

AUTHORS:
Roman Yu. Kuvshinov¹,
Jean-Philippe Galhaud²,
Bruno Morassin³,
Assol S. Andreeva¹,
Patrick Gontard¹

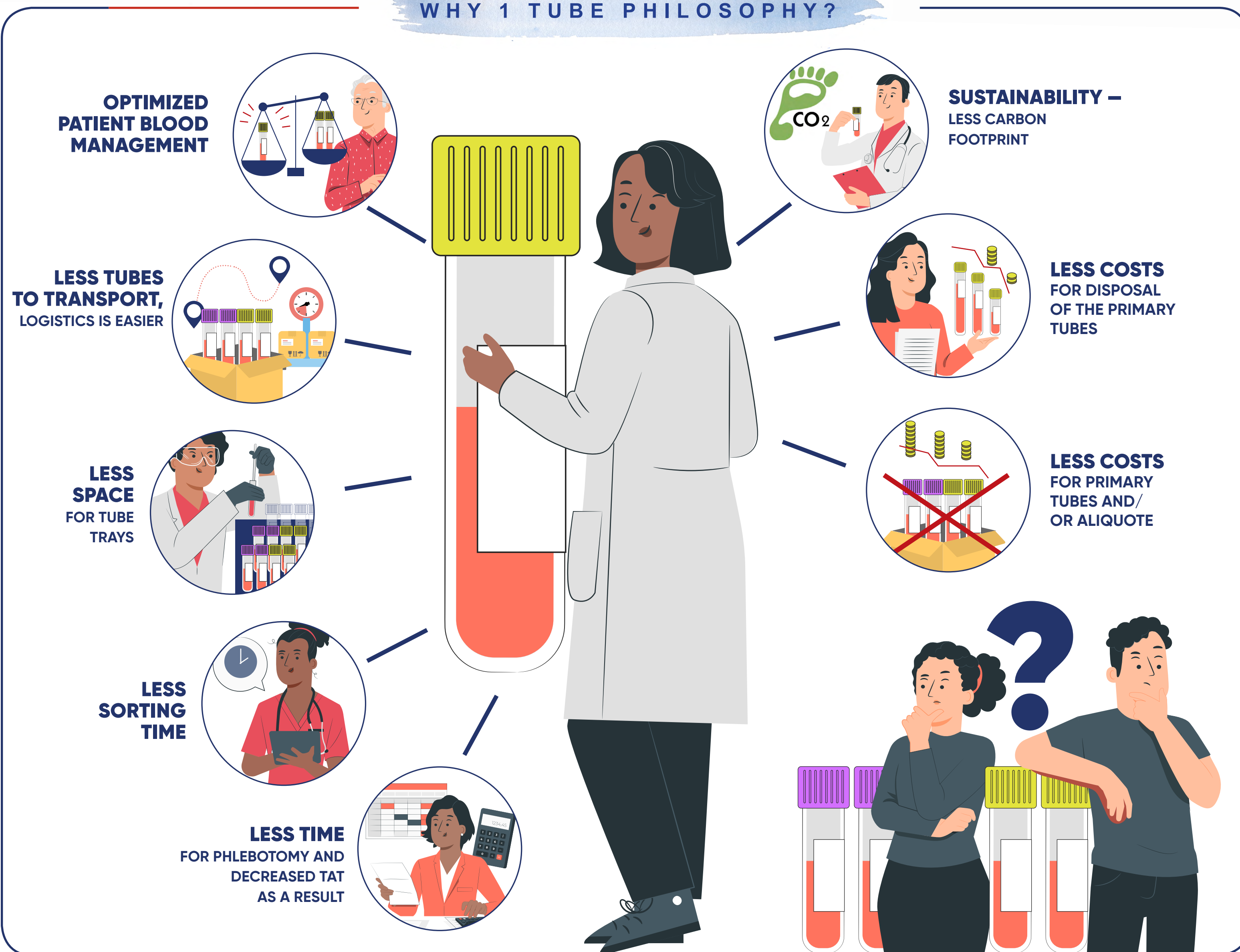
¹GontardCie Group, 157 Kantonstrasse, Freienbach 8807

²Cerballiance Nouvelle Aquitaine, 75 rue de la Morandière, 33185 Le Haillan

³Cerballiance Gascogne, 41 boulevard Saint-Michel, 32100 Condom

LESS TUBES, MORE EFFICIENCY

WHY 1 TUBE PHILOSOPHY?



INTRODUCTION

The number of tubes of the same type in a laboratory depends on several factors:

- specialization and strategy of a laboratory (if there are streams of urgent and particularly urgent tests, insource/outsource proportion);
- sources of collection of biomaterials and position of a laboratory on the competitive IVD market (B2C/B2B ratio, the market position dictates the terms of preanalytics);
- organization of a laboratory production (division into departments and how far these departments are located from each other);
- equipment (throughput for different tests, tube loading principles)
- arrival curve* shape ("snake" vs "two-humped camel")
- working schedule

All these factors should be considered in the design of a laboratory, the philosophy of the tube should be formulated.

Tube philosophy – a philosophical approach to the number of tubes collected and their distribution among departments and analyzers, and to the need for aliquots. Tube philosophy influences many aspects of a laboratory: the organization of operations and specimen collection, logistics and production approach, total cost of ownership**, environmental responsibility, and patient focus. The ideal tube philosophy is when 1 tube type and 1 tube item is used for 1 type of biomaterial, regardless of the number and variety of tests ordered for a patient, for both B2C and B2B samples.

This approach is called one-tube philosophy. In practice, it is not always possible to implement the one-tube philosophy because of the factors mentioned above. The current tube philosophy can be accurately described in numbers by the index of tube philosophy (TP): the number of tubes/the number of requests.

It is useful to consider only standard types of samples such as citrate, fluoride, heparin, EDTA, and serum. Out-sourced samples and microbiological samples are usually not considered. The lower the index, the higher the efficiency of a laboratory.



HOW WE ACHIEVED THIS RESULT?

All processes in a laboratory are interrelated; so, changes in one process lead to changes in the others. That's why, before the introduction of the one-tube philosophy, the following steps were first taken:

- Rewriting of rules for biomaterial collection and logistics;
- Implementation of the new rules in all sample collection sites to standardize processes across the group of laboratories;
- Standardization of tubes (use of only 1 reference for serum and 1 for EDTA);
- Unification of tube barcoding principles;
- Unification of all electronic dictionaries and catalogs in the whole group of laboratories;
- Changes in the sorting logic in the production facilities.



THIS PREPARATORY PHASE TOOK ABOUT 6 MONTHS

Also, some potential risks of the transition from the "n" – to the one-tube philosophy were assessed:

- Risk of increasing number of "not enough material";
- Risk of bottleneck at second sorting machine with additional sorting for immunochemical testing;
- Increased TAT for immunochemical testing;
- Many reconfigurations of existing processes (Collection Points, hospitals, physicians, middleware, LIS, sorters, production flows) are very likely to cause problems.

These and some other risks were calculated, solutions were proposed.

DESIGN OF THE STUDY

Since many changes occurred in the laboratory from 2016 to 2022 (most processes were reconsidered, a new production was established, many new Collection Points were opened, the pandemic COVID-19 occurred), it was decided, in order to compare "apples with apples", to apply the extrapolation technique and consider the factual results of 2022 as a basis and then extrapolate them to the situation before the change, i.e., to 2016. Cerba Nouvelle Aquitaine started the conversion from the 2-tube to the 1-tube philosophy for serum and EDTA tubes in 2016 with the preparation phase. The transformation process included:

COMBINING CLINICAL CHEMISTRY, IMMUNOCHEMISTRY + SEROLOGY TESTS INTO 1 SERUM TUBE INSTEAD OF 2

COMBINING CBC + SEDIMENTATION RATE, AND HBA1C INTO 1 EDTA TUBE INSTEAD OF 2

So, the tube philosophy of 2016 was retro constructed from the real data of 2022 by multiplying by the coefficient. We just wanted to answer the question, "What would we have if we had not transformed the preanalytics in our lab?"



SAVINGS CALCULATIONS

1. Yearly cost savings were calculated using the formula:

$$\text{the number of tubes} \times (\text{cost per tube for 2022} + \text{cost of utilization})$$

2. Yearly CO₂ footprint savings were calculated according to the formula:

$$\text{the number of tubes} \times \text{weight of 1 tube} \times \text{amount of CO}_2 \text{ generated from 1 kg of plastic production}$$

Mass of 1 tube is 92 g (serum), 6.6 g (EDTA), and mass of CO₂ generated by 1 kg of plastic was taken as 3,5 kg.

3. Yearly patient blood savings were calculated as:

$$\text{the number of tubes} \times \text{volume of the tubes}$$

DATA SET DESCRIPTION

Data set for the study was prepared by gathering, cleaning and reworking of the data from different Cerba Nouvelle-Aquitaine data sources:

- Raw data**
 - LIS data (full list of ordered requests for 2022 year) – 1.5 M rows
 - Middleware data – full list of processed tubes for 2022 year – 6 M rows
 - Middleware data – full list of processed tests for 2022 year – 240 M rows
- Configuration data**
 - Preanalytic configuration:
 - List of tube types with test mapping (2022)
 - List of tube types with test mapping (2016-year version)
- List of analyzers**
- List of tests**
- List of production sites**

Final data set was generated in 4 steps:

- Cleaning Raw data:**
 - Excluding all service orders, internal QC, service tests
 - Excluding orders and tests not belonging to Cerba Nouvelle-Aquitaine SCPs
- Preparation of mapping test by test of current preanalytics version and 2016 year version**
- Combining cleaned data with prepared preanalytics**
- Generating new tubes barcodes using old-style preanalytics**

Final dataset configuration:

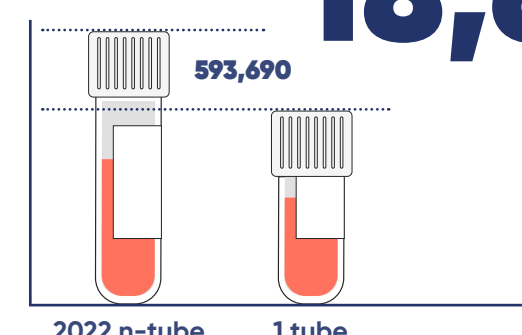
- Rows – 12.5 M
- Each row – one ordered test
- Data set includes:
 - Patient order ID
 - Tube ID
 - Tube barcode (current)
 - Tube barcode (generated for 2016 preanalytics rules)
 - Test code
 - Test name
 - Production site
 - Analyzer
 - Tube type code (current)
 - Tube type code (2016 preanalytics rules)



RESULTS AND DISCUSSION CALCULATIONS STUDY

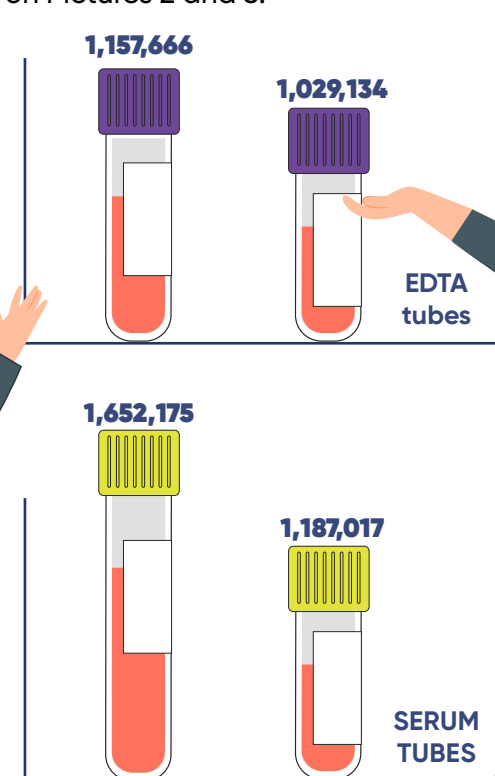
The total number of tubes (Citrate, Fluoride, Heparine, EDTA, Serum) was 2,650,231 in 2022, which is 18% less than it would have been: 3,255,315. So, in absolute numbers the reduction is 593,690 tubes per 2022 year.

SO, IN ABSOLUTE NUMBERS THE ECONOMY IS 593 690 TUBES PER 2022 YEAR, WHICH IS 18,6%

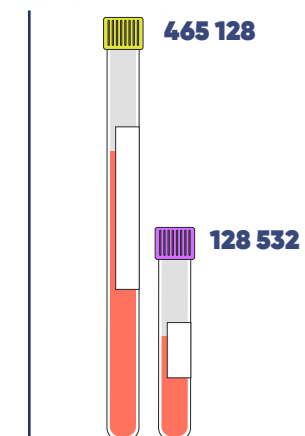


Picture 1. Comparison of the total number of tubes in 2022 (2022 real) and 2022 retro constructed (2022*).

This reduction is due to EDTA and Serum tubes only, and the contribution of each tube type is seen on Pictures 2 and 3.



Picture 2. Comparison of the total number of EDTA (violet) and Serum (yellow) tubes in 2022 (right columns) and 2022 retro engineered (left columns).



Picture 3. The absolute number of saved EDTA and Serum tubes in 2022 year.

Tube Philosophy index for 2022 real and 2022 retro constructed were calculated, and it turned out that Cerba Nouvelle-Aquitaine decreased the index from 2.63 to 2.14 (reduction by 18.6%).

Impact of performed work is presented in the Table 1.

	EDTA	Serum	Total
Economical	51,824 euro	286,909 euro	338,734 euro
Carbon footprint	2,969	14,978	17 947 kg
Patient blood	514 liters	2,326 liters	2,840 liters

Table 1. Variety of direct savings from 18,6 % index reduction.

That's just the direct savings. When we calculate the indirect savings, we have to consider the time saved in almost all processes: Phlebotomy, barcode reading, centrifugation, sorting and tube packing into trays, etc. Also, the reduction in volume, which creates more space and drastically reduces the cost of manipulating samples (personnel, equipment, rental).

CONCLUSIONS

This retro constructed observational study was led between 2016 and 2022 at a Continental European Privately owned group of labs. It was shown that a substantial portion of daily lab phlebotomy is a waste that negatively affects the economy, TAT, the environment and the comfort, compliance and health of the patient. This is why the one-tube philosophy is highly recommended and should be considered as a working standard, especially for large laboratories with a strong position in the market; creating a kind of hub and spoke it centralizes and unifies production with a high level of digitization that allows each tube to be traced from its origin to its result.

*Arrival curve – the curve of arrival of the tubes from collection points to production site by hours
 **Total Cost of Ownership – the concept of relocating to a produced or manufactured object all the costs generated in the lifecycle of the production and not just the variable direct costs like in CPFR.