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Implementation of a Process-Based Cost Model in a Medtech Startup

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Master's Dissertation

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To my family, for the immeasurable support that brought me here.

Thank you!

Implementação de um modelo de custo baseado no processo numa start-up de medtech

Resumo

Este projeto foi desenvolvido numa *Medtech start-up*, área que teve grande crescimento no ano passado. É sabido que todas as empresas devem melhorar constantemente para se manterem competitivas e numa startup esse conceito é vital e deve ser feito com mais rapidez para se manter ca corrida. Para isso, é necessário conhecer muito bem a empresa e ter ferramentas de apoio à tomada de decisão para ser um processo mais rápido e fiável. Uma prática inerente para alcançá-lo é ter um sistema de controlo de gestão na organização. Visto que a empresa sob estudo ainda não possui contabilidade de custos das suas operações, este projeto visa criar um que lhe permita calcular com rigor os custos do seu *core process* e servir como ferramenta de tomada de decisão. A aplicação de uma contabilidade de custos ajudará por exemplo, para encontrar melhorias no processo ou na tecnologia usada para criar valor e comparar opções, para criar orçamentos, colocar preços e escolher projetos lucrativos.

Um modelo de custo baseado em processos (*Process-Based Cost Model*) foi criado para o *Core Process* da empresa - que consiste na aquisição e análise de sinais de amostra usando Fotónica e Inteligência Artificial. Para fazer isso, o primeiro requisito é criar um modelo de processos de negócio (*Business Process Model*) para ter uma visão geral do processo e analisá-lo de forma a identificar oportunidades de melhoria. Tendo em consideração a filosofia *Lean*, foram sugeridas melhorias operacionais para mitigar as atividades sem valor acrescentado e elevar o desempenho operacional. As sugestões consistiam num sistema de rotulagem das amostras e em aumentar o número de fibras utilizadas no equipamento para adquirir mais do que um sinal ao mesmo tempo, de forma a mitigar o *bottleneck* identificado no processo de adquisição de sinal das amostras. As duas soluções foram aplicadas com sucesso e obtiveram-se melhorias. Posterior ao modelo de processos de negócio, recolheu-se dados de consumo dos recursos e os seus custos para criar o modelo de custos numa folha de cálculo.

O modelo de custo baseado em processos ajudou a identificar dois consumíveis utilizado no processo, representando mais de 8% dos custos totais, recomenda-se serem substituído por outros mais económicos ou adaptar a tecnologia de forma a não precisar mais do suporte para amostras. A inclusão de mais uma ponta de fibra óptica para adquirir sinais de duas amostras ao mesmo tempo em vez de uma resultou numa redução de 42% do tempo médio gasto por amostra e do custo em 20% na fase de aquisição do sinal. Além disso, a implementação do sistema de rotulagem também permitiu diminuir o tempo gasto na rotulagem manual dos tubos de micro-centrifugação em 95%, melhorar a qualidade total do processo, e tornar mais económica esta atividade 84%. A fiabilidade do modelo de custo foi testada comparando o custo esperado dado pelo modelo com o custo real de um projeto comercial realizado para uma empresa de biotecnologia. Para tal, foram medidos todos os tempos despendidos pelos colaboradores e recursos consumidos, permitindo confirmar a fiabilidade do modelo, assim como a rentabilidade deste tipo de projetos e segmentos de clientes.

Palavras-chave: modelos de custo, modelo de custo baseado em processos, Modelação de Processos.

Implementation of a Process-Based Cost Model in a Medtech Startup

Abstract

This project was developed in a Medtech start-up, a field that experienced high growth last year. It is well known that all companies must constantly improve to remain competitive and in a start-up this concept is vital and must be done faster for you to stay on track. To achieve this, it is necessary to know the company very well and have tools to support decision-making and make it faster and reliable. An inherent practice to achieve it is to have a management control system in the organization. The company does not have yet any cost accounting of their operations, this project aims to create a cost model enabling them to calculate with rigor the costs of their core process and serve as a decision-making tool, for example, to find improvements in the process or in the technology used for value creation and compare options, to create budgets and pricing and to choose profitable projects.

A Process-Based Cost Model was implemented to the company Core Process – consists of acquisition and analysis of sample signals using Photonics and Artificial Intelligence. To do so, the first requirement is to create a Business Process Model to have an overview of the actual core process, and analyze it looking for improvements. Considering the Lean philosophy, operational improvements were suggested to mitigate the non-value-added activities and elevate the operational performance. The suggestions consisted of a labeling system for the samples, and to augment the number of fibers used in the equipment to acquire more than one signal at the time, to mitigate the identified bottleneck of the sample signal acquisition process. These two solutions were successfully applied, and improvements were obtained. After the Business Process Model creation, information was collected about resources consumptions and their costs to finally create the cost model in a spreadsheet.

The Process-Based Cost Model helped to identify consumables used in the process that represented over 8% of total costs, which needed to be replaced by more economical substitutes or to adapt the technology to no longer need the sample holder. The addition of one more optical fiber tip to acquire signals of two samples at the same time instead of one resulted on a reduction during the signal acquisition phase of 42% of the average time spent per sample and by 20% of costs. Furthermore, the implementation of the labeling system also allowed to decrease the average time spent hand-labelling the microcentrifuge tubes by 95%, to enhance the total quality of the process while making the activity more economical 84%. The cost model reliability was tested by comparing the expected cost given by the model against the real cost of a commercial project carried for a biotechnological company. For this purpose, all time spent by collaborators and resources consumed were measured, the cost model reliability was confirmed as well as the profitability of this kind of project and customer segments.

Keywords: cost models, process-based cost model, Process Modeling.

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Abbreviations

ABC – Activity-Based Costing
AD – Alzheimer's Disease
AI – Artificial Intelligence
BPM – Business Process Model
BPMN - Business Process Model and Notation
IP – Intellectual Property
KPI – Key Performance Indicators
NVA – Non-valued-added Activity
PBCM – Process-Based Cost Model
TQM – Total Quality Management

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1 Introduction

This project was developed in a Medtech Startup as part of a Master Thesis in Industrial Management Engineering at the Faculty of Engineering of the University of Porto. The company name for confidentiality reasons is going to be called on the entire report as "P&A".

The next points will be described the objective of the project, including the motivation and background that gave it place. The company itself, and finally explained the methodologies applied to achieve the objectives.

1.1 Project Background Motivation, and Objectives

In a startup everything needs to change rapidly to adapt its value proposition to market needs and stay competitive. Once P&A is related to the medical area, with the covid-19 pandemic, the world realized that this business area is actually more important than the attention that had been previously paid to them, motive because Medtech companies have now a bigger chance to be more valued and to experience faster growth in the upcoming years.

Having the company nearly one year of existence and counting on two pre-seed investments, is now on its way to have a minimum viable product, try the technology utility with partners to polish its performance and finally make a commercial validation allowing the Series A funding round.

At this point, the board decided to start implementing management control practices. Every company needs to have management control to ensure things are running effectively within the organization. Having control over operations is positive for many reasons: to detect errors or irregularities, take corrective actions and increase productivity. To do it, it is necessary to establish a standard to monitor performance by having a starting reference – a more likely way to accomplish their goals. Also, it is a useful tool for decision making and identifying and comparing new opportunities.

Having said this, P&A is not an exception: they wanted to have a cost model to know with a higher level of detail how the core process costs are distributed, making the main objective of this project to develop it. From the starting point, they already knew the type of cost model they wanted to be implemented – the Process-based Cost Model – for its ease of use to compare options due to technological factors and the production process' design.

This model would be very helpful in several ways. It would be used as a tool for pricing, budgeting, to know the real profit when a project is completed – important to choose which kind of projects the company might be focusing on in the future – and to help the managers in the decision-making process – once you know the weight that

each resource has on the total costs, you can decide with more accuracy which changes in the core process are worth, for example changing the provider, the collaborator who does one task, the type of consumable used or even to change any technological component or change the way the process is done. All this to seek a better operational and economic performance.

1.2 About the Company

1.2.1 Value Proposition and Market Opportunities

P&A is a startup founded in 2019 and has already been featured as one of the most disruptive companies in Europe. P&A is using a patented platform technology that can unlock the potential of targeted therapies and treatment personalization. It is based on Artificial Intelligence (AI) and Photonics, to build a digital library of nano-scale diseases biomarkers and biological profiles. Guided by a micro-lensed optical fiber the instrument emits a highly focused, low-power laser beam into a liquid (bio-sample) and the elastically backscattered light (Rayleigh Scattering) is collected through the same polymeric fiber, creating a new type of disease biomarkers - an optical fingerprint of the sample - which are registered and compiled in the cloud-based biomarker library. The in-house developed machine learning algorithm can deconvolve a signal to identify and quantify several disease biomarkers of interest simultaneously. The analysis is extremely rapid, 2-10 seconds per scan, and does not require the use of consumables.

In a few words, is used a highly focused, non-destructive laser beam guided by a proprietary, chemically nano-fabricated lensed optical fiber. That laser beam hits the sample and is obtained a signal scattered back. That signal is then processed using the artificial intelligence models to create an optical fingerprint of the sample. By comparing the optical fingerprint of the sample with the library of optical fingerprints stored, can detect specific structures in bio-samples.

The value-added with this technology is that from samples collect fingerprints (nano-scale structures), is given a tool to provide personalized screening and stratification in an affordable, fast, portable way for optical biomarker identification and quantification.

Some markets where the product can fit and drastically reduce the cost and time of drug discovery or development are presented below:

Pre-screening tool. With global pharmaceutical and biotech companies to choose the right people for clinical trials according to their biological profiles, help assure homogeneous cohorts.

New-drug tracking tool. Understand if a specific clinical trial is having the desired effect in patients, by tracking the changes over time in their blood optical fingerprints. Assess treatment efficacy easily, providing a tool to help decided when to kill a dead-end trial.

Drug discovery platform. Unlock the power of data from current and previous cohorts, and discover new biomarkers, and new targets, based on the biological profile of the super-respondents on the trials.

In drug development, biomarkers are key for success. They are used to help define mechanisms of action, select drug targets, stratify, and select patients, determine dose, and assess efficacy, making them an indispensable source of information. Particularly challenging is biomarker identification in complex, heterogenous indications, as are

neurodegenerative diseases (NDDs), where there also may be a very large variability between patients.

For this reason, P&A focuses on the challenging Alzheimer Disease (AD) business case to validate its technology. Aiming to accelerate drug development, make it possible for new players to enter AD by significantly lowering the cost of trials, and improving the willingness to participate in trials (when removed the requirement for invasive procedures, making it more comfortable for the patient and efficient for the industry).

For the last 30 years, research in AD and other NDDs has been directed by the amyloid hypothesis. Pharmaceutical companies have lost billions of euros by conducting numerous unsuccessful clinical trials attempting to clear out amyloid plaques from the brain using various drug candidates but unfortunately, no investigational drug targeting β-amyloids (Aβ) has ever been demonstrated to halt disease progression in clinical trials. Contributing to failure is the inability to select patient cohorts specifically enough to develop targeted therapies that could have significant efficacy in correctly stratified patient groups. Despite the remarkably high attrition rates in AD (99.6% - one of the highest failure rates in any disease area), there are at the time of writing 104 ongoing clinical trials in AD (clinicaltrials.gov, 2020).

Today, no single test exists that can conclusively diagnose AD. The only definitive way is to analyze the brain tissue during an autopsy. Diagnosing a patient who is still alive requires conducting a set of tests of cognitive and laboratory tests. Major biomarkers of the disease are amyloid plaques and neurofibrillary tangles, and the loss of connections between neurons responsible for memory. Amyloid plaques consist of fragments of β-amyloid peptide plus other proteins and cellular components. Neurofibrillary tangles consist of abnormal, twisted aggregates of tau protein. Methods used for patient stratification and trial monitoring to evaluate β-amyloid biomarker are Positron Emission Tomography (PET) scans – costing around €2,500-3,500 and requiring the injection of a radioactive tracer agent - and lumbar punctures (a means to extract cerebrospinal fluid (CSF)) – very invasive, costs between €800-1,000 and lasts about 40 min; other common methods are Magnetic Resonance Imaging (MRI) and clinical/cognitive testing, EKG and genetic tests (Insel *et al.*, 2016). Normally 80% of tested patients do not meet the inclusion criteria and some drop out of trials because of these invasive procedures, decreasing the number of enrolled patients further.

The P&A platform offers a fast, cost-effective, non-specific, and label-free approach for identification and quantification of novel biomarkers, which makes it a highly affordable patient screening and stratification tool that will drastically reduce the cost and time of patient enrolment (and monitoring) during clinical trials.

P&A had already demonstrated to readily detected AD biomarkers in biofluids with high accuracy. The developed algorithm for AD can already distinguish between AD and MCI (Mild Cognitive Impairment) with both specificity and sensitivity of 89%, and between AD and Healthy with a specificity and sensitivity of 91%. We can also support early detection and prevention efforts, as it is widely believed that patients with abnormal brain structure volume or metabolism, or a specific biochemical marker profile, are more likely to develop AD than the parent MCI population.

Considering this potential, the AD market panorama for P&A has some front lines. For pharmaceutical companies: just the top four pharmaceutical companies spend over €400M in screening for Alzheimer's clinical trials per year. Due to the heterogeneity of the disease, most of the money is spent on people that are later eliminated from the trial due to a lack of fit with the trial criteria. This makes drug discovery for Alzheimer’s

disease twice more expensive than the average ($5.5B vs the average of $2.7B). Due to these problems, many potential effective drugs are abandoned. P&A help by speeding up the trials, save costs and give them tools to track the evolution of the trials, and also a biomarker discovery platform. An example can be seen in Figure 1, where is shown the cost for patient screening for clinical trials, at left for traditional ways to do screening, and with the right the P&A proposal. Many biotechnology companies face the same issues as big pharmaceuticals while developing and validating novel therapeutics for Alzheimer's. P&A can help them validate their proposals by detecting the nano-scale targets they aim in fluids (E.g., peptides, exosomes, proteins), while also assisting in recruiting the right patients for their clinical trials. And hospitals, where currently, the screening techniques for Alzheimer's disease are too expensive for national healthcare systems to support. The explosion in cases (5 times bigger growth expected in the next two decades) is leaving many hospitals with no choice but to stop doing pathological tests on patients, recurring only to cognitive tests (which are extremely unreliable). Hospitals can see P&A as a pre-screening tool that can narrow down patients from an initial mix of mild cognitive impairment, healthy, and Alzheimer's, into a group where all the population has a big probability of having the disease

Figure 1 - Comparison of patient screening costs for AD.

Considering the label-free and agnostic characteristics of the P&A platform conjugated with the great strength to identify new biomarkers of relevant diseases - which would add immense value for any complex indication - this technology is not limited to neurodegenerative diseases or even clinical challenges, but it can easily be trained and applied to many other verticals as to oncology, cardiovascular and infectious disease (for example a recent application was developed to stratify covid-19 patients).

The P&A vision for the use of their technology is divided into several focuses.

- Pre-screening tool - Choose the right people for clinical trials according to their biological profiles.
- New-drug tracking tool – Assess clinical trial’s treatment effects in patients, by tracking the changes over time in their blood optical fingerprints. Provide a tool to help decide when to end a trial.

- Drug discovery platform - Use data from current and previous cohorts, to discover new biomarkers, and new targets, based on the biological profile. Opening the possibility to apply a drug for a determined group of people with a similar biological profile.
- Companion diagnostic - Once a treatment reaches the market, supply consumers with a companion diagnostics tool able to provide the right treatment to the right patient.
- Risk Management – to forecast based on the biological profile if a determined disease is more likely to develop complex symptoms.

1.2.2 P&A Structure

Personnel and Departments

During the dissertation period, the company had between 12 and 22 collaborators including employees and interns, integrating the two main departments of technology and business, which at the same time are subdivided by the following way:

Technology (CTO, CSO, Lead of Bio-photonics Team)

Biological (Biologist)

Photonics (Photonic and Physics Engineers)

Electronics (Electrical Engineering)

AI (Data Scientists)

Business (CEO, COO)

Marketing (Marketing Manager)

IP (Head of Business Strategy and IP)

Business Development

This project is inserted in the Business Department, aiming to help the business development work with a costing model of the core process (carried out by the technology department), important for decision making and cost control.

Facilities

P&A has its main office in Porto – Portugal, in a medical research institute. The facilities include a laboratory for both biological and photonics fields and an office area for all other desk jobs. Here is where almost all collaborators and all the equipment are located, therefore it is also the place where the production process happens.

P&A has another strategic office in the United Kingdom, where normally the COO is based.

1.3 Methodologies

To create the Process-Based Cost Model several tools were used. The first one was to create a Business Process Maps of the as-is core process using the Business Process Model and Notation through the software *diagrams.net*. To do it was observed how the core process was normally performed and personnel was interviewed to get more details about it, in order to define the process boundaries, identify responsible and actors, and the sequence of activities to finally make the modeling. Then, maps were analyzed

using the DMAIC framework - based on the lean philosophy – to come up with suggestions to reduce the non-value-added activities, increase the throughput and adopt some Total Quality Management practices looking to decrease the costs assuring quality.

Also, through process observation, personnel interviews, time measuring, and invoices data were created two data tables, one with resources, its costs cost driver and unit of measurement, and the other with activities (based on the previously created process maps) and its time duration as well as the number of repetitions needed by unit. By last the cost model was designed in an Excel file spreadsheet.

1.4 Dissertation's Structure

In this first chapter was presented an introduction to the company, motivations and objectives for this dissertation and used methodologies to implement it.

The next chapters will be as follow: In the second chapter is made a literature review – having two main subjects, cost models and business processes. In the third chapter an overview of the current situation is made to explain the P&A's actual state about cost management. In the fourth chapter is explained how was constructed the Process-Based Cost Model and other works done in the dissertation project. And finally, the conclusion, with reflections about what was achieved and future work.

2 Literature Review

2.1 Management and Cost Accounting

Peter Drucker once said, *"If you can't measure it, you can't improve it"*.

Within the business context, management is defined as the act of getting people together to accomplish desired objectives, accounting as a system that records, analyzes, and reports all business transactions and control as a system of activities to monitor if an object performs in a desired way. In order to control an object, the following elements are needed:

- A detector or sensor – which measures what is actually happening.
- An assessor – to compare between the planned or expected and the actual situation.
- An effector – actions to influence the process if the assessor indicates so (Charifzadeh and Taschner, 2017).

Figure 2 illustrates the previously described control dynamic.

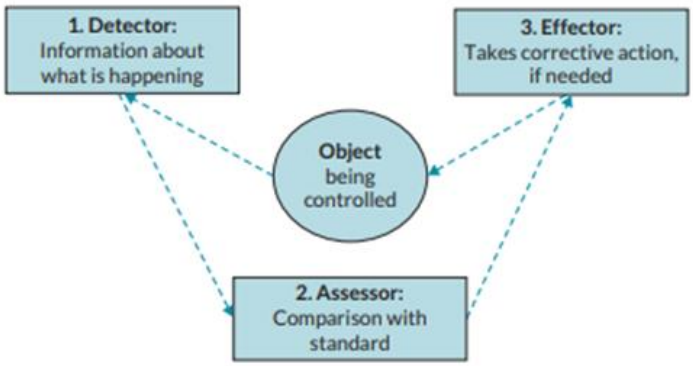


Figure 2 - Control System (Charifzadeh and Taschner, 2017)

To implement a management control system, it is important to think about management accounting, which intends to record information regarding internal businesses to monitor spending and have financial control of the internal operations. Management accounting combines accounting, finance, and management and is concerned to provide information to people within the organization (mainly managers) to assist decision-making, provide information for planning, control, and performance measurement, improving the efficiency and effectiveness of existing operations. Some functions are to

conduct internal audits, know and have control over expenses, explain the financial consequences of business decisions or new projects, and finally based on this help to formulate a business strategy (Drury, 2018).

Cost accounting provides information for management accounting. Measures, analyzes, and reports financial and nonfinancial information relating to the costs of acquiring or using resources in an organization. For example, calculating the cost of a product is a cost accounting function (Horngren, Datar and Rajan, 2012). Cost management is how managers use resources to increase value to customers and to achieve organizational goals. Cost management includes decisions such as entering new markets, implement new organizational processes, and change product designs (Horngren, Datar and Rajan, 2012).

Increasing consumer demand for high-quality at lower costs caused as response a bigger concern for cost management, seeking to reduce or eliminate nonvalue-added activities and to enhance the performance of the value-added activities. To implement it, many companies focused on total quality management (TQM) from the quality point of view and on lean philosophy by the manufacturing side. TQM is seen as a strategy for continuous quality improvement that focuses on measuring and evaluating the quality of products and services at every stage of the production process as well as with the personnel working on it to make it more efficient, with higher quality and value for clients. And Lean seeking to reduce waste by implementing just-in-time (JIT) production systems, simplifying processes, and implementing advanced manufacturing technologies (Drury, 2018).

2.1.1 Costs Models

In cost accounting, there are important concepts to keep in mind. Firstly, to know that a cost object is any activity for which a separate measurement of costs is desired.

Direct costs are the ones that can be directly traced to a cost object, for example, direct materials and labor used can be physically identified with the different products that an organization produces. On the other hand, indirect costs or overheads cannot be traced to cost objects, instead, an estimate using cost allocations must be made of the resources consumed by cost objects (Drury, 2018).

Period costs are those not specifically related to manufacturing or purchasing a product or providing a service that generates revenues. Product costs are costs that are incurred to create a product that is intended for sale to customers (Corporate Finance Institute, 2015).

To produce a map of expenses, a cost model design is needed – a mathematical algorithm that allows estimating the cost of a product, service, project, or of a given cost object (Drury 2018). Cost models normally have an important role in decision-making, thus the costs considered are selected according to their relevance. Relevant costs are those that will change the consequence of a decision, the irrelevant ones will not (Drury, 2018).

There are two costing methods, the job-costing and process-costing. The first is used when the cost object (job) is a unit or multiple units of different products or services – each job normally uses a different amount of resources. On the other hand, process-

costing is used when the cost object are masses of identical or similar products or services (Horngren, Datar and Rajan, 2012).

Cost allocation

Cost allocation is needed to assign overheads to a cost object when there is not a direct way. Then, cost drivers are used to allocate indirect costs. Sometimes there is a clear cost driver for cause-and-effect but other times it might not be so clear, then an arbitrary allocation is used. However, this should be avoided because it is always an inaccurate allocation of indirect costs to cost objects (Drury, 2018).

Cost accumulation systems can be used to assign manufacturing costs to cost objects by different ways. The main ones are direct and absorption costing systems. A direct costing system (also known as a marginal or variable costing system) assigns only direct costs to cost objects whereas the absorption costing system assigns both direct and indirect costs to cost objectives (Drury, 2018). Direct costing systems can only be recommended where indirect costs are a low proportion of an organization's total costs. Absorption costing systems can be sub-divided into traditional costing systems and Activity-Based Costing (ABC) systems (Drury, 2018).

Traditional costing systems allocate overheads to production and service cost centers (typically departments) and then reallocate service department cost center costs to the production departments. In the first stage, a traditional system allocates overheads to production and service departments and then reallocates service department costs to the production departments (Drury, 2018).

ABC systems calculate costs of individual activities and assign costs to cost objects such as products and services based on the mix of activities needed to produce each product or service (Horngren, Datar and Rajan, 2012). ABC assigns overheads to each major activity - rather than cost centers or departments (Drury, 2018).

Cost objects cause the activities, which in turn generate costs, consuming the resources associated with the execution of the products. This method provides a higher level of detail about the source of the costs giving better cost control, but in exchange, it is very complex, time-consuming, requires a large amount of human and financial resources to implement, and demands periodical reviews after implementation (Drury, 2018).

Designing an ABC system may be resumed in the next four steps according to Drury (2018):

1. Identifying the major activities that take place in an organization.
2. Assigning costs to cost centers for each activity.
3. Determining the cost driver for each major activity.
4. Assigning the cost of activities to products according to the product's demand for activities.

Manufacturing activities can be classified by a cost hierarchy by Drury (2018) consisting of:

- **Unit-level** activities are performed each time a unit of the product or service is produced. Consume resources in proportion to the number of units of production.
- **Batch-related** activities are performed each time a batch of goods is produced.
- **Product-sustaining** activities are performed to enable the production and sale of individual products. Customer market research and support

for an individual customer, or groups of customers if they represent the cost object, are examples of customer-sustaining activities.
- **Facility-sustaining** or business-sustaining activities. They are performed to support the facility's general manufacturing process, incurred to support the organization.

When choosing between traditional costing and ABC, the choice should be made on costs versus benefits criteria. Traditional systems are inexpensive to operate, but they are likely to result in inaccurate cost assignments and the reporting of inaccurate costs, which can cause managers to make dangerous and costly mistakes. The result may be a high probability of errors. On the other hand, sophisticated systems as ABC are more expensive to operate but they minimize the probability of errors (Drury, 2018).

2.1.2 Process-based cost model

> *"[…] cost of a product is a function of the process used to make it, at the same time, the cost of operating a process is a function of the design of the product being produced".*
>
> R. E. Kirchain (2001).

Process-based cost modeling (PBCM) is a framework used to create costing models (Nguyen, 2010) resulting from a fusion between cost models and process models and has some similarities with the ABC method (Rezaie, Ostadi and Torabi, 2008). The base model was first described in 1987 and 1988 by Busch and Field respectively (Eriksson, 2018), and it consists of three steps, it requires the creation of three models, the process, the operational and the financial models, and a diagram of these steps can be seen in Figure 3. It begins with the process model – made to know the structure and map a description of the cost object together with its required technical factors (important aspect taken into consideration in this cost model). The result is brought into an operations model focused on the physical operations and conditions, aiming to identify all needed amount of resources to carry out all manufacturing tasks as well as inefficiencies, it is important to highlight that PBCM is driven by directly contributing factors (Field, Clark and Ashby, 2001). Lastly, a financial model, to allocate costs to all consumed resources during the process, for the direct cost this is straightforward otherwise allocation strategies must be employed to estimate the production cost (Field, Kirchain and Roth, 2007).

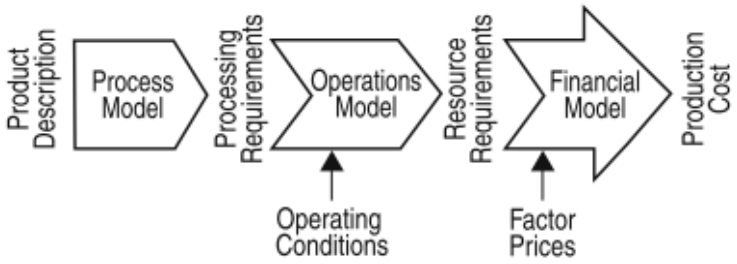


Figure 3 - PBCM's Conceptual Decomposition (Field, Kirchain, and Roth 2007)

In this way, the linking gap of how technical or operational factors has consequences on cost is fulfilled, allowing a better understanding of how the process might be re-designed and improved manipulating process parameters to minimize production costs. Because it allows to quickly simulate technological or operational changes and observe how they will impact the financial model. That is why this cost model is very used to forecast how the cost will be affected when a parameter is altered before it happens and to evaluate among strategic alternatives, once all the procedure factors on which costs relies on are analyzed (Field, Kirchain and Roth, 2007).

PBCM features are congruent with the world's needs, once intensive global competition, and technological innovation, combined with increasing customer demands and expectations, have resulted in product life cycles declines. To be successful, companies must speed up the rate at which they introduce new products to the market and constantly develop new products and services, because being later to the market than the competitors can have a dramatic effect on product profitability. A need for management accounting to place greater emphasis on providing information at the design stage because many of the costs are committed at this stage is vital, to manage their costs effectively and be capable to adapt to new, different, and changing customer requirements and reduce the time to market of new or modified products (Drury, 2018).

2.2 Business Process Modeling

A process is a sequence of tasks caused by a trigger in order to achieve a result with value. Business Process Modeling shows a graphic representation of the internal functioning of the company from the operational perspective; their activities, materials, and data workflow, always oriented to the customer (Faria and Azevedo, 2020).

To manage an existent process, it begins with a study of the actual process to create the AS-IS Model which is critically analyzed looking for improvement opportunities, after suggestions a TO-BE Model can be presented.

Processes within the company are divided into three main categories according to Dumas et al. (2018):

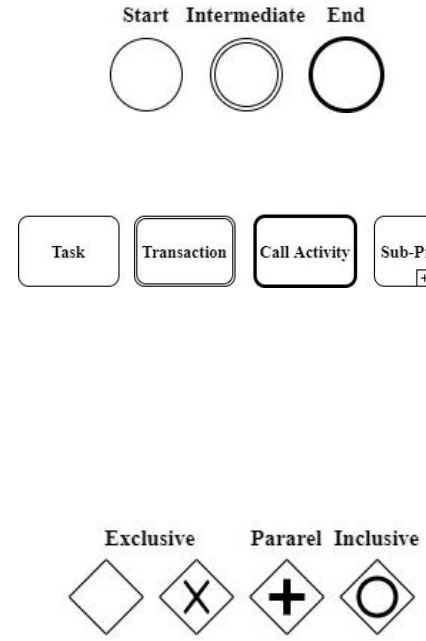
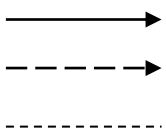
- **Core processes** cover the essential value creation of a company, which is the production of goods and services for which customers pay.
- **Support processes** enable the execution of these core processes. These include indirect procurement, human resource management, information technology management, accounting, financial management, etc.

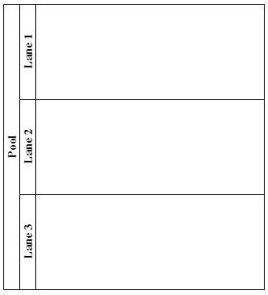
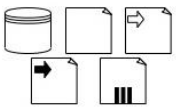
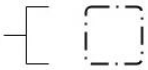
- **Management processes** provide directions, rules, and practices for the core and support processes. These include strategic planning, budgeting, compliance, and risk management, as well as investors, suppliers, and partners management.

2.2.1 Business Process Model and Notation

A BPM may be represented in different notations, the most used is the Business Process Model and Notation (BPMN) due to its standardization. Its main elements are presented in Table 1.

Table 1 - BPMN Modeling Elements. (Sharp and McDermott, 2001), (Dumas et al., 2018), (Object Management Group, 2011)

Element	Graphical Design
• Flow Objects: - **Events** are circular symbols that serve as a trigger causing most commonly a start point, intermediate step, or endpoint of a particular process. - **Activities** are rounded rectangles, illustrating a specific task performed by a person or system. The main types are: tasks: very specific and cannot be disassembled into additional tasks; transaction: involves a payment process. sub-process: indicates a set of additional tasks; and calls: a common process used in other areas of the workflow. - **Gateways** are diamond-shaped symbols that map decision points, either control the divergence and convergence of the workflows in a Process. It will determine branching, forking, merging, and joining of paths. Some of the most used are the exclusive: can be used for exclusive decision or merging; inclusive: all valid paths can be taken (branching or merging); parallel: do not await a certain condition, it forks or joins several paths that can take place concurrently.	
• **Connecting Objects** are marks the sequential flow of objects, normally a combination of lines and arrows. There are four Connecting Objects: Sequence Flows, Message Flows, Associations, and Data Associations.	

• **Swimlanes** is a graphical diagram that traces the tasks flow of a single work process and which actor must carry it out. It can show a process at any level, from a very high view down to one showing each individual task. Its elements are: - Pools: used to model resource classes. - Lanes: pool's sub-classes or single resources.	
• **Data symbols** representing data such as Data Objects, Data Inputs, Data Outputs, and Data Stores	
• **Artifacts**: used to provide additional information about the process. Are divided into in-text annotations and groups.	

Besides this, the process might have an architecture with different levels of detail, on the book ***How Work Gets Done: Business Process Management, Basics and Beyond*** by Arjit Singh Mahal (2010) can be found the structure presented in figure 4. Whereat the most abstract level is presented with an overview of the value chain and decomposed into a more detailed process on the next level.

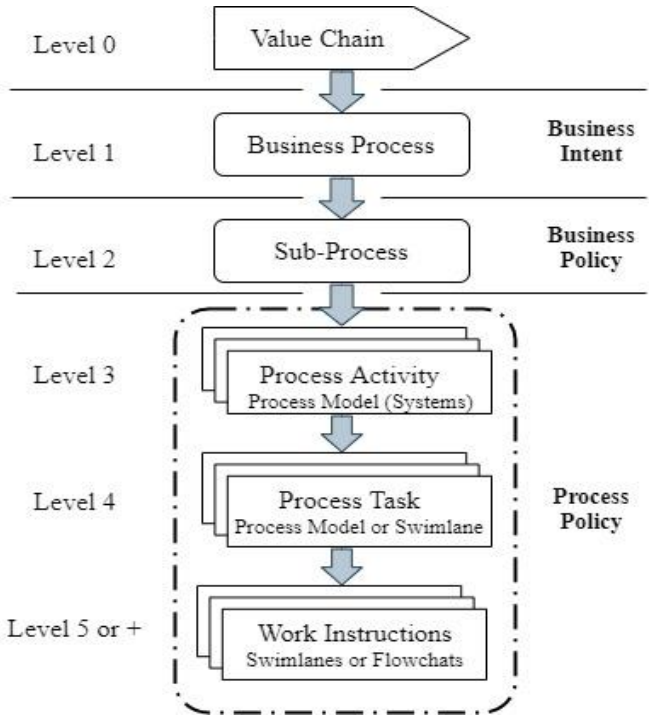


Figure 4 - Levels of detail (Mahal, 2010).

Another resource to represent models is the responsibility assignment matrix also known as RACI, it can be used at a high level (general task groups also called phases)

or at a detailed level (low-level tasks). These matrices reflect the role that human resources play in each activity, normally divided into four rolls that give the acronym name to the matrix, these are:

Responsible – the person in charge to get the task done.
Accountable – is the one responsible for the good execution of the task, only one accountable can exist.
Consulted – people whose opinion are sought.
Informed – people to keep updated of the progress.
(Lloyd, Taylor and Great Britain Office of Government Commerce, 2007).

2.3 How to choose a good key performance indicator

Key performance indicators (KPIs) are quantifiable measurements to monitor critical success factors of a business, related to the goals, strategies, or achieved initiatives of an organization. Goals are usually associated with strategy, while KPIs are usually associated with managerial performance evaluations (Harmon, 2019). The effectiveness of a company's business objectives can be evaluated by KPI's, and for each organization, these are going to be different, depending on what is crucial for their business specifically.

There are four types of important indicators to address and from a business process perspective they are divided as follows:

- Effectiveness: they say about the quality and to do the right thing, are related to core processes.
- Efficiency: they say about costs and to do things right, are related to the support processes.

The last two indicators types are both related to management processes and are:

- Lagging: they reflect business results as a consequence of previous decisions, like profitability and market share.
- Leading: evaluate factors that can lead to future business results, as the number of hours of training, marketing, or improvement actions (Faria and Azevedo, 2020)

External measures are those that say your business is succeeding (these are lagging indicators) such as revenue measures, customer satisfaction measures, or market growth measures, while internal measures are related to how the process is working, like costs of producing a product or quality of internal outputs. Internal measures focus on efficiency, effectiveness, and leading indicators of specific processes (Harmon, 2019).

A KPI combines a unit of measure with a target and a timeframe that can be evaluated. A very used way to designate relevant performance indicators, with clear expectations and progress defined, is based on the SMART concept, consisting of choosing an indicator that fits all the features of the acronym: Specific, Measurable, Achievable, Relevant, and Time-bound (Z. Ishak, S. Fong and S. Shin 2019).

- Specific – to define what you want to measure in a clear way. The more specific the KPI, the easier it will be to track. By this way, expectations are clearly defined and there is a lower risk of misinterpretation.

- Measurable - make sure it is possible to quantify. Define what is being measured. Use a numerical value or percentage to define an expected increase or reduction on a particular activity and to determine whether a target is met or not.
- Achievable - set a feasible KPI, able to motivate personnel to attain it. Personnel's objectives should be aligned with the organization's goals.
- Relevant - ensure it is aligned with the organization's strategic goals in short and long term.
- Time-bound – the time-frame to achieve the goals are set.

  (ELMO Cloud HR & Payroll, 2016).

The steps to create KPI's start by determining the organization and process goals, then recognizing critical success factors (which commonly are within the next performance dimensions: time, cost, and quality (Dumas *et al.*, 2018)). And based on that SMART KPIs are created in accordance with the organization's strategy (Mendling and Vom Brocle, 2018).

KPIs are normally integrated in a Performance Management System. Performance measurement data should de recorded on software such as Tableau, Microsoft PowerBI, or Excel to handle, calculate and graphically represent the KPIs automatically, visualizing the performances of the underlying processes by means of suitable diagrams in a dashboard with the most important information for the organization. Continuous quality improvement must be conducted on KPIs (Mendling and Vom Brocle, 2018)

3 Overview of the current situation

Being a very young company, P&A still has many production processes in development and is changing to improve them. Up to this point, there was never a costing method implemented and consequently, there was no cost management information apart from invoices from accounting. The fast growth of the company pushed them to seek a more accurate cost model that would be capable of adapting quickly to future changes in the processes. Here is exactly where this project is inserted, able to aid in decision making, to control and reduce costs, to quantify and project cost with the aim to generate more accurate budgets for incoming projects and help to define a pricing strategy, and finally to help in the production design to choose the most adequate changes related to operational or technological options.

As there was no previous cost accounting nor process management, research was needed to be done from scratch, to model the process itself as well as study in detail all costs incurred during the complete production process. The information gathering to create the process maps was mainly through observation and crew interviews. Resources and costs tables were done by interviewing the participants, measuring execution times, and looking over the previous purchase invoices – kept by the administration for accounting purposes - to get the costs of materials and equipment.

The cost model developed in this project focuses only on the core processes of the company, the Samples Analysis. In a few words, the core process relies on processing bio-samples with their photonics-based technology to acquire a signal (fingerprint), which is further analyzed and classified using artificial intelligence. A diagram of this process can be seen below.

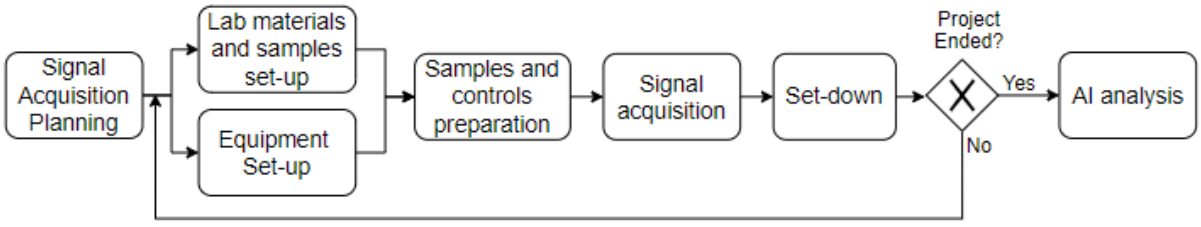


Figure 5 - Samples Analysis Workflow.

This process is carried out by two of the three teams of the technology department: the biophotonics tech team – lab technician, biologists, and photonics specialists – and the data science team. Other members of the company can also be involved as consultive members, like the CTO, science writer, or even the COO.

The company aims to use the developed technology as a platform to make customized projects to their clients based on their needs. So, they do not provide a standard service, as all the client's requirements for one project must be previously agreed based on the company's capability to perform it before the project begins. Based on those requirements, P&A must design the most adequate way to perform the laboratory experience to achieve the desired result for the client.

The main target for this project is the creation of a cost model able to quantify all costs relevant for decision making related to the company core process and be able to link how changes not just in the process workflow but also in technological aspects can impact the cost structure. And due to the customization of each project, a job-costing is needed. For these reasons and for the particular interest of the company CEO himself, the Process-Based Cost Modeling was selected.

As PBCM focuses on direct production costs, it was studied whether this would bring any drawback. The agile approach of the company enables it to have very low fixed costs (as infrastructure, administration, and others) which are not going to be considered for the model due to its low-cost impact and lack of relevance for decision making concerning the core process.

The values used in this report were modified due to confidentiality issues, although this does not interfere with the proposed objectives.

4 Cost Model Implementation

In this chapter would be explained how the three steps of the Process-Based Cost Model were approached and implemented. Analysis of the obtained results as well as how the given suggestions improved the process efficiency and its costs. By the end, the cost model reliability was tested, comparing the forecasted costs with the real ones of a commercial project executed by the company.

4.1 Process Model

The first step to know the process is to model it, which results to be also the first step to construct the PBCM. The modeling begins with the definition of the boundaries of the core process, which starts with the planning of the lab experimental experience for the samples signal acquisition and ends when the AI results report is done. The process maps were done using the Business Process Model and Notation. Due to process complexity and length, it was divided in several phases. This first level of detail is graphically represented in the responsibility matrix (see Figure 6) where all participants, responsible, milestones, and data inputs for every phase can be seen. The second level of detail are swimlanes for each phase, indicating the sequence of tasks and who performs it. Some tasks were considered sub-process due to their complexity. The third level of detail was not done for lack of relevance for the cost model but can be interesting for the company to have it for further business process management, total quality control, to onboard new personnel, and even for the need of any certification.

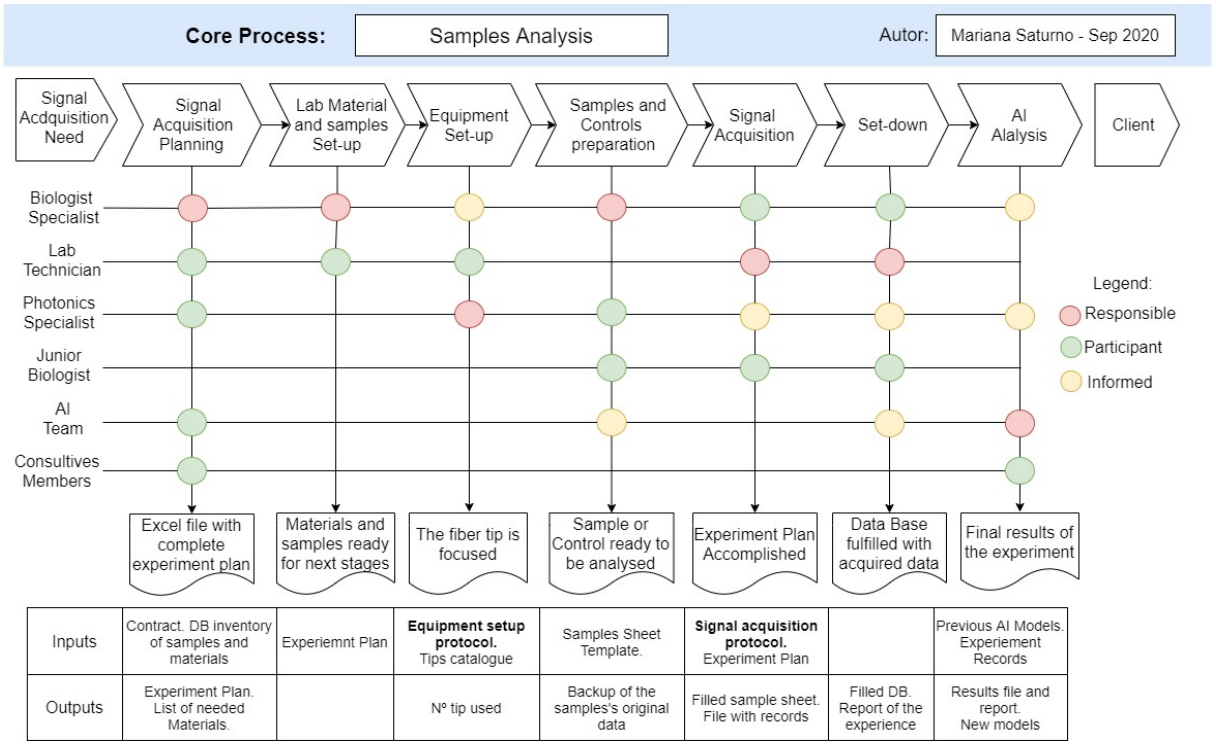


Figure 6 - Responsibility Matrix.

The seven phases are presented below with a concrete description that allows perceiving the essence of them, followed of a figure of its respective process model swimlane for better appreciation. The hardware constructed by P&A using their technology to analyze the samples is an equipment that is going to be called H-P&A.

Phase 1: Signal Acquisition Planning

The biologist specialist is responsible for this phase, who based on the contracted project, must design the laboratory experience, and make a needs assessment to achieve the desired results. Other department members might help as consultive members, providing feasible information on their specialty, estimate required time to perform something, or just an opinion to outline the plan. By the end, the plan must contain the samples specifications, signal acquisition schedule – including the samples analysis order - and list required materials. The lab technician must check if any material or sample is missing, and if so, request it. It is desirable to create a standardized template in the future to exhibit the acquisition plan. A diagram of this workflow can be seen in Figure 7.

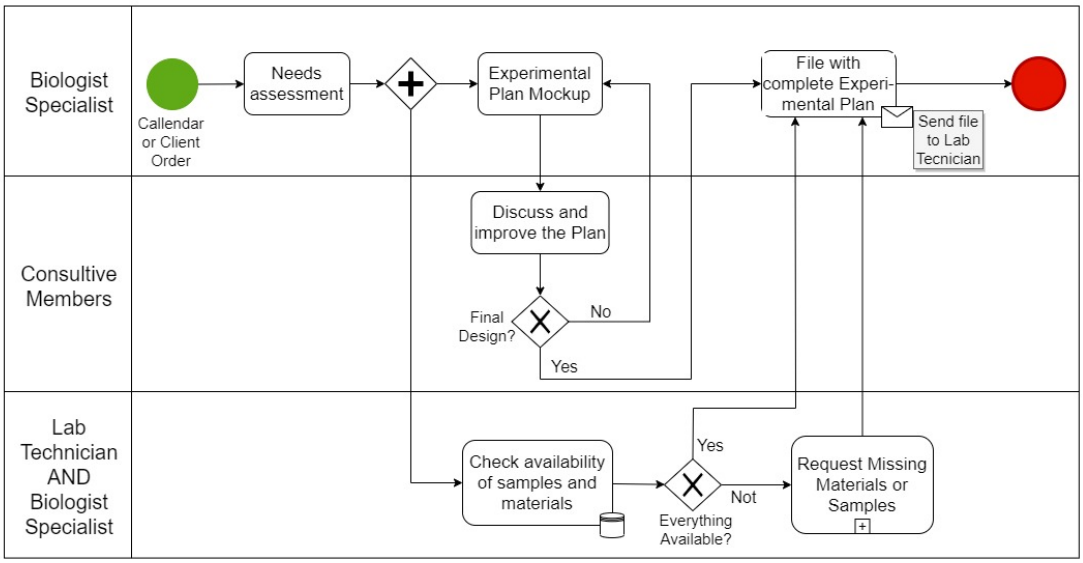


Figure 7 -Signal Acquisition Planning.

Phase 2: Lab Material and samples Set-up

Consists of taking all needed materials and samples to the laboratory bench - based on the experimental plan - before starting the work session. It is normally done by the lab technician. Samples often require specific defrost conditions. The biologist is responsible for it, as well as for labeling each microtube by hand with the data of each sample - this is a non-value-added activity desired to be replaced by a more automated method. See Figure 8.

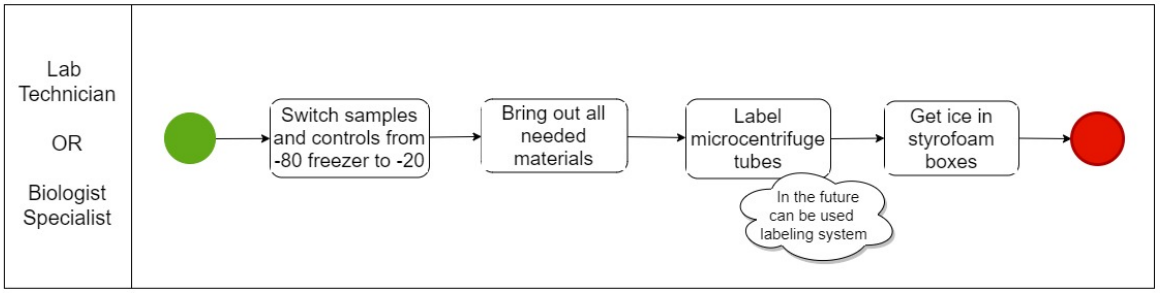


Figure 8 - Lab Material and samples Set-up.

Phase 3: Equipment Set-up

The photonic specialist is responsible for attaching a new optical fiber tip on the H-P&A, update the tips catalog, and check if it is in good condition to start the samples signal acquisitions. This phase also includes turning on the equipment, computer, and software as well as to focus the fiber – which can be done by the photonics specialist or by the lab technician. This workflow can be seen on the swimlane of Figure 9.

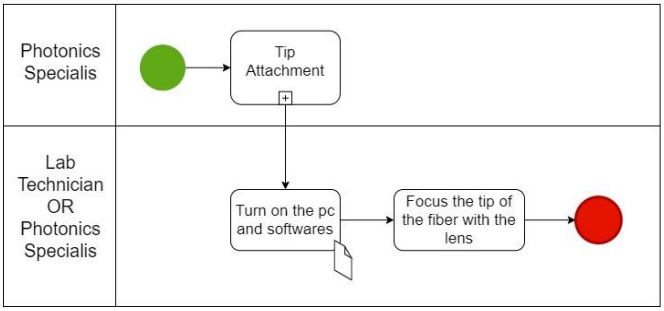


Figure 9 - Equipment Set-up.

The tip attachment was made as a subprocess for being very extensive and specific. Its flowchart can be seen in the Figure 10, explaining with more detail the procedure.

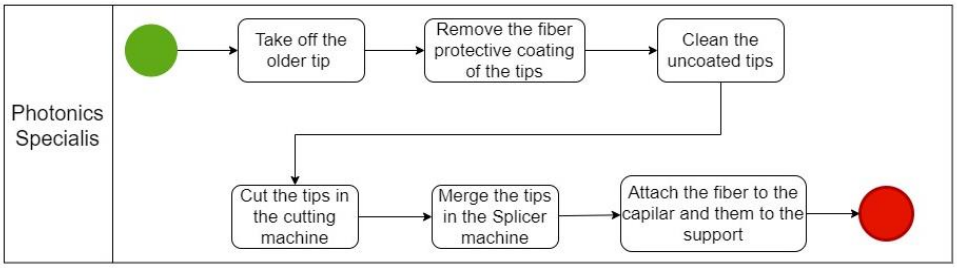


Figure 10 – Tip Attachment.

Phase 4: Samples and Controls Preparation

Relies on the biologist specialist to prepare the samples and controls for analysis according to specific requirements and to keep them on ice until usage. If the samples have a larger volume than necessary for the experiment, they should be aliquoted and saved. Sometimes the jr. biologist can intervene in this process. See Figure 11.

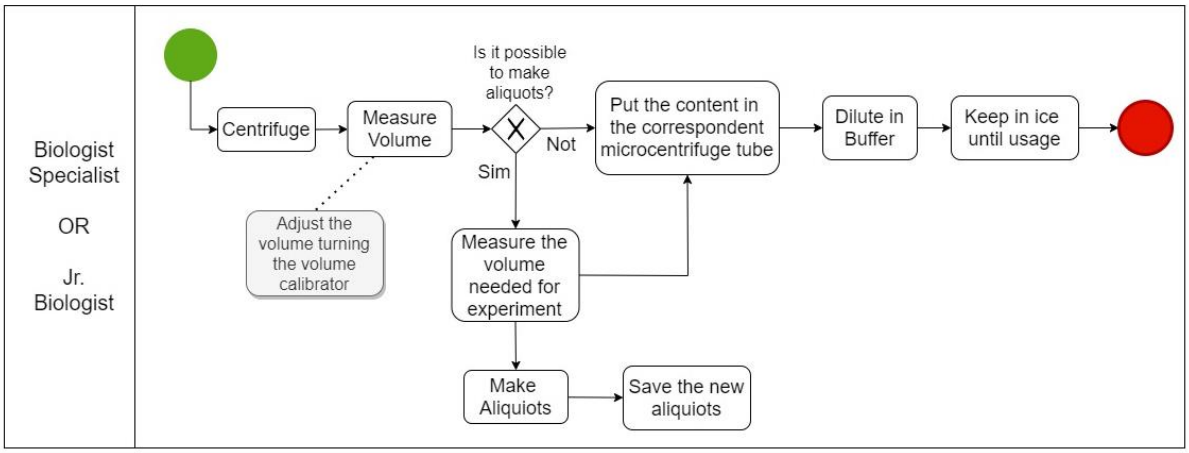


Figure 11 - Samples and Controls Preparation.

Phase 5: Signal Acquisition

Signal Acquisition is the central phase and its modelling can be seen in Figure 12. It consists of analyzing a sample at a time by the H-P&A to acquire the signal. The major steps are to place the sample on the H-P&A support, immerse the optical fiber tip on it, acquire, take out the fiber and clean it with a lye solution, save the file and the sample. The biologist is who handles the samples and switches the ibidis (sample holders) on the H-P&A, while the lab technician is responsible for the acquisition itself and for the good performance of the entire phase, who must always verify the good performance of the optical fiber tip, and in case of disruption ask the photonics specialist to change it.

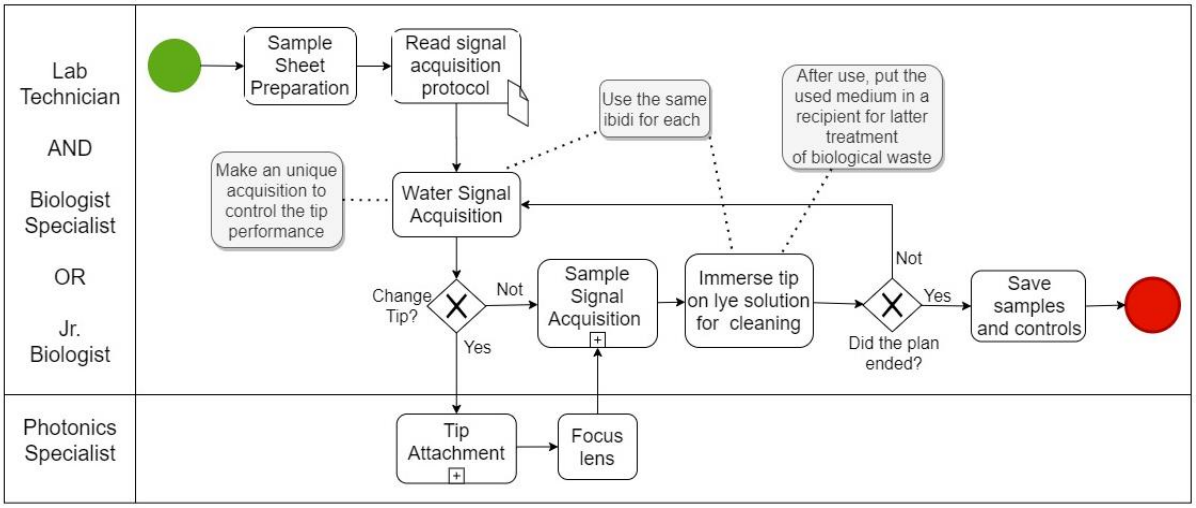


Figure 12 - Signal Acquisition.

Sample Signal Acquisition was also designed as a subprocess for its complexity and is presented in Figure 13.

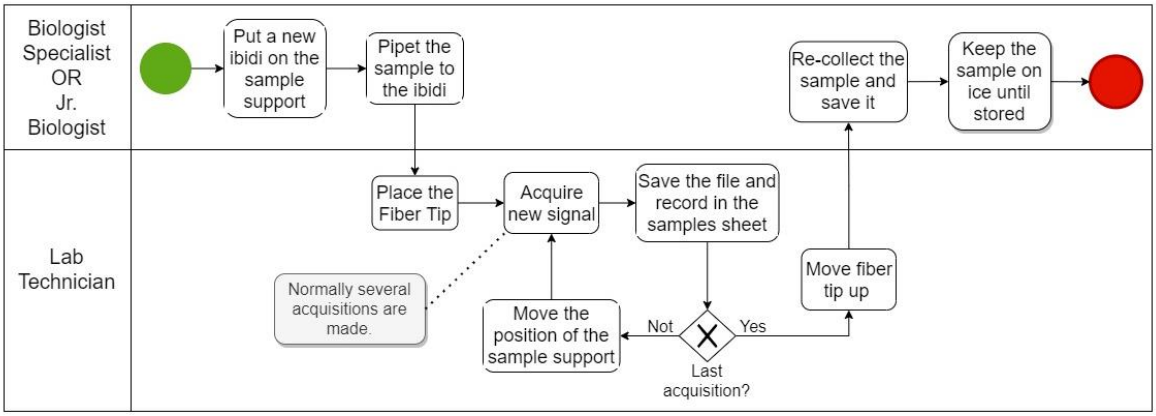


Figure 13 - Sample Signal Acquisition.

Phase 6: Set-down

This phase is also the responsibility of the lab technician. It consists of turning off the equipment, clean the laboratory, send the record to the AI team and insert in the database. See Figure 14.

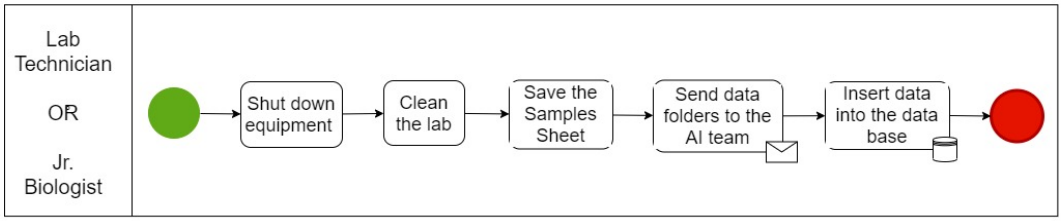


Figure 14 - Set-down.

Phase 7: AI analysis

The AI team is responsible for processing the data using data science to classify the samples as intended using the most adequate models. By the end, a report must be written to present the results to the clients. Its workflow can be seen in Figure 15.

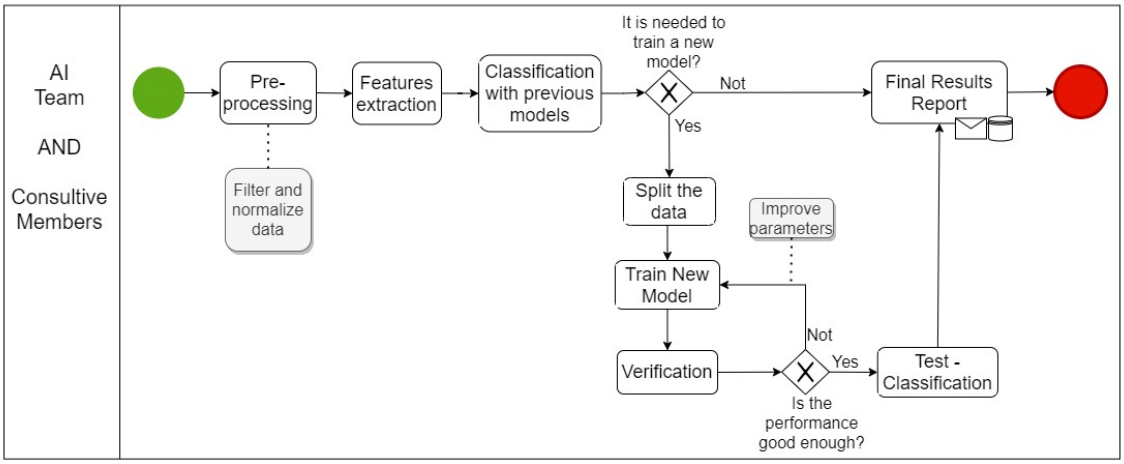


Figure 15 - AI analysis.

From the process analysis, the samples acquisition is proven to be a bottleneck, taking nearly 50% longer than the next slower activity (samples preparation). Also, handwriting the microcentrifuge tubes is a time-consuming non-value-added activity, so the next recommendations are made.

- One more optical fiber tip should be added to the H-P&A allowing to augment the throughput by analyzing at least two samples at a time.
- A labeling system should be implemented to avoid handwriting the microcentrifuge tubes, instead, labels would be printed and stuck on the tubes, this practice is expected to decrease the time spent on this activity, reduce human error, and be the first step toward an automated system for sample traceability and inventory management, without forgetting that it will also allow new bio-samples coming from elsewhere to be labeled with the P&A's identification, which currently is not in practice (samples from outsourced were stored on the -80ºC freezer without any internal identification until unfreeze), increasing the TQM.

4.2 Operational Model – Resources Study

The PBCM second step – the operational model – was done after having the process models. As mentioned before, the PBCM focuses on direct cost, thus, fixed costs were not included such as facilities rent, maintenance, or other administrative. Instead, all direct costs considered relevant for decision making were included based on a cost-benefit criterion. The information documented was recorded in an Excel spreadsheet, with two main tables created in different sheets of the document.

The first table, for the resources, indicating the kind of resource, the cost driver that would be used to calculate the total cost, the unit of measurement used to quantify the consumption, and finally the cost per unit. An extract from that table can be seen in Figure 16.

Table of Resources with cost drivers, units and costs

Resources	Cost Driver	Unit	Cost(€)/Unit	Total Costs
Human Resources				
Biologist Specialist	Time Spend	Minutes	0,433 €	673,24 €
Lab Technician	Time Spend	Minutes	0,346 €	509,52 €
Junior Biologist	Time Spend	Minutes	0,173 €	28,75 €
Photonics Specialist	Time Spend	Minutes	0,433 €	123,03 €
Consultive Member	Time Spend	Minutes	0,433 €	155,88 €
AI Team	Time Spend	Minutes	0,433 €	2.598,08 €
Equipments				
H-P&A	Per Sample Analyzed	Nº	2,963 €	296,28 €
Cutting Machine	Per Sample Analyzed	Nº	0,046 €	4,62 €
Splicer	Per Sample Analyzed	Nº	0,554 €	55,43 €
Optic Fiber Stripper	Per Sample Analyzed	Nº	0,006 €	0,62 €
Pipets	Per Sample Analyzed	Nº	0,064 €	12,76 €
Microcentrifuge	Per Sample Analyzed	Nº	0,028 €	2,80 €
Eppendorf carrossel	Per Sample Analyzed	Nº	0,019 €	1,91 €
Computers	Per Sample Analyzed	Nº	0,739 €	73,90 €
Materials				
Microcentrifuge Tubes	Quantity Used	Nº	0,554 €	55,43 €
Ibidis	Quantity Used	Nº	4,619 €	526,54 €
Pipets tips	Quantity Used	Nº	0,071 €	28,50 €
Optic Fiber	Quantity Used	cm	0,063 €	14,11 €
Optic Fiber Tip	Quantity Used	Nº	35,864 €	537,95 €
Lye	Quantity Used	mL	0,001 €	0,08 €
Masks	Quantity Used	Nº	0,866 €	24,25 €
Protective Suit	Quantity Used	Nº	2,710 €	0,00 €
Gloves	Quantity Used	Nº	0,223 €	12,51 €
Glasses	Per Sample	Nº	0,001 €	0,22 €
Manga Termoretractil	Quantity per Fiber Tip	cm	0,006 €	0,61 €
Buffer	Quantity per Sample	mL	0,016 €	0,13 €
Electricity	Time	Min	0,001 €	0,77 €

Figure 16 – Table of Resources with its Costs drivers and Costs.

4.2.1 Resource Cost Definition Criteria

Human resources

The human resources costs are not real once it is confidential information due to the general data protection regulation. It is up to whoever has access to that information within the company to make these adjustments privately if necessary, to issue more accurate budgets.

To estimate expenses for each collaborator, it was assumed a monthly gross salary and multiplied by 14 (to include holidays and Christmas allowance) plus the sum of all monthly food allowance to compute the yearly expense, then it was divided by the 11 months of the year. Given the total monthly expenses, it was considered the month as having 4 weeks of 40 working hours each and under this criterion, the personnel cost per minute was computed.

Equipment

Assumptions were made to allocate costs of the equipment per each sample analyzed. The first approach was to know how many years the technology would last. Together the CEO and the Biophotonics Team Lead assumed as viable and real that the H-P&A technology would last five years and the average quantity of samples to analyze per year is 2,250 units. This lifetime and allocation criteria were also arbitrated for the other equipment, placing us in the worst-case scenario where they probably would not be used anymore if the technology was replaced. It was also decided that at the end of the five years the equipment would not have any commercial value (residual costs) and the total equipment cost would be entirely diluted by the 11,250 samples (total estimated samples to be analyzed in five years).

Materials

Most of the materials costs were directly traced from purchasing invoices documented by P&A. Some materials are used for several years, such as glasses and lab coats. For those, their costs were divided by the average 11,250 samples in five years as done with the equipment. Water and electricity costs were obtained from the Pordata website (contemporary Portuguese database) for industrial installations because P&A does not have access to it once it is paid by the medical research institution. Electricity consumed was measured with an appropriate instrument during various work sessions.

4.3 Operational Model – Time Study

The second table reflects the process, its activities, and the amount of time that each person takes to perform it. On the table – shown in Figure 17 - can be first seen the phase of the project, the activities, its hierarchy – if it is done by project, batch (work session), or unit (sample) - number of times that an activity is performed in the project, the average time to perform the activity once (in seconds or minutes) and the total time considering the number of repetitions. The duration of equipment setup and signal acquisition phases were obtained measuring the cycle time of the activities while they were performed, and then, the average was computed. The other phases' durations are also average times estimated or measured by the performer itself – mainly because some personnel were working from home or because it was needed a high amount of time to measure. Many activities cycle times were used as cost drivers to allocate human resources direct costs.

Table of activities and time durations for Human Resources

Phase	Activities	Activities	Nº repetition	AVG Time	AVG Time (seg)	total time (seg)	Total Time
Planification	Planification	Project		22500.00		1350000.00	22500.00
	Check materials	Project		30.00			
	Check samples	Project		20.00		1200.00	20.00
Materials and Samples Setup	Put Samples to Defrost	Batch	1608	15.00		1447200.00	24120.00
	Get needed Materials	Batch	1608	5.00		482400.00	8040.00
	Label Microcentrifuge tubes	Unit	11250	2.50		1687500.00	28125.00
	Get ice	Batch	1608	5.00		482400.00	8040.00
Equipment Setup	Tip Attachment	Batch	1608		402.00	646416.00	10773.60
	Turn on pc and softwares	Batch	1608	3.00		289440.00	4824.00
	Focus the fiber on len	Batch	1608		410.50	660084.00	11001.40
Samples Preparation	Samples Preparation	Unit	11250		198.87	2237306.25	37288.44
Signal Acquisition	Samples sheet preparation	Batch	1608	3.00		289440.00	4824.00
	Water signal acquisition	Unit	11250		115.00	1293750.00	21562.50
	Sample Acquisition by steps						
	Place the ibidi	Unit	11250		7.00	78750.00	1312.50
	Pipet the sample	Unit	11250		30.00	337500.00	5625.00
	Place the fiber	Unit	11250		60.00	675000.00	11250.00
	Acquire signal	Unit	82125		33.00	2710125.00	45168.75
	Move the sample	Unit	82125		4.50	369562.50	6159.38
	Save the file	Unit			0.00	0.00	0.00
	Fiber up	Unit	11250		40.00	450000.00	7500.00
	Repipet the sample	Unit	11250		67.00	753750.00	12562.50
	Lye for cleaning	Unit	11250		64.67	727500.00	12125.00
	Save the samples	Unit	1608	5.00		482400.00	8040.00
Setdown	Setdown	Batch	1608	30.00		2894400.00	48240.00
AI Analysis	AI Analysis	Sample	11250	60.00		40500000.00	675000.00
	Results Report	Sample	11250	3.00		2025000.00	33750.00

Figure 17 – Table of Activities and time duration.

4.4 Financial Model

Now that all the necessary data to create the PBCM is documented, only the financial model is missing - allocate costs to all consumed resources during the process. This was done in another sheet of the document having the layout presented in Figure 18.

Phase				
Resources	Cost Driver Unit	Quantity	Cost	Cost Hierarchy
Activity or set of activities				
Activity or set of activities				
Total Costs				

Figure 18 - PBCM table layout.

In the spreadsheet, the Resource must be selected from a dropdown list - linked to the resources table - and the value of the Quantity field introduced. Afterward, the Unit and Cost are going to be automatically filled. The Unit field represents the unit of measurement; the Quantity says the consumed units of resources; the Cost field computes the multiplication of the resource unit cost versus the quantity consumed. And the Driver is an optional field to be filled by hand allowing an easier way to know if the cost is per sample analyzed, per work session, per personnel needed, among others.

On the developed cost model, all the resources, quantities, and drivers of each phase of the process are filled. Many of the Quantity's cells have references to other cells

facilitating the automatic fill when the user interface is changed. Figure 19 exemplify the financial model developed for each phase of the Samples Analysis process, in annexes are presented images of the PBCM for all phases.

Signal Acquisition				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Sample Sheet Preparation				
Lab Technician	Minutes	4824	1,671.08 €	Per work session
Sample Sheet	Nº	1608	56.81 €	Per work session
Markers	Nº	11250	116.91 €	Per Sample
Water Signal Acquisition				
Lab Technician	Minutes	21563	7,469.47 €	Per Sample
Water	mL	16875	29.23 €	Per Sample
Biologist Specialist	Minutes	21563	9,336.84 €	Per Sample
Ibidis	Nº	1608	7,427.03 €	Per work session
Sample Signal Acquisition				
Biologist Specialist	Minutes	27540	11,925.17 €	Per Sample
Lab Technician	Minutes	70078	24,275.77 €	Per Sample
Ibidis	Nº	11250	51,961.52 €	Per Sample
Tip Cleaning				
Lye	mL	16875	9.06 €	Per Sample
Lab Technician	Minutes	12125	4,200.22 €	Per Sample
Biologist Specialist	Minutes	12125	5,250.28 €	Per Sample
Ibidis	Nº	1608	7,427.03 €	Per Sample
General Costs				
H-P&A	Nº	11250	33,331.27 €	Per Sample
Pipets	Nº	11250	717.76 €	Per Sample
Pipets tips	Nº	22500	1,603.23 €	Per Sample
Electricity	Min	162729	84.56 €	Per Sample
Falcon Tubes	Nº	2	1.23 €	Per Sample
Computers	Nº	11250	8,313.84 €	Per Sample
Total Phase Costs			175,208.33 €	

Figure 19 - Examples of the financial models' tables.

4.5 User interface

A user interface was created in another document sheet, where someone interested in estimating a project cost has a unique interface to insert the project inputs necessary to calculate it – since it depends on every project characteristic – such as samples type, quantity, cost, and source (from the client or from P&A). Other inputs about the laboratory experience are also needed:

- Number of acquisitions per test and training sample - training samples are used to build the AI classification model and normally are made more signal acquisitions of the same sample more information than for the test samples which are classified once the model is finished.
- Number of samples to analyze for every work session – being a work session a morning or afternoon of laboratory work to acquire the samples signal – and this dividing total number of samples by the number of samples per work session, the number of work sessions is automatically calculated.
- The number of people required to carry on the experience, to calculate some consumables costs, like masks and gloves.
- Quantity of buffer to dilute the samples.

- Number of samples to analyze per optical fiber tip – they might brake of decrease performance during the analysis, so they must be changed often.
- And finally, two inputs more related to the AI analysis specifically with the cloud services costs, being the number of virtual machines to be used, and the number of days needed to do it.

Another part of the User interface shows the costs of the project. A space was reserved to add a safety margin to the project costs calculated by the model. After consultation with the Biologist Specialist, it was concluded that normally cost can increase due to the complexity of the project - for that reason, the field was called Complexity Cost, and it consists of giving a percentage to be charged over the project costs previously given to create a safety margin for unexpected expenses once this cost model might be used as a budgeting tool.

Thinking about the opportunity to use this cost model as a pricing tool, a pricing section was also included in the user interface, with the option to add a markup percentage over the total costs (project estimated cost + safety margin) and another to apply a discount rate also over the total cost. An example can be seen in Figure 20.

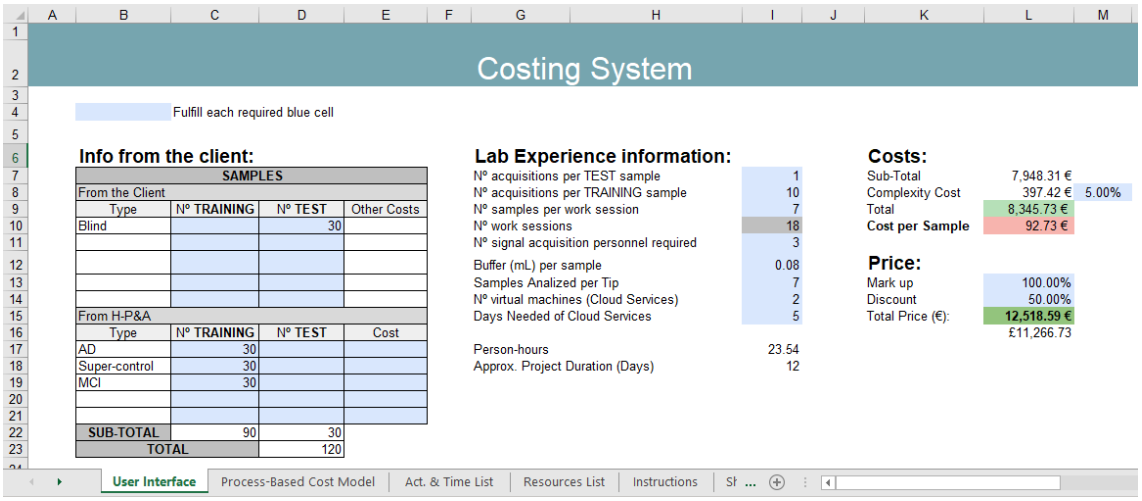


Figure 20 – User interface.

As expected, some indicators are also presented in the user interface, such as the man-working hours, the project duration, and – the main one – the cost per sample. Finally, a series of doughnut charts and tables (below the screen presented in Figure 20) showing the structure of the total cost of the project in three different ways, per each resource individually, per process phase, and per type of resource, they are shown in Figure 21. Its purpose is to create a control Excel file where these records can be documented and compared with the real results as well as with other production process design costs.

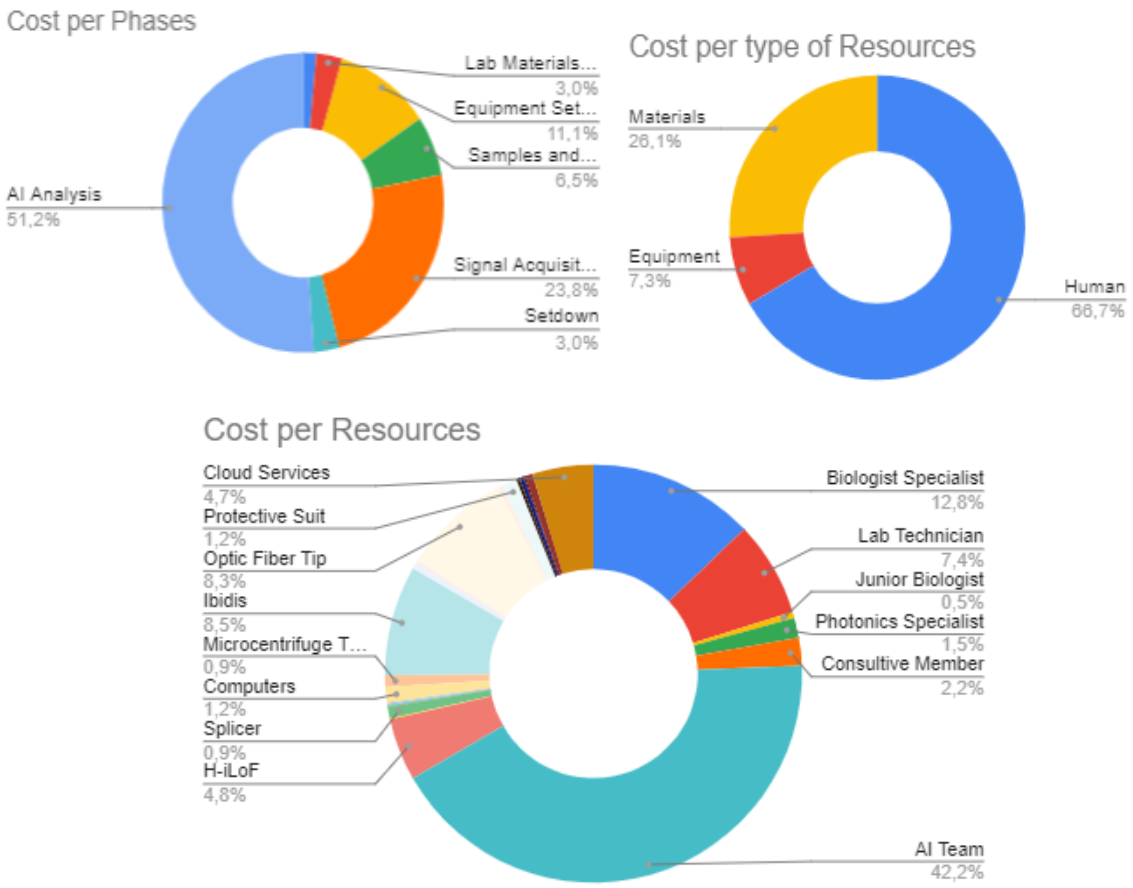


Figure 21 – Charts showing costs structure by different viewpoints

4.6 Results Analysis

Observing the work made up until this point, some recommendations can be proposed. To analyze the process cost it was assumed under the data science good practice that 70% of the 5 years samples would be for training and 30% for test, with that data was obtained the table presented in Figure 22.

#	Resource	%
1	AI Team	40.9%
2	Biologist Specialist	12.5%
3	Lab Technician	9.6%
4	Ibidis	9.4%
5	Optic Fiber Tip	8.1%
6	H-P&A	4.7%
7	Cloud Services	4.5%
8	Consultive Member	2.0%
9	Photonics Specialist	1.6%
10	Computers	1.2%

Figure 22 – Rank of top costly resources.

The first five resources consume slightly over 80% of total costs, making them the most relevant costs to keep under and prioritize their optimization. For this cost model 41 resources were accounted, and 14 of them contribute with less than 0.01%, if those resources were discarded from the list because of its lack of relevance, 18.5% of resources would contribute for the 80% of costs, and it would be very close to fit on the Pareto principle.

Human resources are the major cause of cost, as expected for lack of automatization, leaving P&A with big space for future improvements. The AI Team has large hours of work per project, reflecting 40.9% of costs – at the end of this dissertation, this team consists of only two people. The Biologist Specialist and the Lab technician follow the ranking.

The most outstanding resource costs are the ibidis. They are the fourth higher expenditure representing 9.4% of the total cost. This is alarming because the ibidis are only a consumable, used as sample holders, that do not add any value to the client. Each ibidi costs 156% more than a H-P&A usage per sample and is needed at least one per sample and another two per work session (one for lye and another for water). It is clear that a cheaper solution must be found, either to change the provider or to use a different sample holder.

The second non-human resource of higher cost are the optical fiber tips with 8.1%. The tips are very delicate to handle and break easily, reason why need to be changed very often - in average they endure to seven sample analysis. The photonics team was already looking for a substitute and found an alternative optical fiber tip that was submitted to test alongside the old ones, but the results are still not conclusive of an equal or better performance - although everything seems to indicate so, more studies need to be done. It is known that they were able to analyze 30 samples without any physical wear, but the maximum quantity of samples the tip is able to endure while maintaining a good performance is still unknown.

A clear operational bottleneck can be identified: the sample signal acquisition. The activities contributing to this amount of time are immersing the optical fiber tip in the sample, acquiring the signal, and moving the sample as many times as needed – depending on the type of sample, if it is for training or test –, and finally moving up the fiber – keeping in mind the higher quantity of samples analyzed are for training and require more acquisitions per sample, and consequently, more time. This can be improved by adding more optical fiber tips to the H-P&A in order to augment the throughput since nearly the same time used to analyze one sample can be perfectly used to analyze two, and hopefully reduce in half the average time to analyze one sample. The tech team decided to try it, and 3D printed the supports to put one more optical fiber tip on the H-P&A. Several samples were analyzed using the two optical fiber tips, to measure the new cycle times (also to compare costs) and to verify if both the optical fiber tips have the same performance and discrimination power of one optical fiber tip alone – these tests are very important because once the hardware uses photonics, it was also needed to check if no interference was created. The AI team analyzed the data obtained and did not find significant differences at a 5% significance level.

To compare improvements, either in price or costs, comparisons were firstly made with the same phase of the process where the alteration occurred, due to the high differences in orders of greatness between the phases of the process, some being a hundred times bigger than others in monetary units, for example.

The same cost model previously created was adapted to the changes originated in the process by the insertion of one more optical fiber tip. The investment made to alter the H-P&A was about 1,000€ and caused the reduction of about 9.2% of costs and 10.3% of time for the entire process (all phases). In some activities, the number of repetitions was reduced by half, and a few cycle times slightly changed. Considering just the signal acquisition phase, the cycle time was reduced by 42% when analyzing two samples at the same time and 20% on costs.

4.7 Application of the PBCM on a Real Project

Already having a cost model to estimate the cost of any project, its accuracy was validated with a commercial project from a private biotechnological company. To do so, the standard cost model was used to estimate costs and another document – a copy of the standard cost model – filled with the real consumptions, obtained by measuring times and resources effectively spent to carry out the project. The major contributing resources were the most supervised. Table 2 reflects the identified discrepancies.

Table 2 – Differences between estimated and real costs

Cost Source	Estimated	Real	Commentary	Balance
Ibidis	978.67 €	537.52 €	Near half of the estimated ibidis was used. But there were sterilization costs to reuse them	441.15 €
Needs assessment and experimental planning	202.50€	326.00 €	Needed more time – very complex project	-123.50 €
Equipment Setup	77.51 €	96.89 €	Tip focused and software turned on by the photonics specialist instead of the lab technician	-19.38 €
Glasses and protective suits	138.10€	0 €	Not required	138.10 €
Biologist Specialist – Lab. Experience	952.20 €	1329.38 €	Spent more time than estimated	-377.18 €
Lab. Technician – Lab. Experience	595.82 €	902.00 €	Spent more time than estimated	-306.19 €
Junior Biologist – Lab. Experience	42.88 €	132.00 €	Spent more time than estimated	-89.12 €
AI team, consultive member and cloud service - AI Analysis	5647.25 €	5469.78 €	Spent less time than estimated	177.47 €
Others – Electricity, Parafilm & Retractable Tube)	0.92 € 0.08 € 1.11 €	1.40 € 0.00 € 1.0.6 €	Different consumption	-0.48 € 0.08 € 0.05 €
Optic Fiber Tips	973.18 €	931.76 €	Two tips were saved	41.42€
Total Difference				-117.58 €

As can be seen in the table above, some resources consumption estimations do not match. Mainly the human resources during the laboratory experience were underestimated – this might be mainly because in the cost model it is being accounted the time to perform the activities and not the real-time including idle times or resting stops during the work sessions.

The opposite occurred with the AI team. This analysis was expected to last 16 days, but it was hurriedly performed in 15 days with the help of one more person, the CTO, for nearly one week. There was a lack of data about the time spent in other projects, and the average time spent to make the AI analysis per sample was computed using only two records. But another likely cause is that the AI team and the consultive members who wrote the report did not record all the hours truly spent working on this project.

One resource that makes a very big difference positively is the reduction of ibidis used. Once the team knew its weight on total costs, they decided to reuse some of them. After use, ibidis were sterilized and dried. This decision allows the deviation to be only 1.1%, but if they had not been reused, the deviation would have been 5.0%.

Taking this into account, further time measurements can be made with the purpose to include in the cost model the time the personnel stopped during the signal acquisition phase. Or to use the complexity cost created exactly for this type of estimation errors, and in this case, a 5% safety margin would cover it.

4.8 Other activities performed during the dissertation

Labeling System

The purchasing of a Labeling system as recommended before was seriously embraced. The seriousness of the matter is that many of the samples that come from outside partners remained in the freezer from arrival until they were unfrozen for use without any P&A physical identification and other times without any identification at all. This is a big failure of quality management, mainly because if any accident happened, for example, if samples were dropped, or moved from the place where the biologist stored them or just get confused which is which, it would be very risky. Another inconvenience is that it will not allow the database to be updated properly both with the internal identification, stock, and storage place of every sample. What originally lead to identifying the need for a Labeling system – to change the non-value-added activity of handwriting the microcentrifuge tubes during the signal acquisition process for a better solution - turned out to be a minor problem and a side advantage of the Labeling system implementation.

Since October 2020, several providers were reached, and budgets were asked. All information obtained was presented to the stakeholders in mid-November and the requirements about the labeling system and providers were set considering the panorama. Was decided to buy a printer and labels (able to stick in wet surfaces, -80ºC resistant, and small enough for the microcentrifuge tubes) with an experienced supplier in the medical or laboratory field for samples below -80ºC, with preferences for Portuguese over foreign companies who would also provide a QR and Barcodes portable reader (for further implementation of an Information Management System for traceability and quick access to medical records). After that other companies were contacted but no better solutions under the previously set conditions were found. In December after a final reunion with stakeholders was decided to advance with the

purchase of the printer and labels from a national company and it was carried out successfully. The printer was used for a project of 160 samples, printed at the lowest printing speed (51mm/s), so all the samples were printed in less than a minute and the average time to stick the label on the tubes was of 7.05 seconds over 95% faster than hand labeling and 82% cheaper. The total improvement on the entire project was of 2.6% less time and 1.6% less money. The labels have not been used for outsourced frozen samples to assess the label's physical performance. For the future is needed to learn better how the label designer software works and how to link this with the database.

Prototype Cost Model

The H-P&A is non-portable and very heavy equipment, the company is constructing a portable device cheaper and easier to use. It is in development and the first performance tests to compare it with the H-P&A were made in January 2021. The same methodology used with the H-P&A was applied. The tests were observed, a swim lane for the new signal acquisition procedure was constructed and cycle time measurements were made. With this information was already prepared a spreadsheet, aiming to compute the financial model as soon as data from real uses of the prototype are collected. The construction costs of each device, including components and personnel costs were already documented, and it is significantly cheaper (almost five times). Also, the cycle times of the signal acquisition are expected to be much lower because it does not need to have one person continuously giving the order to acquire but only once.

Participation in Sessions and Interviews Analysis

Was given the opportunity to attend and participate in various sessions of various kinds, from workshops conducted by startup accelerators to international networking events such as the web summit. The information was recorded in a presentation document so that interested parties can access it in the future.

Previous interviews made by the COO were analyzed to make a mental map to link important frequently asked questions, possible partners, or even referrals to potential advisors.

Market Research

At the beginning of the dissertation was made a list of competitors and similar companies with platform solutions in the Medtech field aiming to understand how their business model was and try to identify good or bad strategies adopted by them. It was not a successful task once this market is very closed and not so much information can be found for free, but the list is now documented with the information obtained from more than 40 companies.

Later by the end of the dissertation period, another research was made about a potential customer segment. Interviews were conducted with collaborators of companies that already are supplying these customers to understand what their pains and gains are, price and time sensibility, type of technologies used, and how the market was approached.

5 Conclusions and Future Work

The main objective for this project, to create a Process-Based Cost Model for the company core process, was satisfactorily accomplished using Microsoft Excel software, ending up with an easily configurable cost model able to adapt the production design process evolution with all the relevant costs, enabling to use this cost model as a support tool for decision-making. It proved to be a reliable source of information for decision-making once it can reflect the real cost in a very accurate way, with a deviation of 5% from the real case it was compared with. Besides, it served to calculate how many samples could be analyzed within a budget and defined time for an accelerator program application.

This project is a starting point for the implementation of a control management system, for the efficient management of expenses and also of others, such as a quality management system focused on generating value for customers and vital for the future medical equipment certification intentions.

The company's need to have control over costs was undeniable. It will allow them to be more sensitive about the expenses incurred during their activity and to more intelligently direct their efforts in order to create an efficient production process. As it served during this project to identify the need for a labeling solution and to incorporate one more optical fiber tip.

A cost model must always be updated if there are alterations either in the design of the process itself and fed with more data for the average execution times. In fact, this is a reality of all costing models, whose operation involves constant updates and a long period of data collection. It is important to highlight that when there is the need to estimate the time or make arbitrary allocations, it was always done in a way that it would not be underestimated, preferring consequently the increase in costs and not causing an eventual loss of money for the company.

The cost model for the prototype could not be finished due to the lag between its development period and this dissertation, but a base spreadsheet was delivered, leaving only to the user to insert the average time that an operator effectively spends in performing the analysis of a sample.

Although the main theme of the work was the development of a cost model, it did not end there. It proven essential to understand the complete operation of the company for the realization of the process models and to be able to understand how costs could be accounted for and attributed, not only for this purpose, but also to understand the business model and the company's value proposition, to carry out an informed market research - in the same way, it was necessary to understand how other medical analyses are made with different types of technologies (instruments or biological principles).

Further work must be done to implement a business process management system, to study all the company processes from the higher level, identifying the management, support, and other core processes, until the standard operating procedures or manuals describing the small details of the process.

Market research is another activity that needs to be done continuously, trying to reach out to more people and schedule interviews with the intention to understand another potential customer segment and better know the competitors. The developed cost model might help to analyze which segments are profitable for the company and even to construct a management plan.

SMART KPIs were not included on the project for lack of opportunity to discuss it with the C-Level to align objectives of the KPI's with the mid and long-term strategies but is an important activity that needs to be done in the near future. Instead, some indicators are present in the cost model, they can be registered on another Excel file to keep either control over the production process design changes or over to control the estimated versus the real cost and time duration of the projects.

The dissertation in a business environment allows feeling firsthand the need to combine tools and good practices from different areas of study, aiming to develop richer and more complete projects by having them present in mind during the planning stage. Also, it gives the chance to apply the knowledge gained on the degree on a very useful and impactful project.

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Annexes

Examples of the PBCM for all the phases pf the Samples Analysis Process

Experiment Planning				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Needs assesment and experimental plan				
Biologist Specialist	Minutes	22,500	9,742.79 €	Per project
Photonics Specialist	Minutes	60	25.98 €	Per project
Consultive Member	Minutes	60	25.98 €	Per project
Check Samples and Materials Availability				
Lab Technician	Minutes	30	10.39 €	Per project
Biologist Specialist	Minutes	20	8.66 €	Per project
Total Phase Costs			9,813.80 €	

Lab Materials Setup				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Label Microcentrifuge Tubes				
Markers	N°	11250	116.91 €	Per Sample
Biologist Specialist	Minutes	28125	12,178.48 €	Per Sample
Get Samples, Materials and Ice				
Lab Technician	Minutes	40200	13,925.69 €	Per Work Session
Biologist Specialist	Minutes	8040	3,481.42 €	Per Work Session
Total Phase Costs			29,702.51 €	

Equipment Setup				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Software Setup and Focus Tip				
Photonics Specialist	Minutes	15825	6,852.60 €	Per Session
Tip Attachment				
Photonics Specialist	Minutes	10774	4,665.11 €	Per Session
Cutting Machine	N°	11250	519.62 €	Per Sample
Splicer	N°	11250	6,235.38 €	Per Sample
Optic Fiber	cm	24120	1,512.33 €	Per tips required
Manga Termoretractil	cm	10849.98	65.77 €	Per tips required
Optic Fiber Tip	N°	1608	57,668.73 €	Per tips required
Optic Fiber Stripper	N°	11250	69.28 €	Per Sample
Total Phase Costs			77,588.82 €	

Samples and Controls Preparation				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Samples and Controls Preparation				
Biologist Specialist	Minutes	37289	16,146.61 €	Per Sample
Junior Biologist	Minutes	18645	3,229.41 €	Per Sample
Pipets	N°	11250	717.76 €	Per Sample
Masks	N°	4824	4,177.71 €	Per work session and personnel
Microcentrifuge Tubes	N°	11250	6,235.38 €	Per Sample
Pipets tips	N°	22500	1,603.23 €	Per Sample
Cryobox Sample Holde	N°	139	3,900.23 €	Per each 81 samples
protective suit	N°	4824	13,073.44 €	Per work session and personnel
Gloves	N°	9648	2,155.70 €	Per work session and personnel
Glasses	N°	33750	18.71 €	Per sample and personnel
Buffer	mL	900	14.34 €	Per Sample
Eppendorf carrossel	N°	11250	214.77 €	Per Sample
Lab Sample Holders	N°	11250	37.41 €	Per Sample
Microcentrifuge	N°	11250	315.23 €	Per Sample
Lab Coat	N°	33750	90.93 €	Per Sample and personnel
Parafilm	cm	7	0.06 €	Per work session
Total Phase Costs			51,930.93 €	

Signal Acquisition				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Sample Sheet Preparation				
Lab Technician	Minutes	4824	1,671.08 €	Per work session
Sample Sheet	N°	1608	56.81 €	Per work session
Markers	N°	11250	116.91 €	Per Sample
Water Signal Acquisition				
Lab Technician	Minutes	21563	7,469.47 €	Per Sample
Water	mL	16875	29.23 €	Per Sample
Biologist Specialist	Minutes	21563	9,336.84 €	Per Sample
Ibidis	N°	1608	7,427.03 €	Per work session
Sample Signal Acquisition				
Biologist Specialist	Minutes	27540	11,925.17 €	Per Sample
Lab Technician	Minutes	70078	24,275.77 €	Per Sample
Ibidis	N°	11250	51,961.52 €	Per Sample
Tip Cleaning				
Lye	mL	16875	9.06 €	Per Sample
Lab Technician	Minutes	12125	4,200.22 €	Per Sample
Biologist Specialist	Minutes	12125	5,250.28 €	Per Sample
Ibidis	N°	1608	7,427.03 €	Per Sample
General Costs				
H-P&A	N°	11250	33,331.27 €	Per Sample
Pipets	N°	11250	717.76 €	Per Sample
Pipets tips	N°	22500	1,603.23 €	Per Sample
Electricity	Min	162729	84.56 €	Per Sample
Falcon Tubes	N°	2	1.23 €	Per Sample
Computers	N°	11250	8,313.84 €	Per Sample
Total Phase Costs			175,208.33 €	

Setdown				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
Setdown				
Lab Technician	Minutes	540	187.06 €	Per work session
Napkins	N°	180	6.60 €	Per work session
Ethyl Alcohol	mL	900	45.99 €	Per work session
Paper roll	Meter	9	17.61 €	Per work session
Alcohol Splash	N°	120	0.08 €	Per sample
Biologist Specialist	Minutes	540	233.83 €	Per work session
Total Phase Costs			491.17 €	

AI Analysis				
Resources	**Cost Driver Unit**	**Quantity**	**Cost**	**Cost Hierarchy**
AI Analysis				
AI Team	Minutes	7200	3,117.69 €	Per sample
Results Report				
Consultive Member	Minutes	360	155.88 €	Per sample
Cloud Services	N°	10	346.41 €	Per sample
Total Costs			3,619.99 €	

TOTAL COST 7,948.31 €