Benchmarking trial and EQA NGS in (hemato-)oncology

Vanessa Ghislain
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Benchmarking defined

point of reference
Bencharking 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

Art. 33bis

...

Art. 33ter
Financing NGS

Art. 33bis

...

Art. 33ter
Financing NGS

Art. 33bis

Pilot study
Convention
Financing NGS

Art. 33bis

Pilot study
Convention

Benchmarking trial
Financing NGS

Art. 33bis

Pilot study
Convention

Art. 33ter
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

Colon

Lung

High – low concentration of hot spot mutations
Samples

Colon

Lung

High – low concentration of hot spot mutations

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,…
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Thank you!

Vanessa GHISLAIN
vghislain@wiv-isp.be

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