

## PERFORMANCE MEASUREMENT IN A BRAZILIAN CLINICAL TRIALS UNIT

### MENSURAÇÃO DE DESEMPENHO EM UMA UNIDADE DE PESQUISA CLÍNICA BRASILEIRA

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#### **ABSTRACT**

**Background:** There is growing interest on costs of clinical trials; critical topic for business decision making; therefore, the aim of this work is to identify how a successful Brazilian case measures its economic performance even with restriction regarding its accounting data.

**Methods:** Single case qualitative method. Interviews with four people of different hierarchical levels and the analysis of the 2005 balance sheet, payrolls and payment slips were carried out.

**Results:** Besides indicating how the clinical research unit of the case measures its results, a diagram of how other units and organizations could follow such procedure to carry out their own performance measurement was pointed out as well.

**Conclusion:** The use of contribution margin and break-even point for the performance calculation benefited the managerial decision-making of the unit studied, serving as basis for its own strategy and use of its idleness. This is a reference model for decision-making of managers in other research units.

**Key words:** *Economic performance; Economic result; Non-Profit Activity*

#### **RESUMO**

**Background:** Há um interesse crescente sobre custos em ensaios clínicos; tópico crítico para a tomada de decisão empresarial, por isso o objetivo do presente trabalho é identificar como um caso de sucesso brasileiro mensura seu desempenho econômico mesmo com restrições nas suas informações contábeis.

**Métodos:** Método qualitativo de estudo de caso único. Realizou-se entrevistas com quatro indivíduos de diferentes níveis hierárquicos e análise de balancetes, folhas de pagamentos e notas de pagamento do ano de 2015.

**Resultados:** Além de apontar como a unidade de pesquisa clínica do caso mensura seu resultado foi apontado um diagrama de como outras unidades e organizações poderiam seguir tal procedimento para realizar uma mensuração de seu próprio desempenho.

**Conclusão:** A utilização de margem de contribuição e ponto de equilíbrio para cálculo do desempenho favoreceu a tomada de decisão gerencial da unidade estudada, servindo como base para estratégia da mesma e uso de sua ociosidade. Este é um modelo de referência para tomada de decisão de gestores em outras unidades de pesquisa.

**Palavras-chave:** Performance econômica; Resultado econômico; Atividade sem fins lucrativos.

### **BACKGROUND**

The costs of clinical trials worldwide presented growth and generated great concern in the last decade<sup>1</sup>, increasing the discussion and interest of studies on the subject<sup>2,3,4,5</sup>. Such costs used to involve the use of resources associated to the delivery of a very specific service<sup>6</sup> which makes its measurement difficult.

The suitable measurement of costs, return and, consequently, economic performance, is essential for any business<sup>7,8</sup>. As the organization reaches these results, the proportion of its success becomes clear<sup>9</sup>; therefore, it is expected that the intended volume of the right product for a certain existing need is placed in the market by a company<sup>10</sup> being financially viable<sup>11</sup>.

Identifying how much to produce, how much to charge or even whether a service may or may not be delivered, is key investment and coordination decisions for a company<sup>12</sup>. Being the Clinical Trials Units (CTU) specialized research entities which can help in the design and central coordination of studies<sup>13</sup>, it is understood that they also have to measure their performance in order to make the decisions described.

At the limit, what is always sought is the number of services to be delivered so that the CTU have a result that does not imply loss<sup>14</sup>. From this moment on, called break-even point, it is understood that there is good performance and positive results<sup>15,16</sup>.

Thus, the aim of this work is to understand how a clinical trials unit measures its performance in order to make managerial decisions, even having incomplete information on its costs. Generating a framework which may serve as a reference model for several other clinical trials units, as well as precedents for the improvement in performance assessment in other activities and non-profit organizations.

### **METHODS**

Questions such as “how” and “why” are more explanatory and are used to leading to the use of case studies, historical researches or experiments; nevertheless, case study is the preferred one in examining the contemporary events and when the researcher has little or no control over such events<sup>17</sup>. While lab experiments isolate the phenomena from their contexts, case studies emphasize the rich and actual context in which the phenomena take place<sup>18</sup>.

In fact, case studies can be used to carry out several objectives, such as: provide a description, test theory, or generate theory<sup>19</sup>. With this work, it was sought to not only describe the mechanisms by which the CTU measures its performance and makes its managerial decisions, but also to suggest a diagram of “boxes and arrows”<sup>18</sup> that can be used by other clinical trials units.

### **Collection Methods**

Since the data triangulation enabled by multiple collection methods provides stronger evidence of the constructs within the research, helping to deal with the problems of validity and reliability<sup>17</sup>, this study used three methods: in-depth interviews with the managers and financial officers, document analysis and observation.

The interviews were held from February to September/2017, with 4 people of different hierarchical levels of the organization: manager in charge of the CTU, coordinator of clinical studies, hospital financial officer where the CTU is linked to and the financial director of the foundation responsible for the CTU.

The documents analyzed were: 2015 balance consolidated by the foundation in charge of the CTU, 2015 balance and payrolls consolidated by the hospital referring to the CTU data, payment invoices regarding the protocols used in the case assessed.

The data used by the CTU, and consecutively in this research, refer to 2015, as it can be observed above. The need of complete data on the year led to the use of this year which was the most recent one and whose balance sheet was complete and closed. The study was not harmed, since there were no great changes in the values used, due to an internal policy of freezing the expenditure by the hospital.

Table 1 – Case Study Protocol

Question of the Study	How does a trials unit measure its performance in order to make managerial decisions?
Analysis Unit	Mechanism of performance measurement.
Time Limits	From February to September/2017.
Venue	Brazilian Clinical Trials Unit.
Construct Validity	Theoretical-practical contraposition, based on the theme state-of-the-art.

Internal Validity	Use of 3 evidence sources: interviews, observation and documents.
Study Fundamental Questions	<ul style="list-style-type: none"><li>- What does the CTU understand by performance?</li><li>- What data do they have for calculating performance?</li><li>- What do they do in order to ascertain whether this performance is being reached?</li><li>- How is this performance used in managerial decision-making?</li></ul>

### **Case description**

Linked to a public university hospital, the unit was founded in 2005 and it has a 30-people staff who is allocated in a facility containing file rooms, meeting and training rooms, dedicated and air-conditioned lab, pharmacy and nursing. The CTU works with the main pharmaceutical companies of the world.

When an agreement with a client is signed, a research protocol (each protocol regards a drug to be tested and it has the defined number of visits each trial attendee must carry out in the trials unit) begins. The number of exams per visit, the number of visits per attendee and the number of attendees in the protocol are defined by the agreement. The amount to be earned by the CTU per each visit carried out, based on the type and number of exams to be performed in the visit, is also defined in the agreement.

Two kinds of protocols can be performed: Academic, developed by research professors aiming to increase knowledge in a drug; and that of the pharmaceutical industry, aiming to launch a new product in the market. The company follows, and pays, each visit carried out by a research attendee. Thus, the control by the CTU for this kind of protocol is performed by visit. Academic protocols are paid by the total of exams carried out, leading to a control per number of exams. The managers used one protocol of each kind for calculating performance.

## RESULTS

### Measurement of the unit's fixed costs

Fixed costs are those necessary for the physical functioning of the organization. It is everything that does not change values in case of increase or decrease of production and sales volumes, which does not depend on the activity level<sup>20</sup>. As the production volume increases, the unit fixed costs decrease. The higher the number is, the greater the gains of economies of scale and the lower the unit fixed costs<sup>21</sup>.

It is easy to notice that regardless the existence of the CTU, the hospital costs, its sponsor, would still exist, and hence constitutes a sunk cost: *“Sunk cost is a cost that has already been incurred and cannot be avoided regardless of what a manager decides to do”*<sup>16</sup>.

Following the concept presented, it was ruled out the fact that costs would not be changed by the absence of CTU, therefore, just the costs associated with its existence, that is, the relevant cost for decision-making, were kept (table 2).

Table 2 – Fixed Costs relevant for decision-making

2015 Fixed Costs (in R\$)	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarte r	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter	TOTAL
<b>PAYROLL COSTS, CHARGES, BENEFITS</b>	360,907	380,272	384,236	387,304	1,512,718
<b>SERVICES/OVERHEADS/MAINTENANCE.</b>	22,859	31,386	87,646	46,824	188,714
<b>CONSUMPTION</b>	19,447	25,292	49,679	10,193	104,612
<b>OTHER COSTS</b>	23,707	8,519	12,466	5,176	49,868
<b>PERMANENT</b>	2,630	11,918	978	1,208	16,734
<b>TOTAL</b>	<b>429,549</b>	<b>457,387</b>	<b>535,005</b>	<b>450,704</b>	<b>1,872,645</b>

It is seen that the CTU existence resulted, in 2015, in a R\$ 1,872,645 incremental cost to the hospital. As comparative measure, it is noticed that such costs are below the average found in clinical trials units in the United Kingdom, which in 2014 was about £769,637<sup>5</sup>, equivalent to R\$ 3,185,527.54 according to the quotation value on December 31, 2014<sup>22</sup>.

### Revenues and contribution margin of the protocols

The manager of the trials unit, to measure its performance, selected an industry protocol regarded as recurrent profile as a basis. This protocol had its contract signed in 2014 and it terminated in 2017, with a 12-month active visit implementation period.

The protocol pointed a total of 13 visits carried out during its implementation, with administrative surcharge of 15% of the amount defined for the visit (table 6). At first, each visit included 10 attendees. During each visit, it is necessary that the attendee complies with the health restrictions the protocol requires for his/her continuity, therefore, 6 attendees reached the last level of visits. In all, 94 appointments were carried out, and on average, there were 7.23 volunteers per appointment.

Cross-checking the amount received per visit with their recurrence, a total income of R\$ 153,640.00 due to this protocol was ascertained. The amount was confirmed by cross-checking the data of invoices issued and the payments received in check account - stage carried out with the monitoring of the coordinator in charge of the protocol.

When the variable cost component of the analysis of a product or service is withdrawn, the Contribution Margin per Unit, difference between the sales price and the variable cost of each product, is obtained<sup>23</sup>.

Based on the amounts charged to the industry and the amounts of variable cost - stipulated via the price chart of the *Sistema Único de Saúde* (SUS) – it is verified that the protocol contribution margin is R\$124,380.53 (table 3).

Table 3 – Contribution Margin of the industry protocol

<b>Contribution Margin</b>	<b>Value (in R\$)</b>
Revenue (amount charged to the industry)	R\$ 153,640.00
Variable Cost ( SUS value)	(R\$ 29,259.49)
<b>Protocol Contribution Margin</b>	<b>R\$ 124,380.53</b>
Contribution Margin per Volunteer (7.23 volunteers)	R\$ 17,203.39
Contribution Margin per appointment (94 appointments)	R\$ 1,323.20

Then, a sample of the academic protocol, also pointed as of recurrent profile, was analyzed. The protocol had its contract signed in 2014 and it terminated in 2017, with a 12-month and 15-day active visit implementation period.

The protocol pointed a level of 4 visits carried out during its implementation. Each visit included 30 attendees, with no decrease during its implementation. In all, 120 appointments were performed.

With the calculation of the unit value of each exam cross-checked with the number of exams carried out in this protocol, it was possible to ascertain a total income of R\$129,577.00. The amount was confirmed by cross-checking the data present in the proofs of delivery of the promotion agency - stage performed with the monitoring of the trials unit manager.

For the academic protocol, based on the amounts charged for the exams carried out and the amounts of determined variable cost, the R\$ 103,091.73 contribution margin was pointed (table 4).

Table 4 – Contribution margin of the academic protocol

<b>Contribution margin</b>	<b>Amount (in R\$)</b>
Revenue (amount charged for the exams)	R\$ 129,576.50
Variable cost (SUS value)	(R\$ 26,484.80)
<b>Contribution margin</b>	<b>R\$ 103,091.73</b>
Contribution margin per volunteer (30 volunteers)	R\$ 3,436.39
Contribution margin per Appointment (120 appointments)	R\$ 859.10

### **Break-even point**

According to Garrison et al. (2012), the method of contribution margin has, as focus, the idea that each unit sold provides a certain volume of financial contribution margin to cover the fixed cost. To identify how many units must be sold in order to reach a break-even balance, the total fixed expenditures are divided by the contribution margin per unit, as demonstrated in the formula which follows:

$$\text{Break-even point in units sold} = \frac{\text{Fixed Expenditures}}{\text{Contribution margin per unit}}$$

Thus, it is possible to identify that the break-even point for the CTU assessed, when it performs its services to pharmaceutical industry, it is equivalent to 15 protocols or 1,415 appointments per year (Table 5). And if all the protocols implemented were academic ones, 18 protocols or 2,179 appointments would be necessary in a year (Table 6).

Table 5 – Break-even point of the industry protocol

Break-even point	
Yearly CTU fixed cost (R\$)	R\$ 1,872,645.00
Protocol contribution margin (R\$)	R\$ 124,380.53
Contribution margin per Volunteer (7.23 volunteers)	R\$ 17,203.39
Contribution margin per Appointment (94 appointments)	R\$ 1,323,20
<b>Protocol break-even point</b>	<b>15.06 protocols/year</b>
<b>Volunteer break-even point</b>	<b>108.85 volunteers/year</b>
<b>Appointment break-even point</b>	<b>1,415.24 appointments/year</b>

Table 6 – Break-even point of the Academic Protocol

Break-even point	
Yearly CTU fixed cost (R\$)	R\$ 1,872,645.00
Protocol contribution margin (R\$)	R\$ 103,091.73
Volunteer contribution margin (30 volunteers)	R\$ 3,436.39
Appointment contribution margin (120 appointments)	R\$ 859.10
<b>Protocol break-even point</b>	<b>18.16 protocols/year</b>
<b>Volunteer break-even point</b>	<b>544.95 volunteers/year</b>
<b>Appointment break-even point</b>	<b>2,179.78 appointments/year</b>

### Forecasts

With the information described, the CTU makes expenditure forecasts and capacities for its managerial decision-making in each yearly period.

Since it carried out 266 appointments for industry protocols in the first quarter of 2018 and 359 appointments for the academic ones (table 7), based on the calculations presented (tables 4 and 5), the CTU assumes that the contribution margin

for such period was R\$ 351,971.20 for the industry protocols and R\$ 308,416.90 for the academic ones. Amounts which were repeated during the other semesters of the year, as expected, summed up a R\$ 2,641,552.40 total contribution margin to cover fixed costs. Such amount is about 1 million reais above the fixed costs generated by itself, as identified in table 1.

Table 7 – Appointments carried out in 2018

Month	Industry Appointments	Academic Appointments	Total
January	76	98	174
February	104	131	235
March	86	130	216
<b>Total</b>	<b>266</b>	<b>359</b>	<b>625</b>

That is, operating under these circumstances, the unit has an expected forecast of 1,064 appointments for the industry and 1,436 academic appointments, totalling 2,500 appointments, value way above the break-even point. Thus, positioning itself as a surplus unit whose performance is positive.

Nevertheless, the inventory of the implementation capacity of the unit is 300 appointments a week. That is, 15,600/year or 1,300/month. Keeping the proportion of the contribution of the implemented industry and academic protocols, the CTU could generate a contribution margin of R\$ 16,483,584.00 a year (Table 8).

Table 8 – Maximum expected contribution for the CTU

Appointment capability	Contribution Margin
Industry Maximum Contribution Margin (6,640 appointments)	R\$ 8,786,048.00 /year
Academic Maximum Contribution (8,960 appointments)	R\$ 7,697,536.00 /year
<b>15,600 appointments generate yearly margin:</b>	<b>R\$ 16,483,584.00 /year</b>

With such information to hand, the unit manager traced expansion strategies to obtain greater results and seize its existing idle capacity.

## **DISCUSSION**

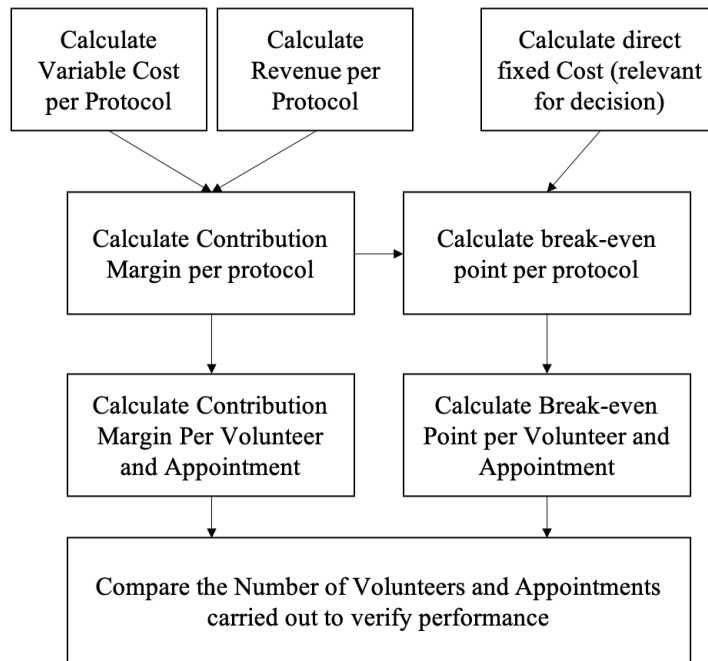
The results presented show that both protocols studied have contribution margin to cover similar fixed costs, composing about 80% of the revenues achieved by each one.

By the analysis of the break-even point, it is ascertained that the industry protocol has lower break-even point, presenting better performance than the academic one. Even with longer duration time, the result shows that the margin generated by the industry protocols are greater and ended up generating less need of year appointments so that the CTU reach positive results.

In any case, it is important to highlight that this comparison assumes that all the other academic and industry protocols carried out by the CTU will have the same contribution margin and implementation time that those used in the research. For a more consistent analysis, the managers should calculate an average contribution margin, statistically relevant, among different protocols.

Assuming that the continuity assures that the result is the best way to indicate an organization's performance<sup>11</sup>, even non-profit, this measurement way becomes a valid model for performance verification in the clinical trials unit studied.

This layout ensures that the organization which does not have all its accounting data organized and structured can, based on a sample of few protocols, understand its performance and economic result. It can be summarized by the following steps:



Picture 1. Steps to measure Performance via Break-even Point  
Source: created by the authors.

These steps evince the role of accounting in “providing economic, physical, productivity and social data relevant so that each user can make decisions and carry out their appropriate judgements safely”<sup>24</sup>.

Since planning is the process of deciding which course of action should be taken for the future<sup>24</sup>, it can be seen that the result assessment in a non-profit activity is a useful treatment for the suitability of its future activities and resource control, bringing important information for planning by the managers.

Since a non-profit organization must revert benefits to the society, the administration and the bodies involved may judge the efficiency before applying resources in the entity. In the study, it can be inferred that if the CTU operates with fewer active protocols than the break-even point, it would have low average performance. Nevertheless, since the operation has more protocols, the performance is considered positive.

It is also worth highlighting that a complete analysis of the economic result should compare these profits, calculated with the break-even point, to the opportunity cost of the capital invested in the CTU. Despite not being the aim of this study, its

importance in identifying whether the clinical trials unit is being feasible or another investment alternative would bring better return is elucidated by this paragraph.

### **CONCLUSION**

With the measurement presented, the manager ascertained, within the limitations regarding the number of protocols used as basis, whether the number of protocols in the implementation stage - and the number of appointments - is in accordance with the break-even point presented.

This datum is extremely important, since problems regarding the origin of accounting information limit the complete survey on the composition of costs of trials units. In fact, due to the limited information on costs, this CTU did not look into this information at all, incurring the “I think/ we think” and conflicting opinions among the agents involved in its management.

It can be said that this study pointed that the case selected measures the performance of the non-profit activity through its economic result, by means of the contribution margin and the use of break-even point. This form can be replicated to other non-profit activities, ensuring more faithful information for the managers on the possibility of long-term continuity of the organization, premise of any organization<sup>11</sup>.

Socially, this calculation brings the efficiency concept for the CTUs, referring to the benefits provided to the society, since their economic results evidence the ability of using scarce factors in order to generate products and services with higher economic value than the resources consumed, solving problems and meeting the needs which would not be met by isolated factors<sup>12</sup>, including the continuity of the generation of intangible benefits which were not the focus of this work.

It is necessary to reaffirm that the limitations present in the study point the need of subsequent researches. It is recommended to:

- Replicate the steps of the research to a multicase study with other clinical trials units;
- Carry out research including not only tangible financial benefits and results, but also intangible benefits derived from the institution activities.

## LIST OF ABBREVIATIONS

CTU: Clinical Trials Units

SUS: Sistema Único de Saúde, denomination of the public health system in Brazil inspired by the British National Health Service.

## DECLARATIONS

*Ethics approval and consent to participate:* Not applicable.

*Consent for publication:* Not applicable

*Availability of data and material:* Not applicable

*Competing interests:* The authors declare that they have no competing interests.

*Funding:* Not applicable

*Acknowledgements:* Not applicable

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