Global Insights on Medical Laboratory Operations:
How World-Class Performers are Combining Dynamic Costing, Lean, and Quality Management Systems to Deliver More Value

Pre-analytics	Analytics

Money

Time

Quality

Non-production environment

Characteristics of cost efficient Labs

- Unique philosophy
- Clear focus on science, medicine and results that can be trusted
- Respect of standards, accreditation
- Qualified staff at all levels
- Proper use of technology
- Clear production concept

Non-production environment

Cost sensitive Pre-analytical issues

Most of problems are due to pre-analytical issues - quality of biomaterial, request or phlebotomy:

- Part of bio-material arriving to the labs might contain clots, hemolysis etc.
- Pre-analytical procedures are rarely respected - bio-material might arrive non-centrifuged, in non standard pre-analytics
- Basics such as labelling not respected - wrongly sticked barcodes, or not controlled by IT - unreadable barcodes
- Closing, counting and temperature conditions of transport boxes
- Tracing and custody during all pre-analytical steps
- Educate equip and re-educate your prescribers, collectors and phlebotomists about pre-analytics or nothing will be improved

Non-production environment

Unvalidated quality and procedures are expensive

- Not enough bio material means re-phlebotomy and reprocess for the same initial price
- Body liquids in non-conform transport pots can lead to cross contamination of other samples, become unacceptable for analytical stage and cause unnecessary logistics costs
- SST non gel separated tubes are acceptable for hospital labs, not for long logistics > 2hrs
- Transportation requirements such as UN3373 boxes and temperature control systems should be applied
- 80 is cheaper than 100, but 400 is definitely more expensive than 100
- 12 percent re-runs is far too high

Production environment

Gold standards of cost efficiency in Diagnostics

- Unique platform for each test cluster inside the lab or group of labs
- What can be done by a machine must be done by a machine
- All machine must be connected either to middle ware or to LIS
- Internal (per shift) and external (per reference interval) Quality Control
- Manual is not bad, provided it is accredited SOP
- Documentation of every process is a must and must be respected
- Unique qualification system for all staff as support for constant Quality of Production and Results that can be trusted
- Auto-validation as a standard, human validation for cases of interest

Production environment

Local vs Central distribution of production

- Centralize every assay which can be centralized, starting with routine
- Retro engineer your production concept to your expected Total time to results (TTR) and Volumes
- STAT is STAT, Routine is Routine
- Man vs Machine vs Time
- Constant arbitrage, no magic solution
- Golden rule is intelligent horizontal consolidation
- Multiple sites = multiple teams = multiple costs

Production environment

Data, reports and short-term production planning

- Data and «Data that can be trusted» are not equal
- Do not trust anybody more than data
- Extract data from systems, so people have little chance to manipulate. Trust data extraction to professionals.
- People hate automatic data collection, they cannot hide anymore
- Machines do not have one personality only- Use this to fit various production needs
- Design theoretical models, validate them and then make evidence based decisions
- Do not hesitate to regularly challenge your existing concept and verify simulations

Production environment

Problems of technological steps

- Track Vs. no track
- Evolution is a staircase, not a rocket
- Qualifications need to be adapted
- Systems need to be deployed and mastered
- Human process Vs. Machine process - «it is my job!»
- New systems are usually designed to reproduce old processes
- Tender documentation design and bias
- System ancillaries as important as system itself
- TCO more important than CPRR
- Hidden costs outside of CPRR

Production environment

Cost sensitivity of quality

- Perception Vs. reality
- Documentation and SOPs
- Standards, certification and accreditation, international or local must be respected, always cheaper on the long run
- Do not certify bad processes, clean them before. Do not be afraid to ask help from Vendors
- Be open – help to compare internally and externally
- Quality is reflection of qualifications and consistency of staff education
- Machine is rarely wrong unless Man taught it to be
- Auto-validation which can be trusted is a help, not a competition

Study case

- Worldwide Medical Diagnostics Laboratories with a workload of over 10.000 tubes a day face high indirect or hidden production-related costs that are not easily identifiable and attributable

- Costs mostly depend on production platform, workflow, analyzers used and contractual obligations on Total Around Time (TAT)

- And yet…, decisions on which platform to choose are still made based on:
  - reagent costs
  - final discount
  - Immediate availability of machines
  - Bundles

- The major part of the operation costs, which directly depends on the chosen platform, is usually not fully taken into consideration

Holistic & Methodological Approach

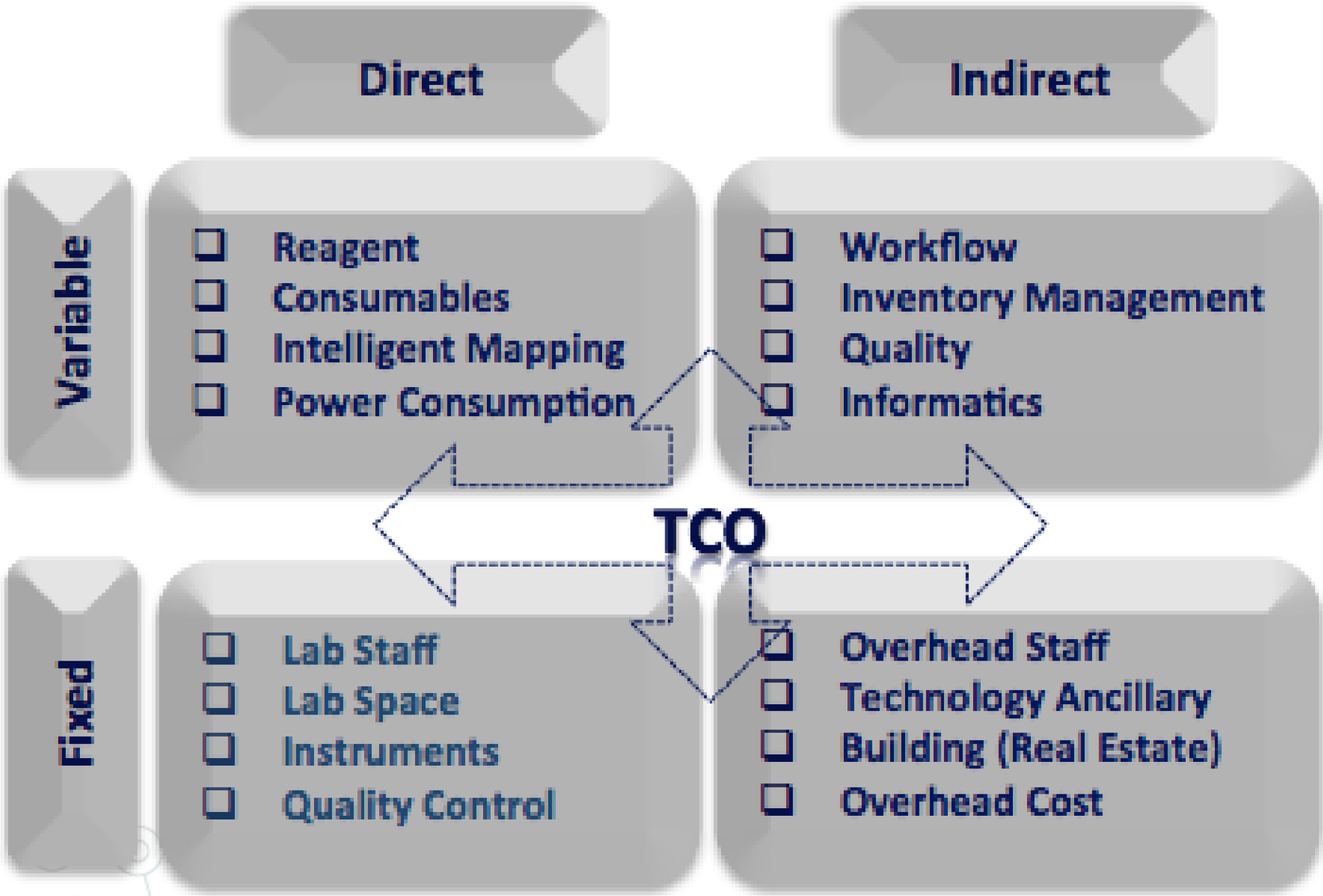
Cross departmental joint effort:

How can we achieve that ?	Initiate & validate theoretical model
	Repeated data validation (small and large scale)
	Multi-parameter monitoring, full platform assessment possibility
	Repeat of critical measures (Quarter, 6 months)
	TCO perfect SMART management tool
	Enables dynamic follow-up of all relevant cost components
	Data re-validation through follow-up study

Methods

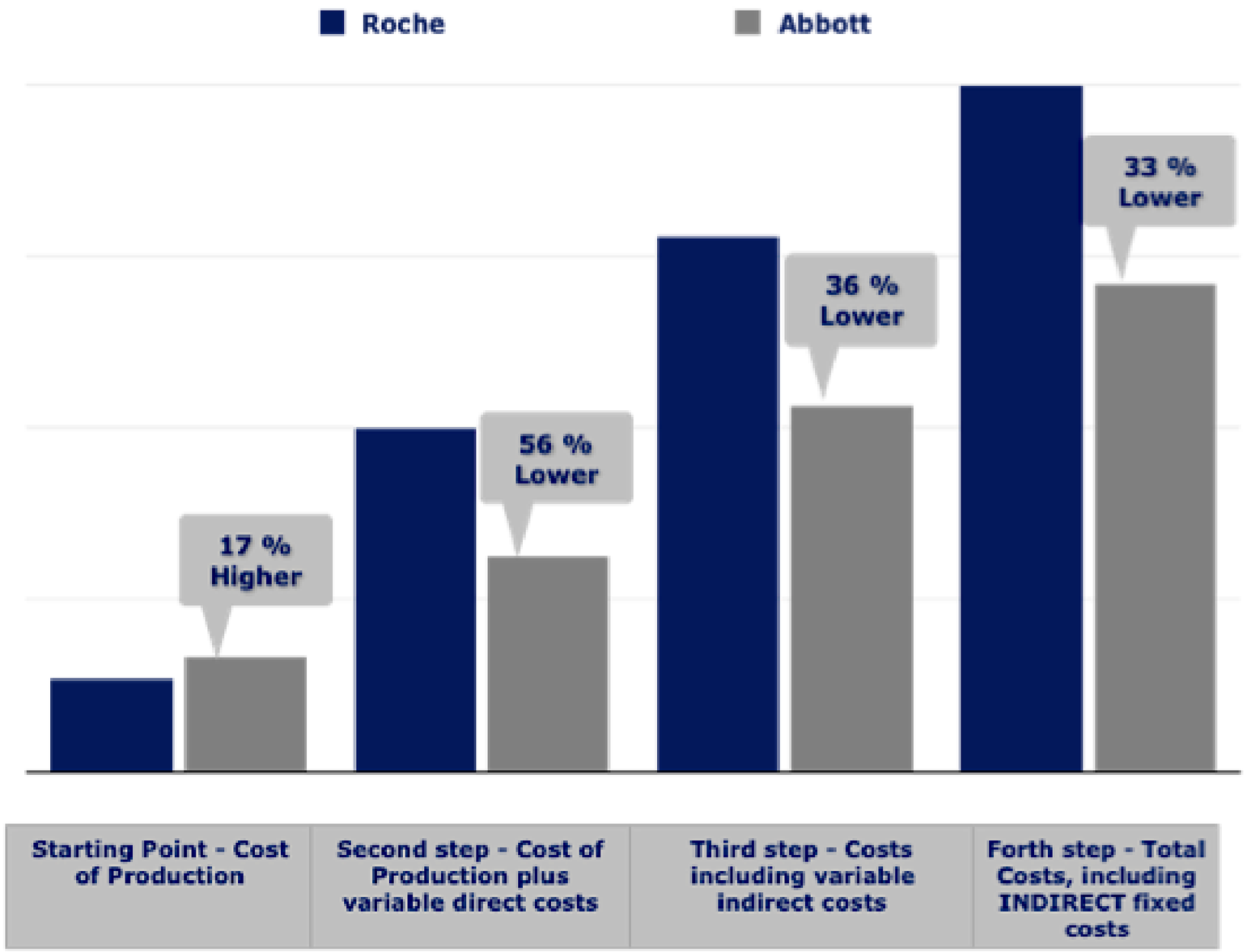
- Main Laboratory routine operation of Immunoassays & Clinical Chemistry alternating on a monthly basis, between instrumentation of its main providers Abbott and Roche.

- Fully identify and attribute direct and indirect costs



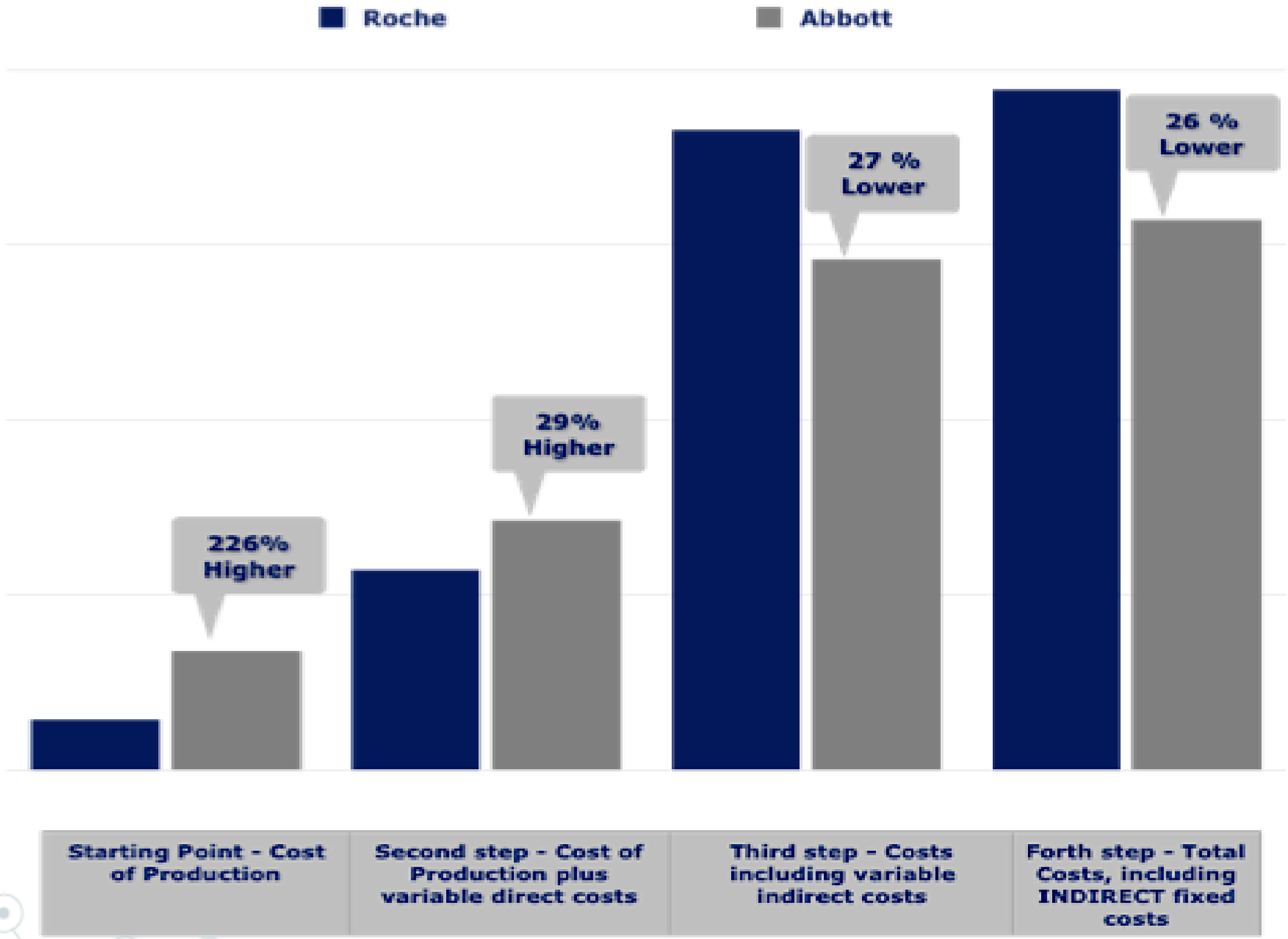
Results

Overall Absolute Values of Costs for Immunoassays with % variances



Results

Overall Absolute Values of Costs for Clinical Chemistry with % variances



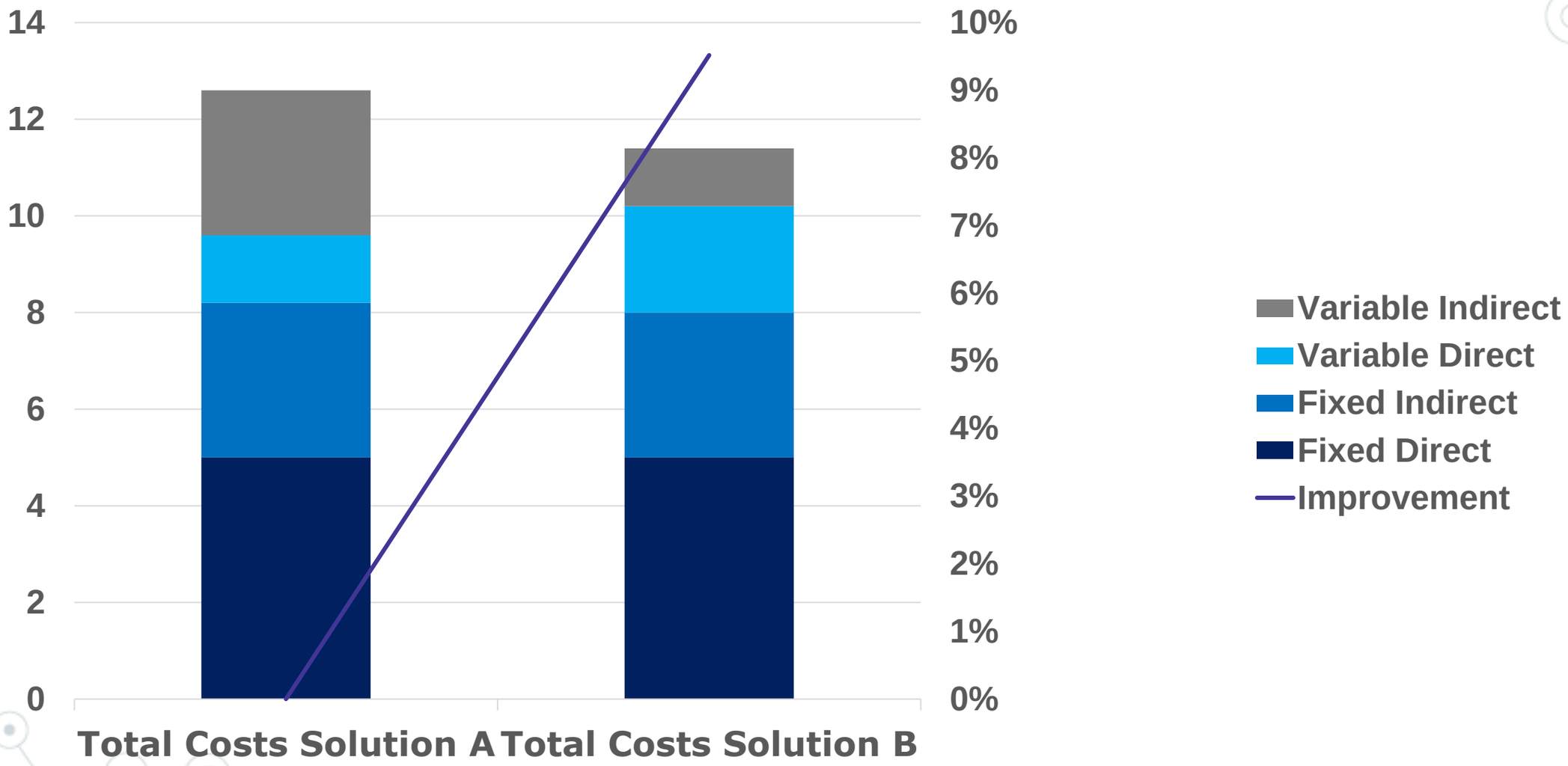
Conclusions

Retrospective analysis suggests, that this novel methodological approach is more advantageous compared to the conventional procurement approach since it is:

- An efficient tool to put focus on EBITDA without losing focus on quality, complexity and time
- TCO enables practice of «evidence based» management and technology procurement decisions
- TCO empowers the Lab specialists to participate fully in procurement decisions with a holistic approach
- TCO enables labs to create economic dashboards for each catalog object, machine and production center facilitating future resource allocation and budgeting exercises

Case study

- Private Laboratory Seoul, Korea.
- TCO based Main Laboratory routine operation of Immunoassays & Clinical Chemistry switch to alternative supplier.



Case study

- Looking for additional profitability improvement :

Workshop and assessment – March 2017.

  - Top management coaching (owner, CEO, COO, production director, medical director, etc.)
  - Full laboratory assessment (production, pre-analytics, logistics, IT)
  - 45 concrete tangible recommendations for efficiency improvement and creation of a 1 year roadmap to increase EBITDA substantially
  - Full “Lab efficiency toolbox” Workshop

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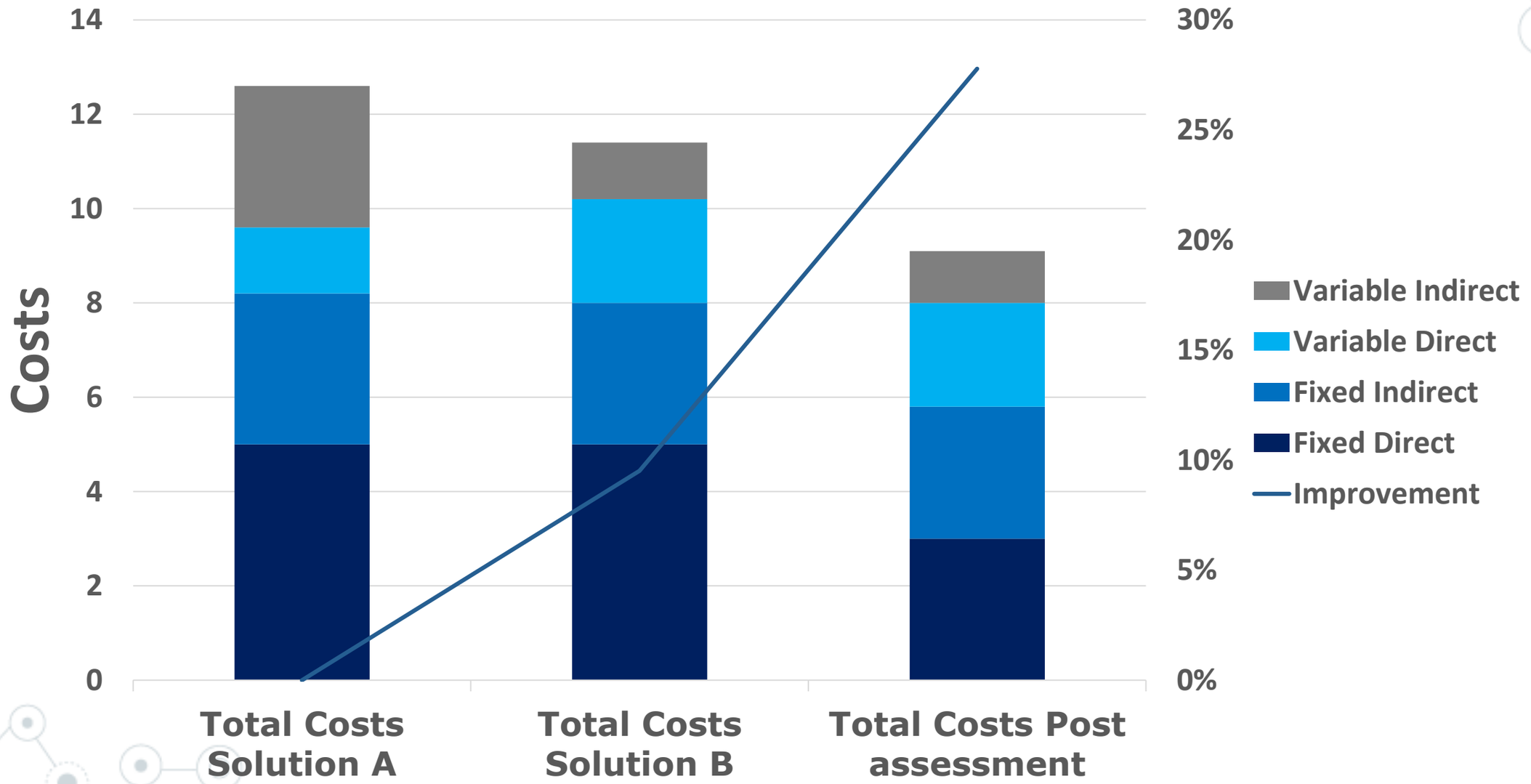
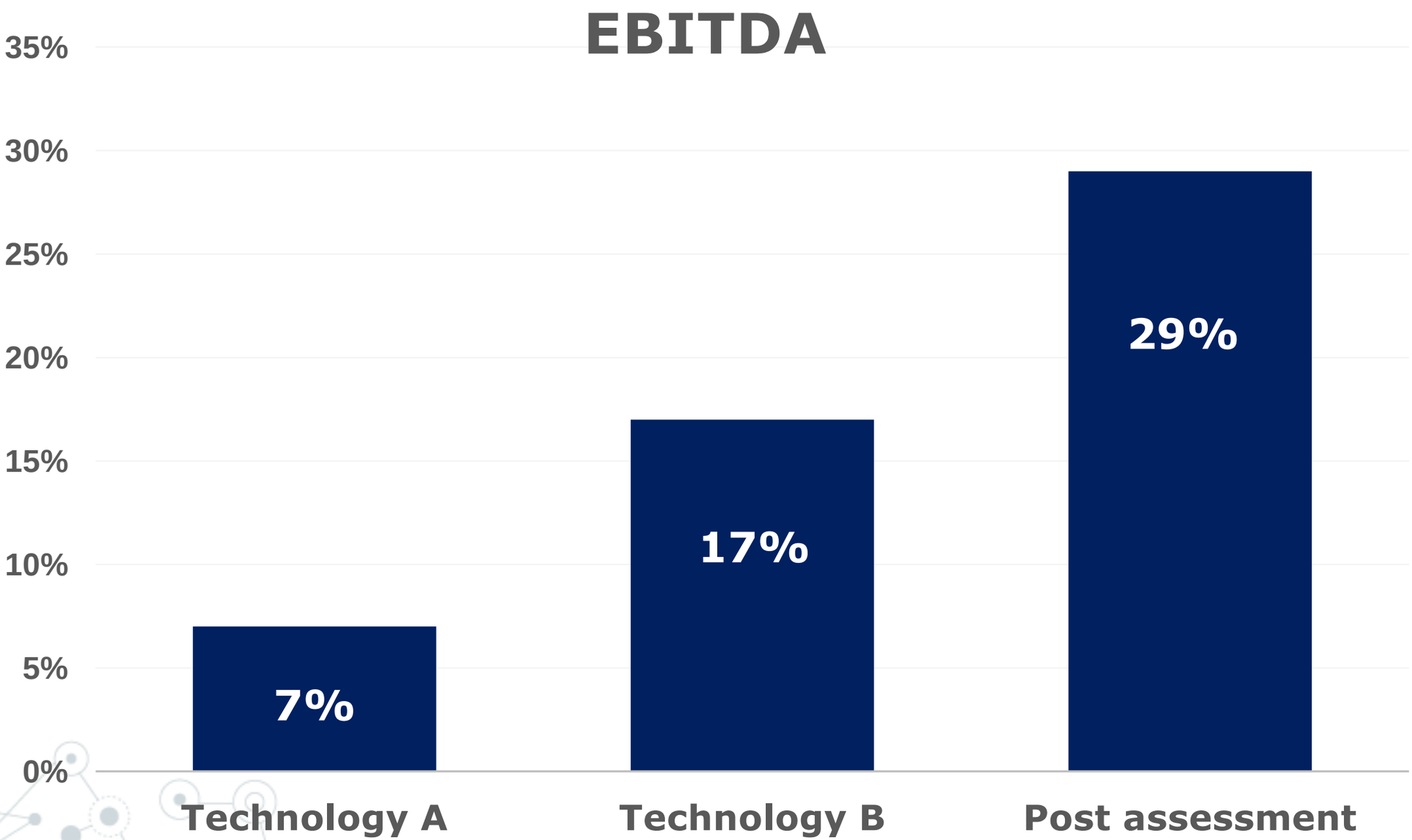


Case study

- Tube distribution philosophy reengineering
- Improvements of workflows
- Implementation of golden rules in pre-analytics
- Overheads reduction
- Machine-readable blanks
- Personal training and coaching
- Process mapping for top 40 tests

Case study

- Preliminary results – October 2017 – EBITDA + 22%



3rd Study case

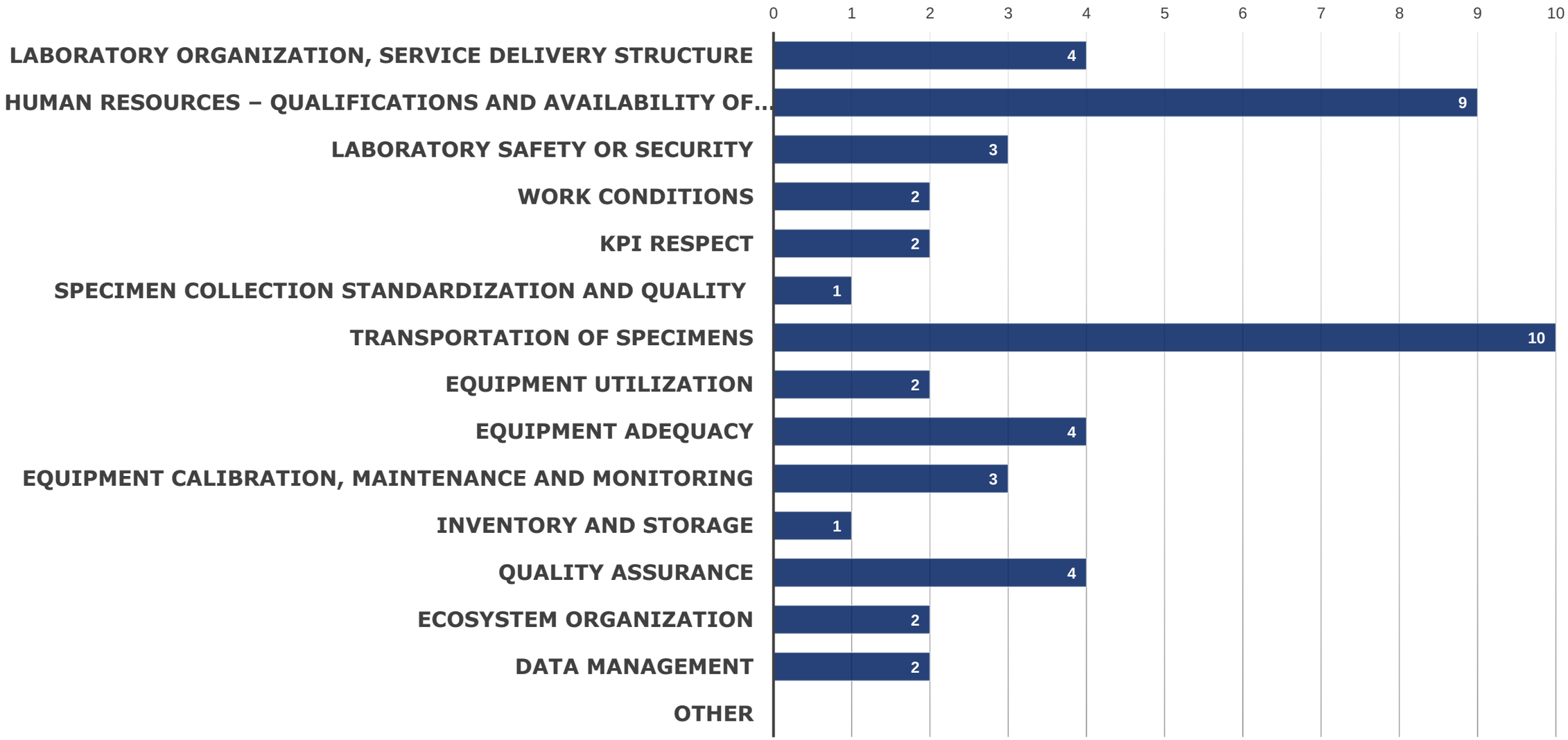
Australia (hospitals and laboratories, government structure)

- Training for top management of the network
- Full assessment of 6 laboratories (production, pre-analytics, logistics, IT, BI)
- Recommendations for efficiency improvement
- Full “Lab efficiency toolbox” Workshop
- Internal and external benchmarking of production sites against other laboratories

Case study

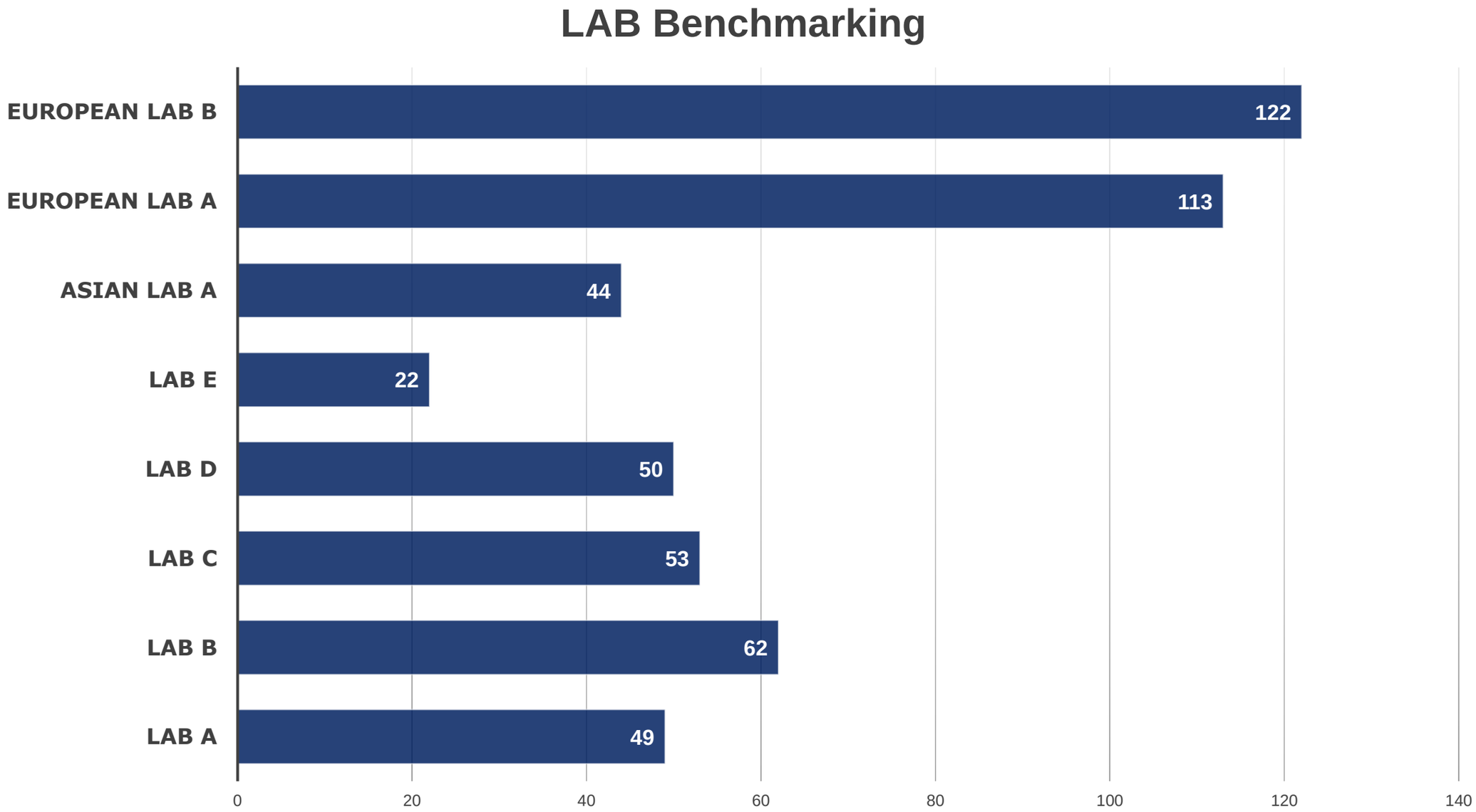
- Unique system of internal and external benchmarking of production sites against other laboratories.

- Fully describe lab activity, weak points and bottlenecks



Case study

- Worldwide lab to lab benchmark.
- Evidence based assessments history



Case study

- Full assessment reports and the list recommendations for efficiency improvement and creation of a 3 year roadmap to increase EBITDA substantially

- Planned annual intermediate reassessments to see the progress

- Top management consulting and coaching program for 2 years

Thank You!

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