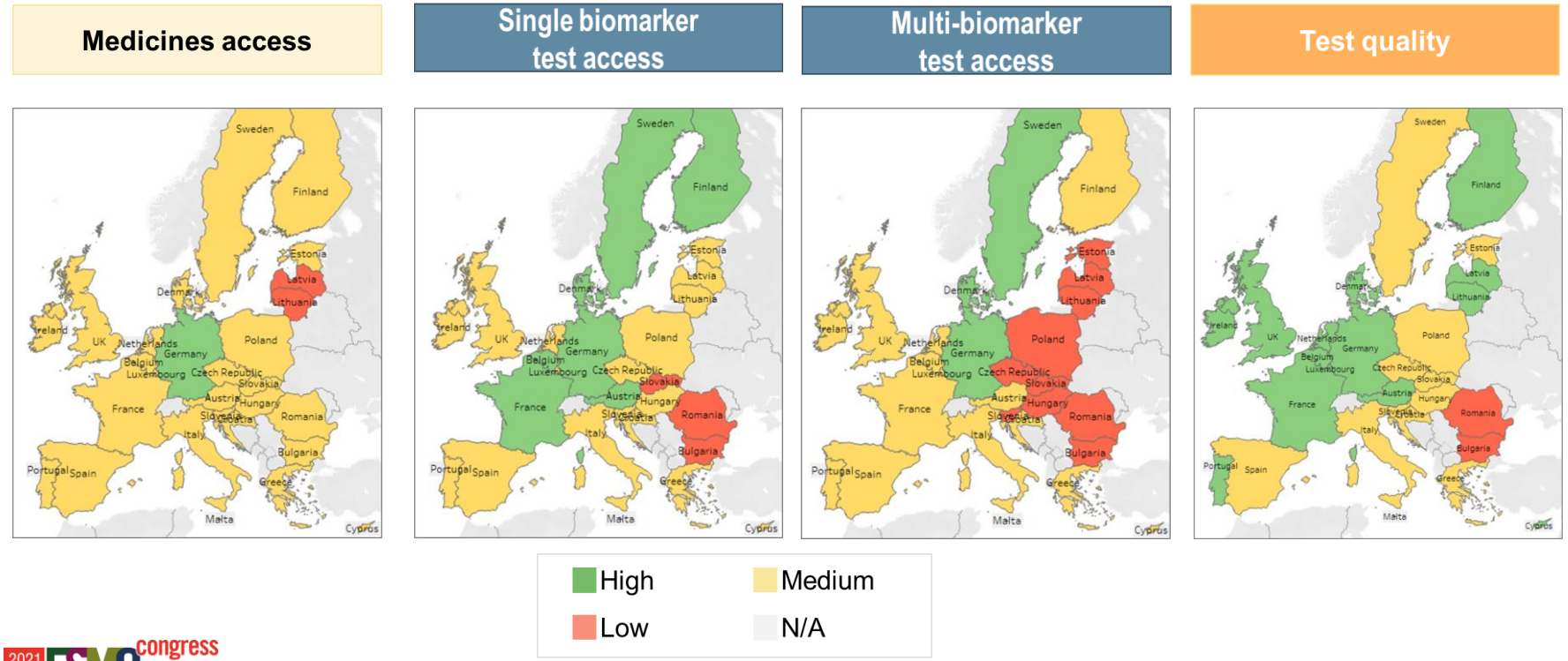
Significant variations in drug and test access as well as test quality across Europe



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Key barriers to high quality biomarker testing

Key metrics investigated	Key barriers
Precision medicine availability	▪ Significant delay in medicines access following EMA approval triggering a lag in biomarker test access ▪ Some precision medicines launched but not reimbursed
Biomarker test infrastructure	▪ Regional variations in diagnostic lab coverage ▪ Variation in or lack of availability of different test technologies and capabilities
Approval and integration of tests	▪ No / weak link between approval process for medicines and the relevant biomarker test(s), resulting in delays ▪ Slow integration of new biomarker tests into SoC
Test funding and reimbursement	▪ Funding not sufficient to support testing capabilities / infrastructure across regions or widespread testing ▪ Lack of funding for larger gene panel tests
Test uptake and continued use	▪ Low awareness of availability and referral pathways for new tests / technologies ▪ Lack of centralisation of biomarker data
Test quality	▪ Lack of participation in EQA schemes (budget limitations) ▪ Limited ISO accreditation in a number of countries ▪ High send-out rates impact turnaround times

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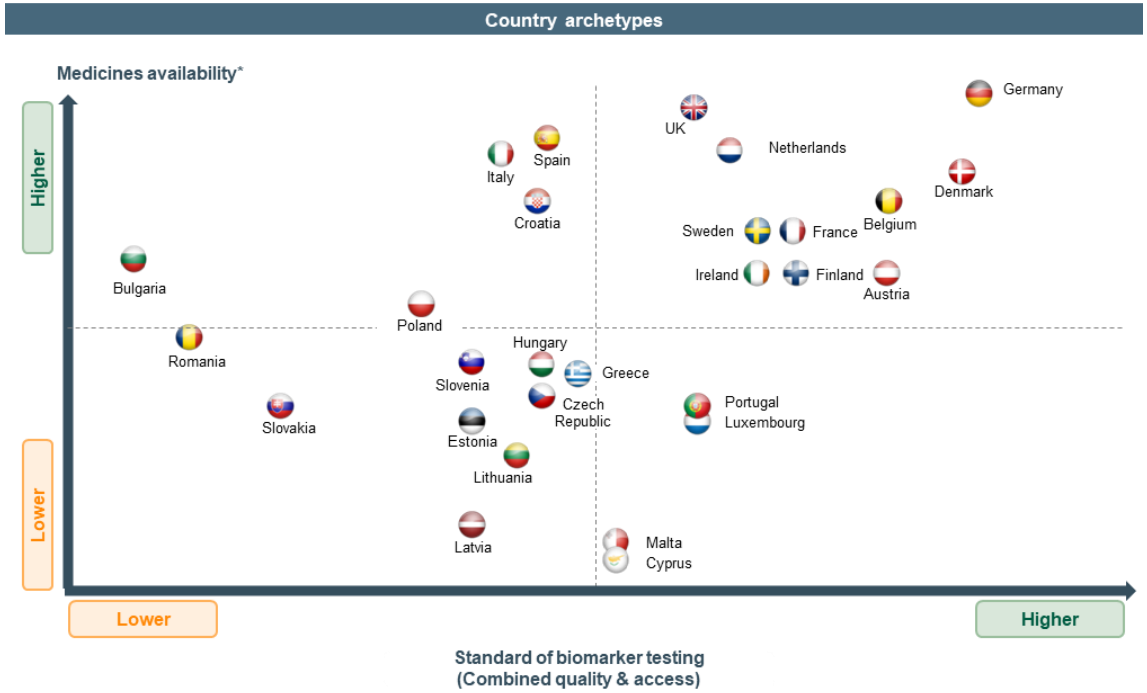
Germany, Denmark and Belgium are among the EU's leading countries for precision medicine and test access



Precision medicine in Europe: a call to action

- All cancer patients eligible for biomarker-linked therapy must undergo testing for all clinically relevant biomarkers that are indicated for precision medicine, with use of extended panels where appropriate

- The following actions are needed to improve in a short term the access to biomarker testing:
  - ✓ Parallel approval of the medicine and associated testing
  - ✓ National system for biomarker test value assessment
  - ✓ Dedicated biomarker test budgets
  - ✓ Mandatory ISO accreditation and EQA scheme participation
  - ✓ Regional testing centres
  - ✓ Stakeholder education
  - ✓ Centralised national data collection
  - ✓ Horizon scanning for future testing needs

- In the next future, all patients with a cancer diagnosis should undergo comprehensive, ongoing tumour testing throughout the episodes of care

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- L.E.K. Consulting

*major sponsors