



WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

Benchmarking trial and EQA NGS in (hemato-)oncology

Vanessa Ghislain

Brussels, 25/10/2016

Benchmarking defined



Benchmarking defined

*The practice of a business comparing
key metrics of their operations
to other similar companies*

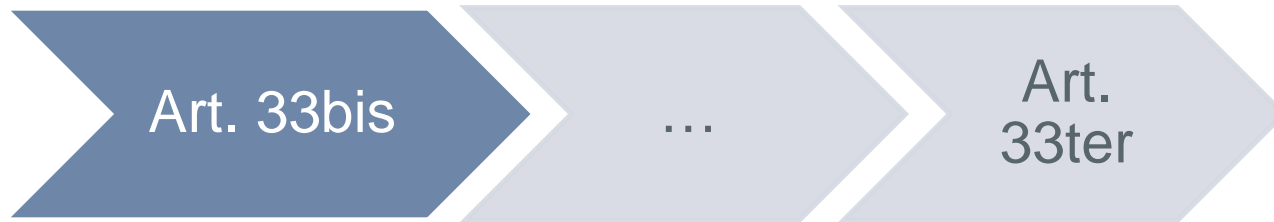
Benchmarking trial

- “interlaboratory test”
 - X proficiency test
 - X EQA (external quality assessment)
- **Research**
- No consequences for license or accreditation
- Samples may not be used for EQA

Aim

- Examine the ability of the validated/accredited NGS assays to accurately and reproducibly detect clinically relevant mutations (solid tumors) in each of the participating laboratories
- Compare the performance of different NGS methods currently used (art. 33bis) by different laboratories in Belgium
- Develop a national EQA program : same standard!

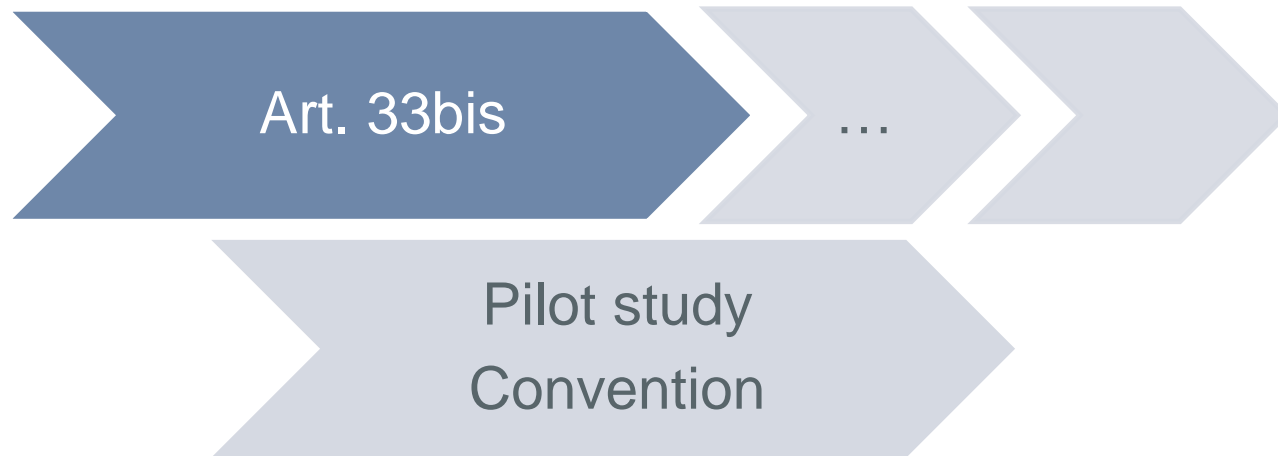
Financing NGS



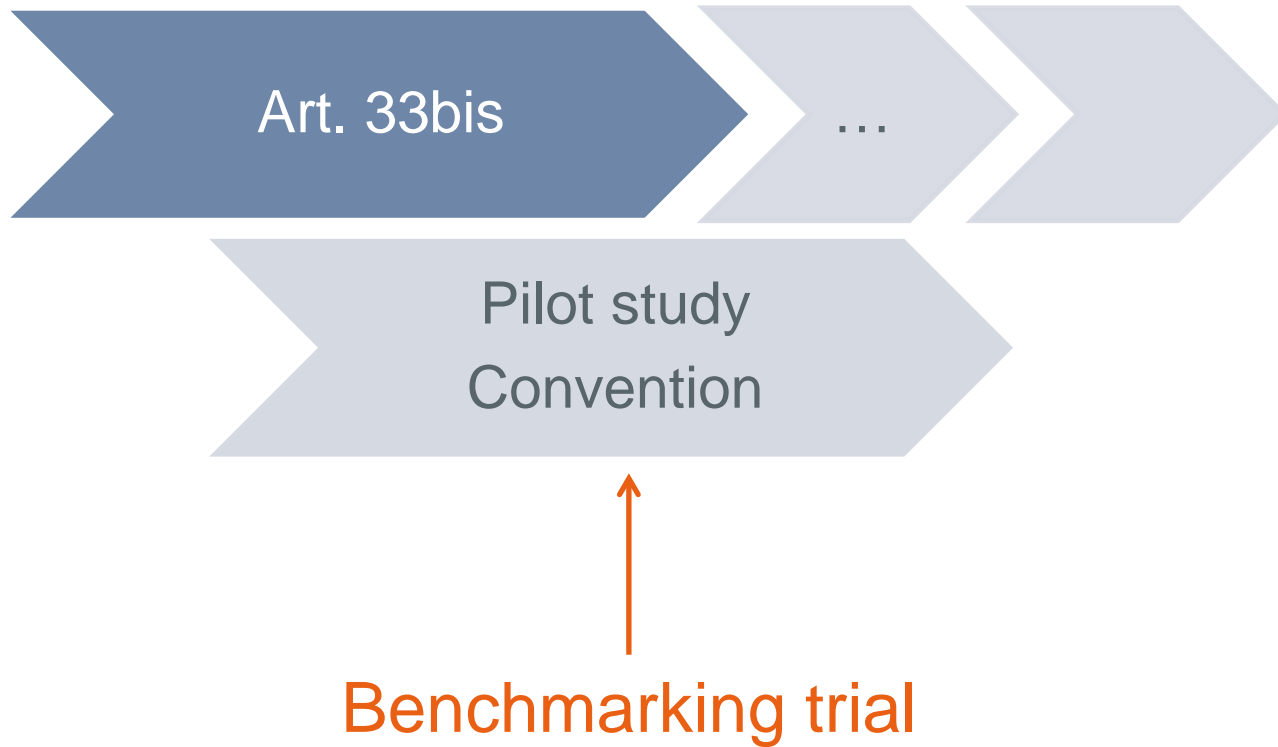
Financing NGS



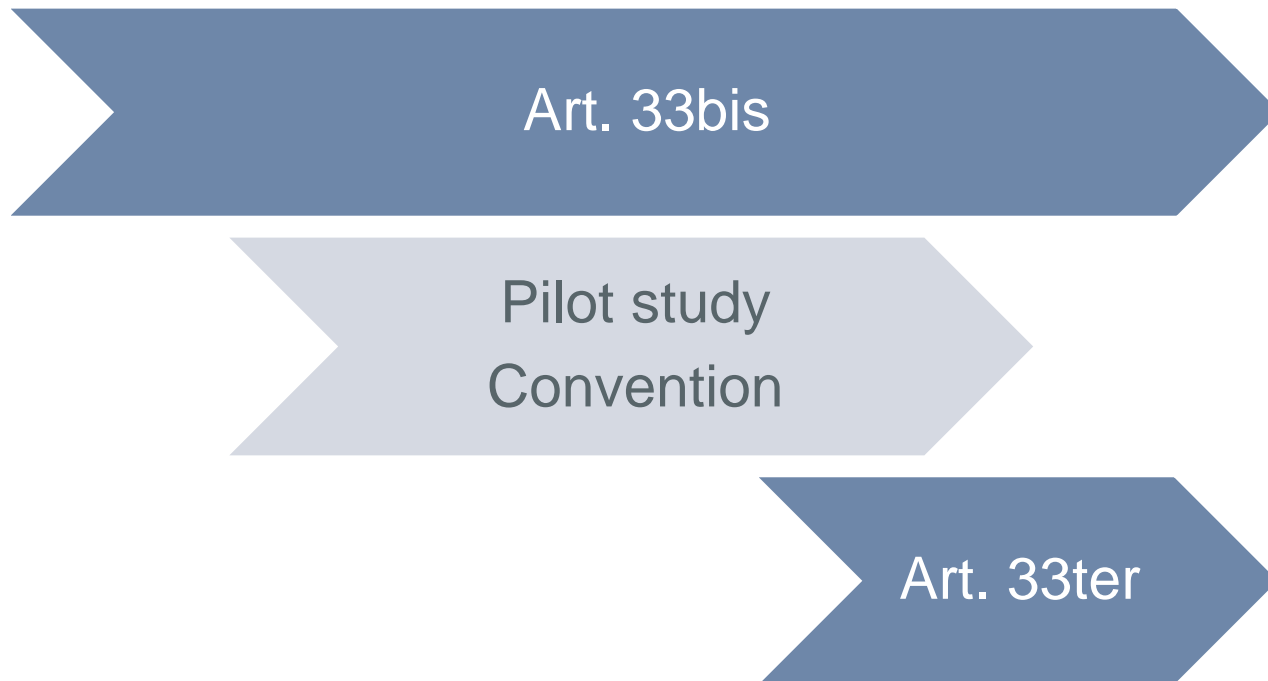
Financing NGS



Financing NGS



Financing NGS



Analytical performance parameters



- ✓ Analytical sensitivity
- ✓ Analytical specificity
- ✓ Overall accuracy
- ✓ Intra-laboratory reproducibility
- ✓ Inter-laboratory reproducibility

Methods

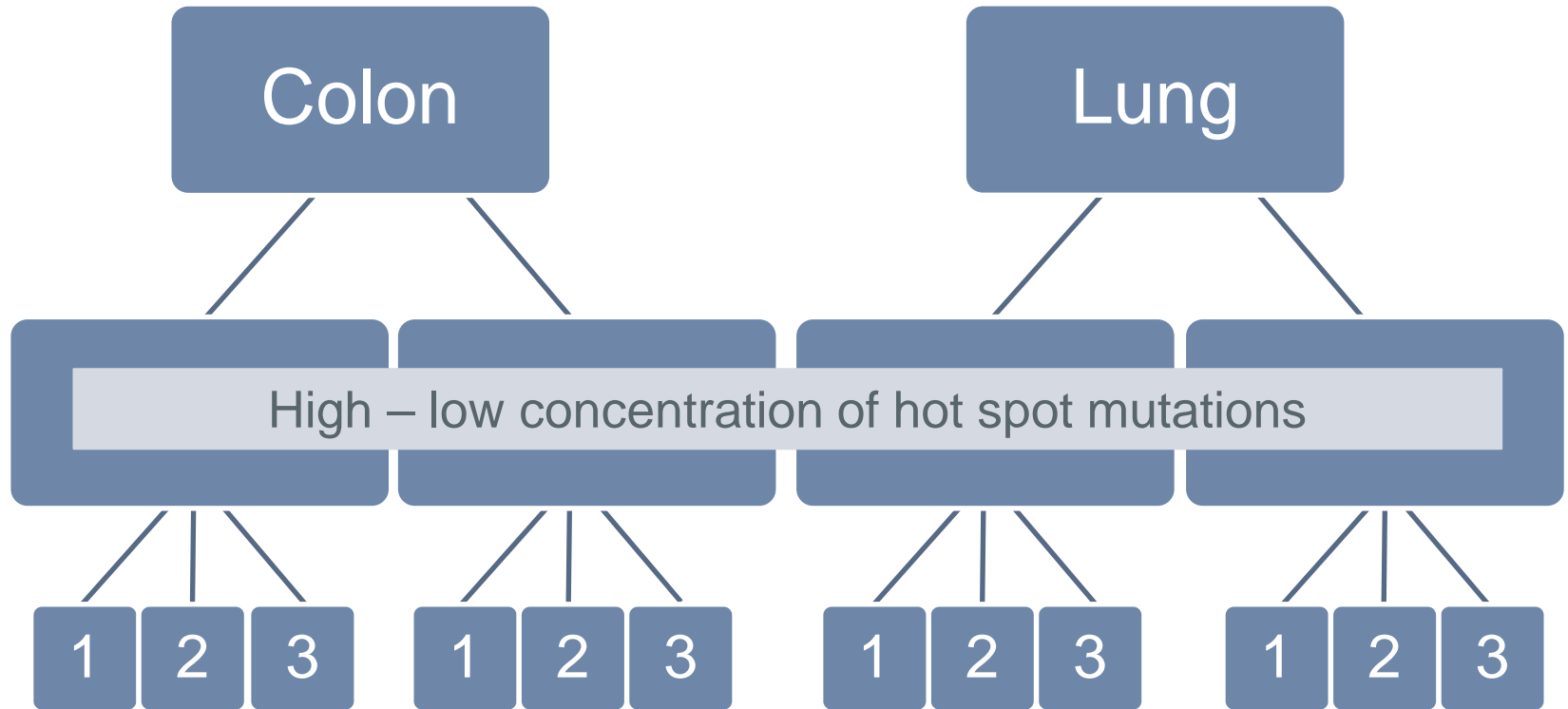
- Participation is open to all Belgian laboratories who meet the actual legal conditions :
 - ✓ License (pathology, clinical biology, centre for human genetics)
 - ✓ Accreditation ISO15189 for medical laboratories

Methods

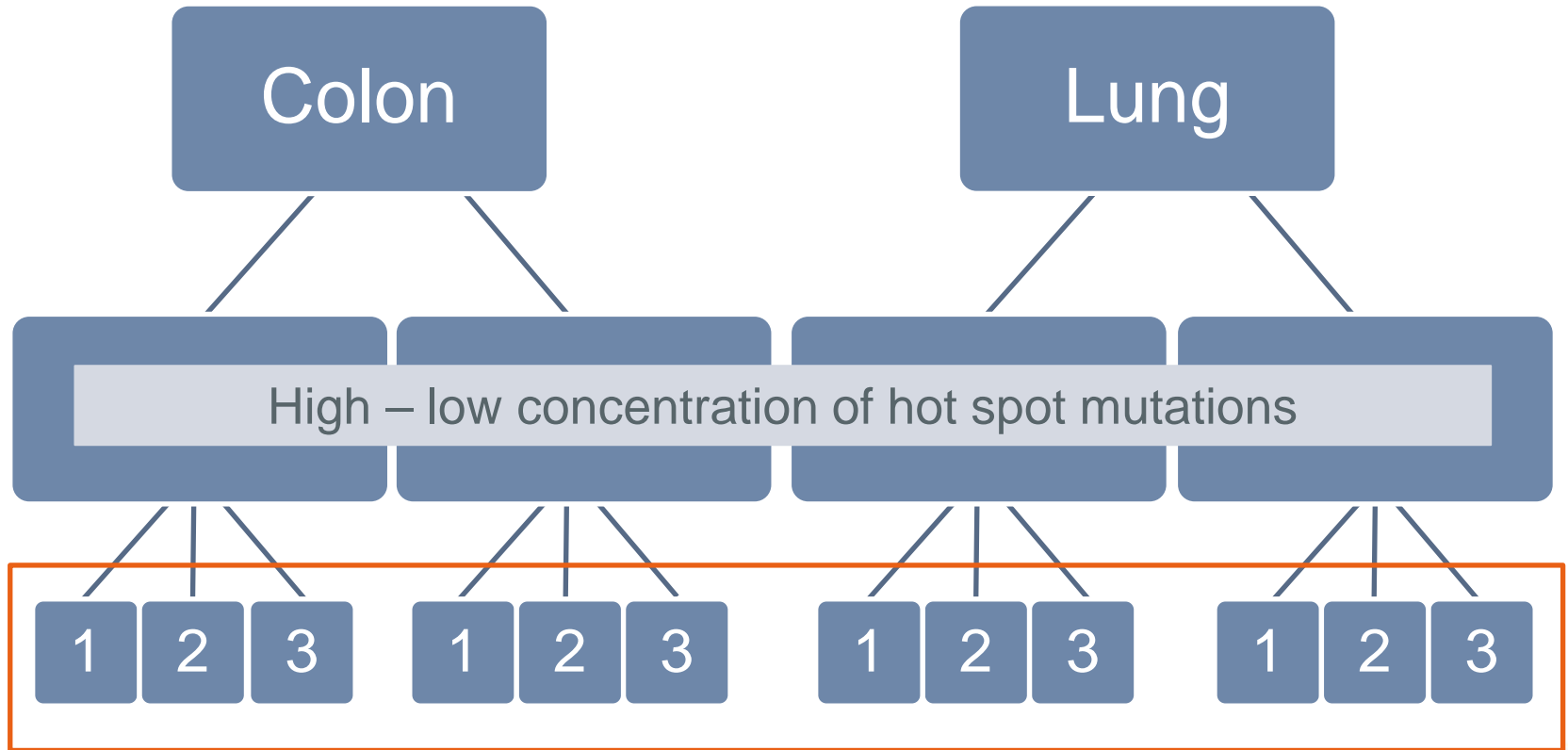
- “Optimal” sample material
- Well-characterized genomic DNA from tumor cell lines
- Supplied by WTSI (UK)



Samples



Samples



12 samples

Methods

- Analyze samples by NGS as routinely performed, using your standard methods for :
 - ✓ sequencing
 - ✓ variant detection as determined by the bioinformatics pipeline for data analysis
- Report :
 - ✓ Methodology
 - ✓ Interpretation (targeted gene panels : provide results for those chromosomal positions interrogated by your panel)
 - ✓ Raw data files

Where we are now

- Labs have been invited to participate
- Markers (gene list) being defined
- Shipment of samples asap
- Set-up a expert committee who will be involved in the assessment of the results,...

Where we are now

- Labs have been invited to participate
- Markers (gene list) being defined
- Shipment of samples asap
- Set-up a expert committee who will be involved in the assessment of the results,...

TO BE CONTINUED...

Thank you!



Vanessa GHISLAIN
vghislain@wiv-isp.be

WIV-ISP
Dept. Quality of medical laboratories
www.wiv-isp.be/QML/