

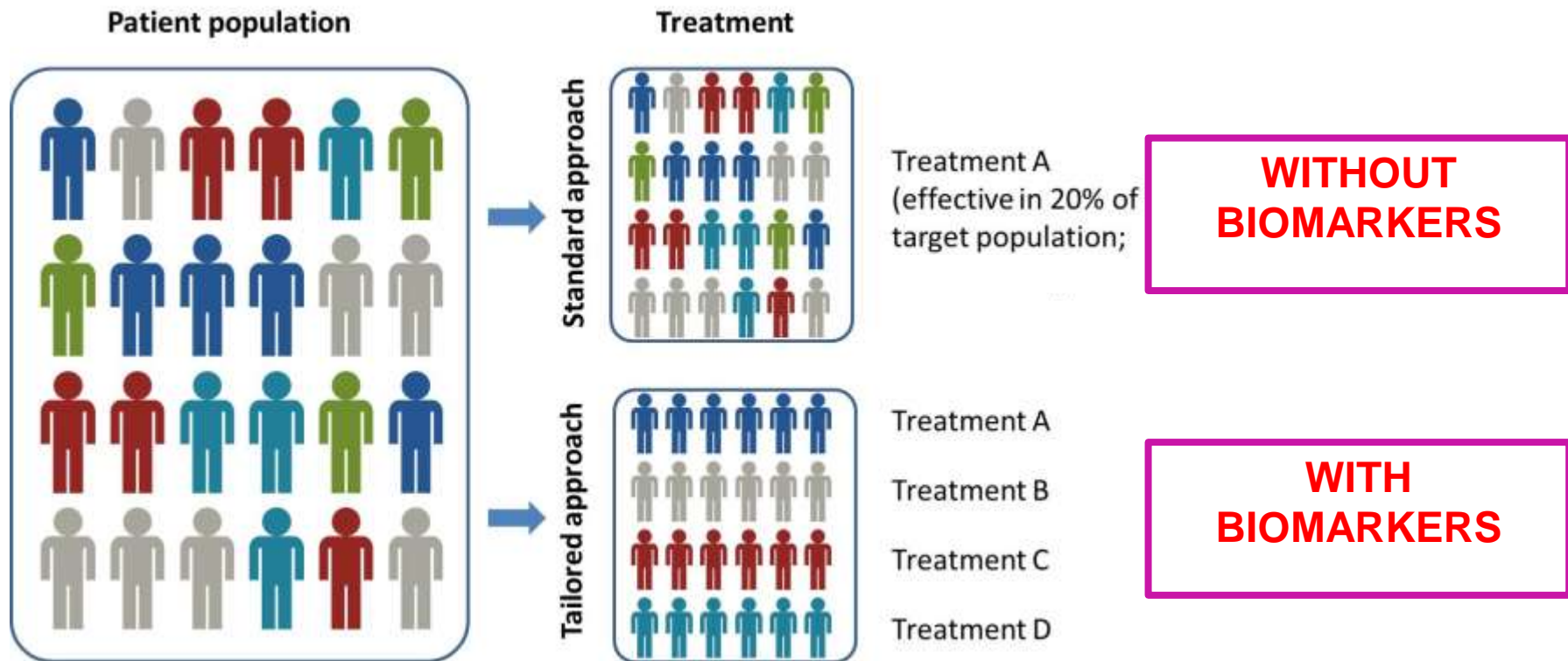
# Organization and quality of biomarkers testing in Europe

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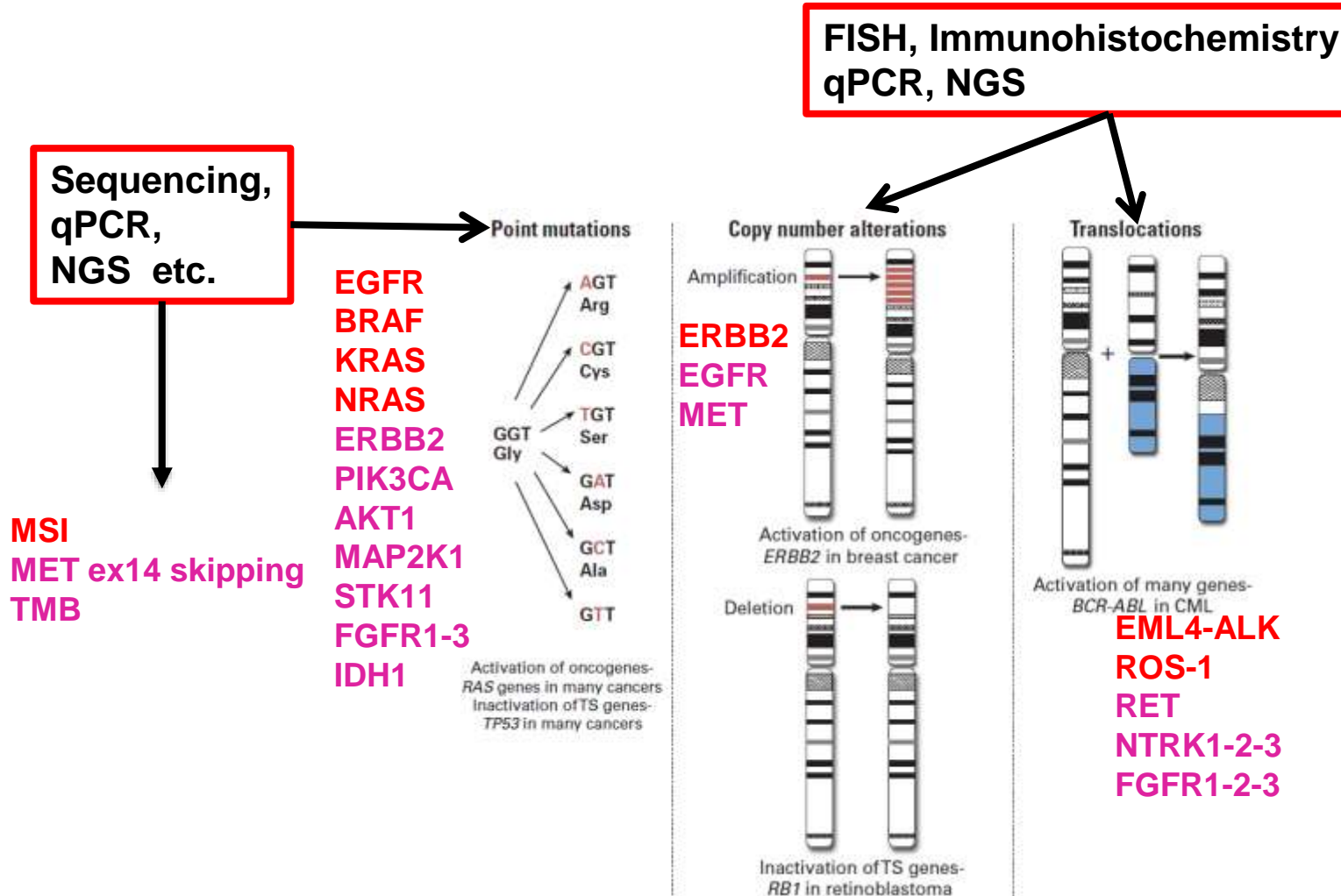
**IQN**Path

International Quality Network for Pathology

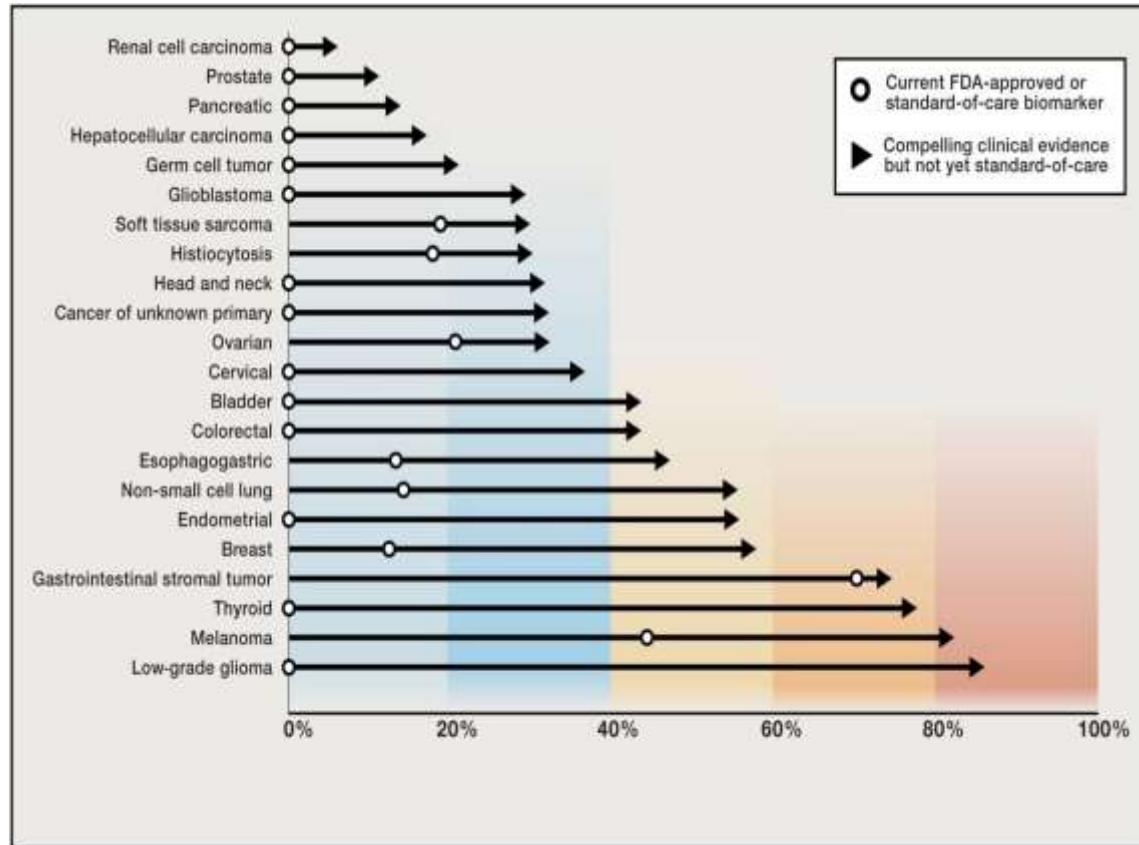
# Target-based agents + predictive biomarkers: PRECISION MEDICINE



# The major classes of genomic alterations that give rise to cancer



# Druggable Alterations in Oncology Today and in the Near Future

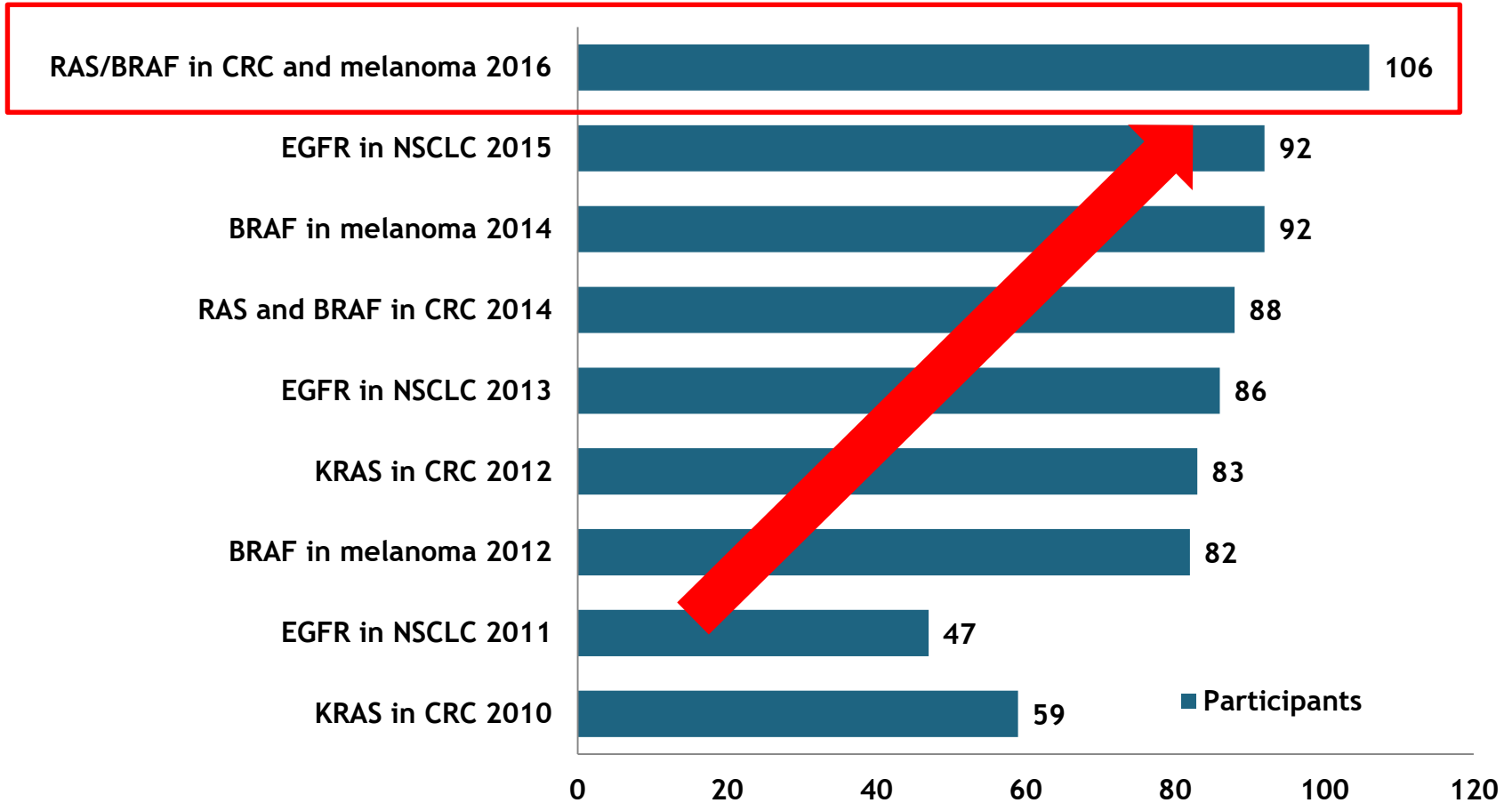


# Molecular genetics platforms in France



- The 28 molecular genetics centers are regional hubs for expert molecular testing. The centers were selected through competitive calls for proposals.
- The centers are located throughout the country, with an average of one center per administrative region; their number is not expected to increase.
- Each molecular genetics center is a partnership between several university hospital and cancer center laboratories with complementary expertise

# AIOM-SIAPEC EQA schemes: the RAS/BRAF quality control program 2016



# Results of the AIOM-SIAPEC EQAs (2)

CRC Quality Control Scheme (passed %)	1° round	Scheme results
KRAS EQA 2010*	96,6	96,6
KRAS EQA 2012	88,0	95,2
RAS and BRAF EQA 2014	63,6	89,8

NSCLC Quality Control Scheme (passed %)	1° round	Scheme results
EGFR EQA 2011	70,2	87,2
EGFR EQA 2013	70,9	80,2
EGFR EQA 2015**	87,0	NA

Melanoma Quality Control Scheme (passed %)	1° round	Scheme results
BRAF EQA 2012	79,3	89,0
BRAF EQA 2014**	81,5	81,5

In those schemes consisting of two rounds, many centers could overcome their errors and pass the quality control program.

The CRC quality control scheme in 2014 is the first to report data on full RAS and BRAF testing.

\*5 samples; \*\*one single round

# Organization and quality of biomarkers testing in Europe

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- Clinical development and possible short-term approval of new target-based drugs requiring complex biomarker analysis (tumor mutation burden, gene fusions, liquid biopsy), make it necessary the development at European level of a new policy of management of biomarkers' testing.
- This project aims to provide a starting point for discussion that contributes to developing a new governance for the management of tests for biomarkers.
- *The output of this project is the preparation of a white paper on the status of biomarker tests in Europe, with particular regard to the problems of access to tests for biomarkers and the quality with which the tests are conducted.*



# Actions

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- A survey about availability of biomarkers testing in European countries;
- Information from scientific societies/EQA providers on the organization of biomarker testing and on the procedures for the introduction in the clinic of new biomarkers in selected European countries;
- Data from EQA providers about: number and geographic location of laboratories providing biomarker testing; performance of laboratories participating to EQA schemes; variation in performance observed in EQA programs over the time.

# Output

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- The data collected will be used to evaluate differences between European countries with respect to the number of laboratories carrying out tests for biomarkers, the presence or absence of national or regional networks with centralized testing facilities and the effects of the organization on the possibility of patients to receive the tests and on the quality levels of the tests.
- The data will be published and presented in an international conference to the major stakeholders in the field (EMA, European Commission, European Parliament) in order to open a discussion on the need of a governance in the field of biomarker testing which might lead to greater possibilities for patients to access high quality tests.

# Participating institutions

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- The European Society of Pathology (ESP)
- UK NEQAS
- The European Molecular Genetics Quality Network (EMQN)
- The Italian Association of Medical Oncology (AIOM)
- GEN&TISS
- The German Society of Pathology (DGP)
- The European Federation of Pharmaceutical Industries and Associations (EFPIA)
- The European Cancer Patient Coalition (ECPC)