

Implementation of a strategic planning process oriented towards promoting business process management (BPM) at a clinical research centre (CRC)

707

Received 25 August 2016
Revised 12 January 2017
14 April 2017
9 July 2017
26 April 2018
Accepted 17 June 2018

Victor Cattani Rentes and Silvia Inês Dallavalle de Pádua

*Business Administration Department, School of Economics,
Business Administration and Accounting at Ribeirão Preto,
University of São Paulo, Ribeirão Preto, Brazil*

Eduardo Barbosa Coelho,

Monica Akissue de Camargo Teixeira Cintra and

Gabriela Gimenez Faustino Ilana

*Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto,
Brazil, and*

Henrique Rozenfeld

*Production Engineering Department,
São Carlos School of Engineering,*

University of São Paulo, São Carlos, Brazil

Abstract

Purpose – This work explores the potential benefits of aligning the strategic planning process with a BPM program in a clinical research center (CRC). The purpose of this paper is to define a process for executing strategic planning oriented towards the promotion of a BPM program.

Design/methodology/approach – The method applied is action research. This allowed the solution of a practical problem and at the same time the proposition of a new approach to promote BPM in alignment with strategy, which was synthesized in the model presented.

Findings – The analysis and structuring of the strategic planning process, with the assessment of the as-is situation, were adequate as a preparation step for the first cycle of a BPM program in the CRC. Based on lessons learned along the research project, a model was proposed for the strategic planning process oriented towards promoting BPM.

Research limitations/implications – The model was conceived from a single application at a CRC, through a cycle of action research. This is one of the limitations of this work. The model was not yet sufficiently tested in other contexts. This represents opportunities for future research.

Practical implications – The evaluation step in the action research cycle revealed that the organization in focus was satisfied with the results. New management practices in the organizations in focus were implemented as a result of this work.

Originality/value – Process improvement initiatives are a novelty in the CRC context, and this work may serve as a reference for CRC managers seeking to improve overall performance. The proposed model in this work indicates that a BPM program should start with strategic planning. An initial assessment of the as-is situation of the organization in focus was performed based on the analysis of the undesirable effects in the organization's management practices, using a technique of the Theory of Constraints. The use of this technique facilitated the identification of solutions to the root causes identified in the assessment. The level of the assessment was deeper in comparison to results obtained with traditional tools used in strategic



The authors would like to thank CNPq for their financial support. The authors are also indebted to all participants of the organization in focus, for their ample contribution to this action research project.

planning processes. The assessment supports the definition of actions oriented to solving the majority of the management dysfunctions of the organization in focus.

Keywords Strategic alignment, Strategic planning, Action research, Business process management, Clinical research center, Clinical trials management

Paper type Case study

1. Introduction

Business process management (BPM) has increased performance for companies of all sizes and industries. BPM programs aim to shift the management orientation of the firm from a functional perspective to a process perspective. Gębczyńska (2016) highlights that process-oriented firms outperform functional-oriented ones, since the latter, among other factors, respond to changing market requirements more rapidly. According to Harmon (2007), BPM programs provide a systematic way for companies to achieve strategic goals.

BPM is a novelty in the context of clinical research and clinical trials processes. These processes are normally carried out in Clinical Research Centers (CRCs) to guarantee safety and efficacy for new medications under development by biopharmaceutical firms, before market introduction. BPM has significant potential to enhance performance for research centers involved in clinical trials. According to Eisenstein *et al.* (2008), management practices at CRCs are important factors in the development process of medication or medical equipment. Management dysfunctions at CRCs influence the costs of executing clinical trials, and therefore influence the overall costs of the development of new medication or medical equipment (Eisenstein *et al.*, 2008). According to Daudelin *et al.* (2015), clinical research's particular complexity inevitably results in high costs and delays, and these may ultimately incur in substantial financial and human costs, as the introduction of successful drugs to patients and the public are hindered.

The benefits of BPM are well documented and recognized by companies in other industries, but several factors are known to hamper its potential, and the rate of failure for BPM programs is still reportedly high (Trkman, 2010). Minonne and Turner (2012) studied companies promoting BPM in German speaking countries in Europe, gathering data regarding several BPM practices, and concluded that one of the most significant challenges for BPM promotion is properly aligning it with organizational strategy. Several authors agree that one of the main reasons for failure in BPM promotion is the lack of alignment with company strategy (Lederer *et al.*, 2017; Trkman *et al.*, 2015; Morais *et al.*, 2014; Niehaves *et al.*, 2013; Minonne and Turner, 2012; Trkman, 2010; Harmon, 2007). Albeit identified in the literature as a critical success factor for BPM programs, alignment with strategic planning is scarcely detailed in a step-by-step process through real case applications.

This research explores tools for achieving alignment between strategic planning and BPM in a CRC context. It highlights the benefits from this alignment for a subsequent BPM program. The objective of the research is to define a process for executing strategic planning oriented towards the promotion of a BPM program in a CRC. The organization in focus is a CRC located in one of the most prestigious University Hospitals in Brazil. The center develops academic clinical research for the Hospital, as well as clinical research sponsored by multinational pharmaceutical companies for the development of new drugs in various medical specialties. Action research is the method applied, as it enables the design of new solutions and approaches for performance enhancement of the organization in focus, while permitting simultaneous generation and synthesis of scientific knowledge.

The paper is structured as follows: the next section presents the literature review on BPM, relationship between strategic planning and BPM, assessment tools that support strategic planning, and clinical trials management. The research methodology is then discussed in Section 3, and the results presented in Section 4. After that, in Section 5, a model

for strategic planning oriented towards BPM promotion in CRCs is proposed, and the final remarks are made in Section 6, including the main contributions, the work's limitations and suggestions for future research.

2. Literature review

The literature review covers the relevant topics for this work. BPM is first presented, including a brief analysis of life cycle models. Secondly, the literature on strategic planning and BPM is discussed. Third, contributions from the literature on clinical trials management are shown to adequately understand the specific context in which the action research project is applied.

2.1 Business process management (BPM)

BPM is defined as a management discipline that integrates strategy and objectives of an organization, by focusing on end-to-end processes. It encompasses strategy, objectives, culture, organizational structures, roles, policies, methods and technology in order to analyze, design, implement, manage, transform and establish governance over processes (Association of Business Process Management Professionals (ABPMP), 2013). BPM is an alternative to the traditional functional management approach. The traditional functional approach, predominant in the last century, favors the formation of "islands" in the organization: information tends to be compartmentalized; difficulties arise in the integration and communication between the different departments, which ultimately results in inefficient management of the organization and poor overall performance (Paim *et al.*, 2008).

Morais *et al.* (2014) argue that BPM programs should have well-defined steps, which are translated into a life cycle model that is aligned with strategic objectives. Additionally, according to Rosemann and Bruin (2005), all methods for BPM promotion are based on the process architecture, which captures the relationships between key business processes and support processes and the alignment with strategy, goals and organization policies (Rosemann and Bruin, 2005).

There are several models for BPM life cycles found in the literature, and the variation between them, regarding the steps to be taken in the cycle, are minimal (Houy *et al.* 2010). The BPM life cycle proposed by the ABPMP (2013) establishes the comprised steps in a BPM cycle: planning, analysis, design and modeling, implementation, monitoring and control, and refining. Morais *et al.* (2014) reviewed the literature on BPM life cycles, comparing different models, and observed that in the ABPMP model as well as the models studied, there is little emphasis on organization strategy and the comprehension of the relationships between business processes through process architecture. Morais *et al.* (2014) proposed a framework that explicitly encompasses the alignment between strategy and business processes, with the following activities:

- validate the organization's strategic direction;
- identify the relationships among stakeholders;
- consolidate strategic criteria;
- establish business process architecture;
- identify performance measures;
- align process governance;
- establish process priorities;
- align capacities/resources for processes; and
- define the organizational transformation portfolio.

Based on their review, Morais *et al.* (2014) proposed a framework that integrates strategic planning with BPM life cycle. The framework is presented in Figure 1.

Strategic planning is not part of the BPM life cycle, and it must not be carried as frequently as each new cycle. However, alignment between strategy and process improvement initiatives is key to success. According to Morais *et al.* (2014), there is a low presence of activities associated with strategy in the BPM literature, and this suggests demand for propositions on how to handle strategy in BPM. The life cycles reviewed by Morais *et al.* (2014) do not include strategy formulation in their steps, nor do they define specific activities commonly used in strategic planning processes. Instead, they assume strategy is already available before the BPM cycles, which start in the validation of strategy, not with strategy formulation.

There is a vast collection of BPM cases described in the literature. Many cases are in healthcare settings, and these present relevant contributions to this work. The research by Leu and Huang (2011) and Yarmohammadian *et al.* (2014) are briefly discussed here. The work by Griffith and White (2005) will be analyzed in the next part of the literature review, which covers relationship between strategic planning and BPM.

Leu and Huang (2011) present a BPM implementation case in a mid-size hospital in Taiwan, with 300 clinical beds. Leu and Huang (2011) optimized the clinical process of the hospital's emergency department. The implementation of the case is described in their work. Clinical data for 16 months were collected, which were then used to study the performance and feasibility of their method. Figure 2 illustrates the initial framework for the project.

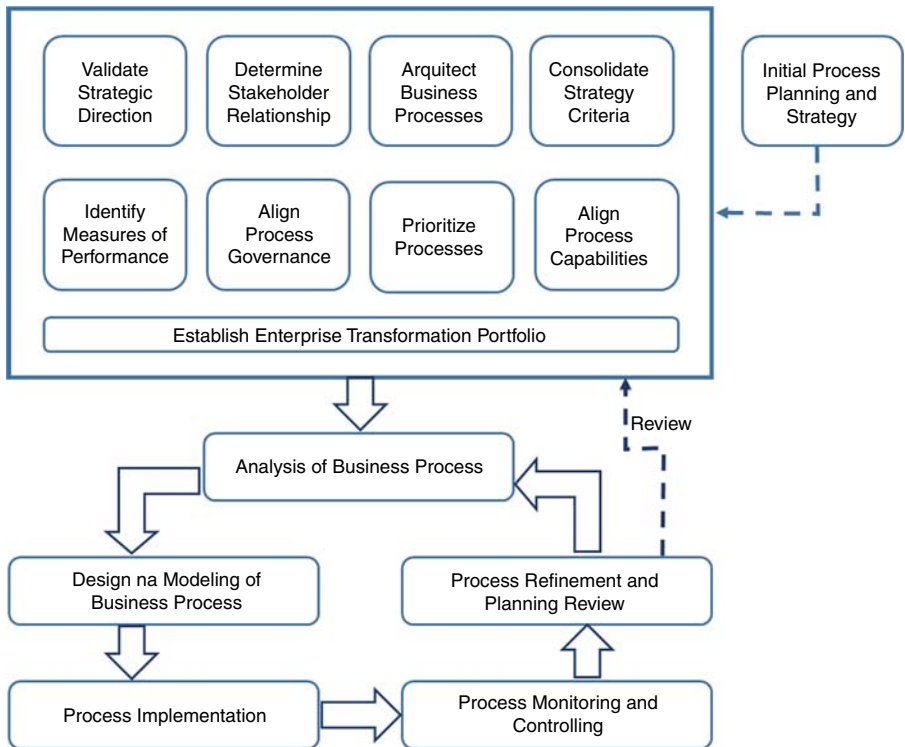
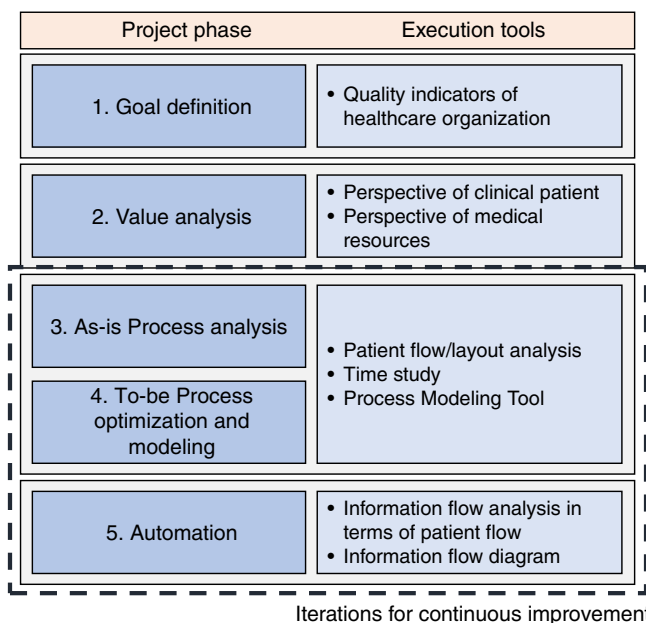


Figure 1.
BPM framework

Source: Morais *et al.* (2014, p. 427)



Source: Adapted from: Leu and Huang (2011, p. 412)

Figure 2.
Framework for implementation of BPM in a hospital

The framework includes goal definition, value analysis, as-is process analysis, to-be process modeling and computerization. In the first phase of their study, the goal as well as the implementation boundary in the hospital was defined. For this purpose, quality indicators of the healthcare organizations were designed as performance indicators. In the second phase, the core value of the hospital was defined, considering the clinical patient service and medical resource deployment. This indicates some alignment with strategic planning, without depth. In the as-is process analysis phase, the on-going processes in the hospital were summarized, after which the patient flow was analyzed in terms of service time and facility layout. The methods of time study and layout analysis were applied during this phase. At the same time, the gap of IT application was assessed in terms of patient flow. In the to-be process-modeling phase, the clinical processes were re-designed and workflows were modeled using extended event-driven process chain diagram. Finally, the re-engineered clinical processes were computerized. The data collected at the end of the project evidenced positive results on some of the performance measures, such as bed occupancy rate and nursing hours. However, indicators of medical quality did not improve significantly, and the authors point to two reasons for this. First, the process improvements were carried in the emergency department only, not the whole hospital. According to Leu and Huang (2011), performance in medical quality in this project depended on other departments, and local process optimization (undertaken in the emergency unit alone) restricted performance improvements in this case. These results hint to a lack of alignment between the isolated BPM initiative performed in the emergency department and the hospital's strategic goals. The second reason pointed by the authors are the fact that process improvements changed the original operations of the emergency department in the hospital, and time is needed for the organization to adapt to these changes (Leu and Huang, 2011). This rationale highlights that BPM needs to be an on-going transformation process, and not a one-time project.

Yarmohammadian *et al.* (2014) applied BPM techniques in a teaching hospital. They defined the criteria used to select the processes they would work on: “direct contact with customer, repeatability, time, distance, complexity, related units, dissatisfaction, and potential to improve.” They then listed the following processes in the hospital (to be pondered using the before mentioned criteria): “Dismissing, Admission, Drug and supply recording in hospital information system, Transfer patients from emergency unit to other departments, Prescriptions recording, Transfer patients from recovery to wards, Social worker, Admission patient in radiotherapy department, Official correspondence, and Preparation of synthetic drugs.” Five processes were selected to be improved (those that scored the highest using the selection criteria). The improvement action plans followed pre-determined steps, which contained well-known process improvement techniques. The results of the action plans for each process considered in the project were presented in the organization at the end, but the authors do not mention the sustainability of the BPM project inside the hospital. Additionally, there is no mention of the hospital’s strategic goals; no link between strategic goals and the criteria and processes selected; and no indication of how the process improvements would help reach strategic goals.

These examples illustrate the potential benefits of process improvement initiatives in healthcare settings. However, these case studies do not portray how strategic planning and BPM should align. The following section explores the connection between strategic planning and BPM. It presents relevant frameworks and concepts, as well as a case study that examines the relationship between strategy and BPM. These topics serve as a reference for the action research project, and posterior proposal of an integrated model of strategic planning for BPM.

2.2 Strategic planning and BPM

The literature on strategy formulation and implementation is vast. There are several different approaches to the subject. Porter (1996) defines strategy as the creation of differentiated positioning, which requires execution of a unique set of activities by the company. Magretta (2002) distinguishes strategy from business models. Essentially, a business model defines whom the clients are and how the company intends to profit by delivering a value proposition. Strategy is about how to beat the competition by being different (Magretta, 2002). According to Gębczyńska (2016) “strategy is a specific action model which defines objectives, tasks and performance standards applicable to structures, processes and behaviours.” The effectiveness of strategy implementation depends on the ability of top management to decompose it to lower managerial levels: strategy must inherently match individual and lower levels of management (Gębczyńska, 2016).

Porter (1996) states that effective strategic positioning brings sustainable competitive advantages for the firm and it come from three distinct sources:

- (1) when the company meets a few requirements of many customers;
- (2) when the company meets many requirements of a few customers; and
- (3) when the company meets many requirements of many customers in a limited market.

According to Porter (1996), strategic positioning implies that the company should execute different activities from its competitors, or similar activities, but executed in different ways. According to the resource-based view (RBV) of the firm, the valuable strategic resources of the company determine its performance in competitive and dynamic environments (Collis and Montgomery, 2008). The RBV combines internal analysis of phenomena occurring inside the company with external analysis of the industry and the competitive environment (Collis and Montgomery, 2008). This approach views the organization as different combinations of assets and capabilities, either tangible or intangible (efficient processes, for example), and these assets and capabilities are frequently inter-departmental and supra

divisional (Collis and Montgomery, 2008). This argument is implicitly consistent with BPM, as it emphasizes integration and communication between different departments. The authors, however, do not explicitly connect RBV to BPM.

Armistead *et al.* (1999) highlight the difference between strategy and the process of strategic planning: the first representing the “what” of strategy, as described by Porter (1996), and the second representing the “how” to obtain it. Kaplan and Norton (2008) propose a cycle for strategy formulation, linking it to process improvements. The cycle is presented in Figure 3. Strategic planning should be initiated by certain activities, such as the definition of mission, vision, and values of the company, strategic analysis and strategy formulation. These activities direct the rest of the cycle.

During step 3 of the cycle, key processes are improved. However, Kaplan and Norton (2008) do not detail how to organize the process improvement initiative, as do many other authors in the BPM literature. For more details on each phase of the cycle, see Kaplan and Norton (2008).

Many researchers characterize the alignment between strategic objectives and the goal of the BPM efforts as an essential element for the success of BPM projects. Niehaves *et al.* (2013) argue that the constant alignment between the external environment and BPM programs is essential for its success, but do not detail how to guarantee this alignment. Trkman *et al.* (2015) emphasizes the relation between BPM and strategy, stating that BPM is an important element in strategy execution. Thus, BPM and strategy must be linked for high performance in the long term (Trkman *et al.*, 2015; Harmon, 2007). According to Armistead *et al.* (1999), when organizations promote BPM at a strategic level, they need to examine their form and structure to achieve higher performance.

Bandara *et al.* (2009) indicate factors to be considered in the alignment between strategic planning and BPM:

- assessment of corporate goals, objectives and key performance indicators (KPIs) should be outlined;

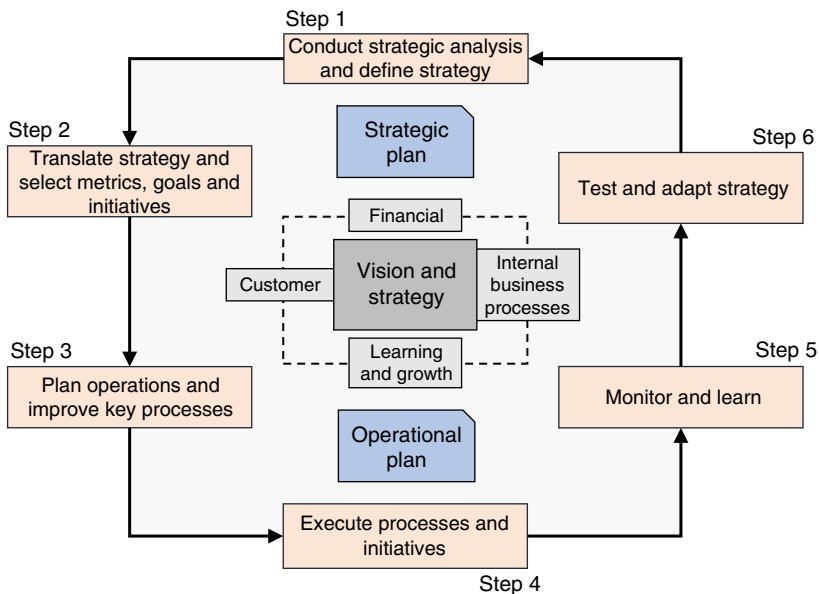


Figure 3. Balanced scorecard

Source: Adapted from Kaplan and Norton (2008, p. 3)

- BPM initiative objectives should be selected based on organizational strategic objectives;
- a manageable set of appropriate process measures from strategy should be derived;
- the outcome and milestones of the project should be evaluated against strategic objectives;
- in the formulation of strategy, the process capabilities should be considered;
- understanding organization's process capability should contribute to strategic goals and objectives;
- major corporate processes that support the business objectives and goals should be identified;
- stakeholders' requirements should be considered in the prioritization of the processes; and
- strategic objectives should be considered in prioritization of process improvement initiatives.

Kachaner *et al.* (2016) claim that many companies do not have an effective strategic planning process, which ultimately results in poor strategy and poor overall performance. CRCs are not exempt from this critique. Lederer *et al.* (2017) affirm that a key objective of strategic management is ensuring the implementation of strategies in the day-to-day operational business processes of enterprises. However, strategies are often neither documented nor directly linked to business processes, and mid-term targets to be reached are therefore sometimes not available (Lederer *et al.*, 2017). These arguments suggest that strategy and BPM should be closely aligned in implementation projects, but they do not detail methods and tools to be used for this end.

Harmon (2007) illustrates, in Figure 4, one way of thinking about the relationship between the work of a process group and a strategy group within the organization. The on-going work of the strategy group is described in the upper box. The strategy group may spend a significant portion of their time considering what the competition is doing or how customer tastes are changing, but, ultimately, to determine if the current strategy is working, they need performance measures. Specifically, they need to know which activities

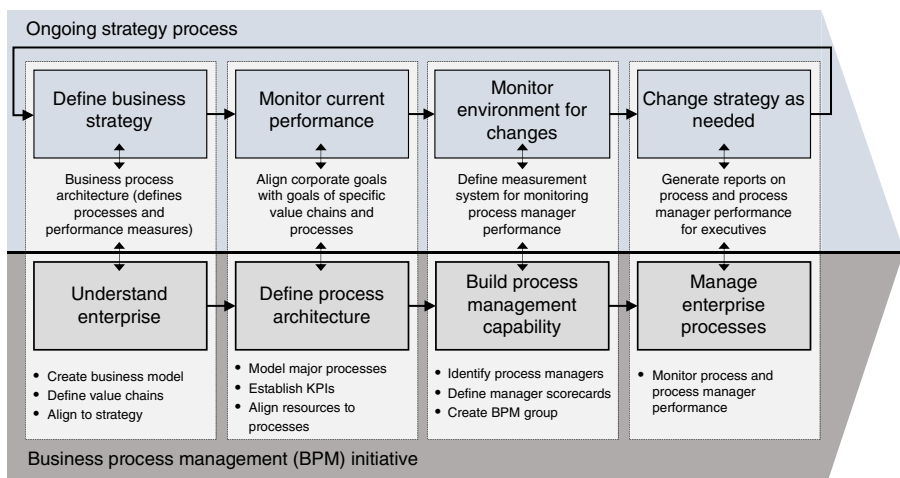


Figure 4.
Relationship between
strategy group and
process group inside
an organization

Source: Adapted from: Harmon (2007, p. 63)

are generating what type of results. The strategy group needs the process group to generate a constant flow of data. Data, however, should not originate from functional units, but from processes, from the way processes interact with each other, from the way processes performance is measured, and from a comprehensive understanding of how processes interface with customers (Harmon, 2007).

As stated by Hernaus *et al.* (2016), BPM programs should “support the goal of the business by strategically aligning process-related activities, providing operational discipline and achieving employees’ buy-in.” BPM projects and initiatives should preferably be initiated by top management in the organization. C-level managers have to consider the strategic implications of process-based activities and make important decisions about: process-driven goals, resource allocation, authority and responsibility levels, KPIs and process infrastructure (Hernaus *et al.*, 2016). This argument relates to the proposal of Harmon (2007), emphasizing the importance of the relationship between the work of those responsible for strategy and those responsible for operations management.

Adamides (2015) investigated the integration of operations strategies and corporate strategy, arguing that this integration is facilitated by the incorporation of operations strategy formation practices/routines in the corporate strategy-making practice. In other words, “operations strategies (content) can be aligned with the competitive ones easier if their formulation practices (routines) are associated/integrated with the practices (routines) of competitive strategy making (process-based integration)” (Adamides, 2015). This argument reinforces one of the factors presented by Bandara *et al.* (2009), specifically the one that states that formulation of the strategy should consider the process capabilities. According to Lederer *et al.* (2017), several stages in the business process life cycle are not aligned to strategy. Strategies are not systematically considered in optimization initiatives, and process models and resources are oftentimes not designed and planned to support strategies. Moreover, middle managers need methods to communicate and convince team members to act in a strategic manner, thus specific tools are necessary to support them (Lederer *et al.*, 2017).

Kachaner *et al.* (2016) differentiate time horizons on which strategic planning and its implementation are carried in successful firms. Strategic planning and implementation should be conducted on three different time horizons: in the long-term time horizon, the purpose of strategic planning should be to define, validate, or redefine mission, vision and values of the firm. It should contemplate the next five years or more; in the medium term, the purpose should be to identify the steps needed to reach the company’s vision of itself, typically within the next 3–5 years. Focus should be on the definition of clear action plans that describe the strategic initiatives needed; in the short term, the purpose is to explore options for strategy execution and its acceleration. Progress must be evaluated, and people should be stimulated for creativity and dialogue (Kachaner *et al.*, 2016).

Griffith and White (2005) examined documented cases of hospitals that won the Baldrige National Quality Award in Healthcare[1] at the time of their research, and present the case of St Luke’s Hospital (SLH), where the management system aligns strategic planning with process improvement initiatives. The Baldrige criterion, in general, covers a broad range of businesses and strategies, and are organized into seven sections: leadership, strategy, patient relations, worker relations, information management, operations, and results. Figure 5 represents SLH’s strategic planning process, as presented by Griffith and White (2005).

According to Griffith and White (2005), SLH’s strategic process integrates strategic goals with process improvements. As shown in Figure 5, the strategic planning process is based on three dimensions:

- (1) from strategic (level 1) concerns through several levels of accountability (levels II–IV);
- (2) from long-term to short-term (90 day) action plans; and
- (3) from strategic goals to process improvement to individual development plans.

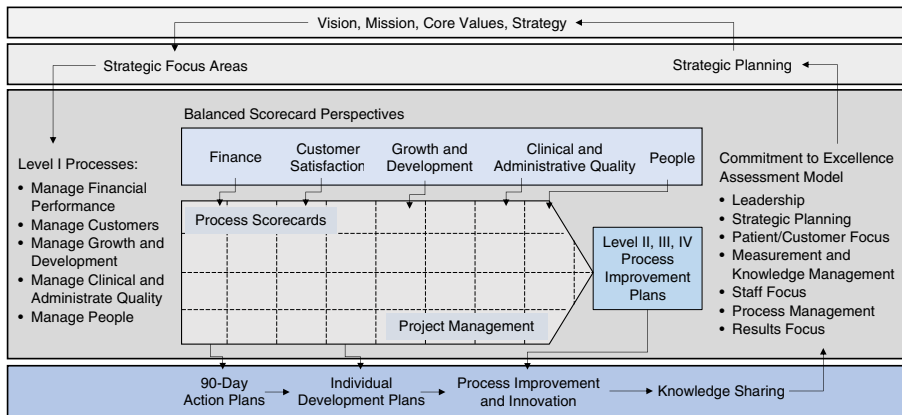


Figure 5.
St Luke's Hospital's
strategic process

Source: Adapted from Griffith and White (2005, p. 176)

At SLH's strategic planning process, measures, goals, and process improvement plans are articulated at each step of each dimension, and strategy roll-out is improved by feedback from each of the three dimensions (Griffith and White, 2005). In regards to process improvements, the Baldrige Award considers organizations to be a set of work processes (Griffith and White, 2005), and in that sense, it is congruent with the BPM approach. As argued by Griffith and White (2005), in order to be awarded the Baldrige Award, each process in the organization should be described and monitored by performance measures that usually cover: availability, cost, quality, customer satisfaction and worker satisfaction. The benchmarks, goals, and stakeholder opinions from the strategic planning criterion should be used to identify opportunities for improvement (Griffith and White, 2005).

In conclusion, many researchers point to the importance of alignment between strategic planning and process improvement initiatives such as BPM. There is an in-depth conceptual investigation into the matter, with valid points made. However, many publications present, to some extent, general theories, and do not contribute to managers in CRCs, and other contexts, on the specific steps to be undertaken for the proper alignment between strategy and BPM promotion. The system presented by Griffith and White (2005) is embracing on the matter, but it lacks a detailed strategic process (containing specific activities) for the identification of priorities (or strategic focus areas, as shown in Figure 5) for level I process perspective and balanced scorecard perspective. The use of specific tools that enable managers to identify strategic priorities and goals for their organization is not present in the literature.

Therefore, action research projects that describe implementation steps for aligning BPM with strategy may contribute to existing literature by identifying effective practices and success factors for achieving such alignment. The description of tools applied and methods used yield interesting considerations to be made for implementation projects, thus advancing scientific knowledge on how to obtain alignment between strategy and BPM. Such projects may also assist managers in their deployment efforts by serving as a reference to be emulated and improved upon. The present study describes a practical application of strategic planning aligned with BPM in a Clinical Research Center (CRC) where clinical trials processes may be significantly optimized through BPM.

The following section in this work shows assessment tools that may be contemplated in a strategic planning process oriented towards BPM. The tools are helpful for in-depth

analysis and for identification of strategic opportunities for improvement in the organization, including the designation of the crucial processes that need to be changed or improved in a BPM program.

2.3 Strategic assessment tools

There are many well-known tools commonly applied in strategic planning processes, such as:

- strengths, weaknesses, opportunities, and threats (SWOT) analysis;
- Porter's five forces analysis;
- business model analysis using Business Model Canvas; and
- current reality tree (CRT), of the Theory of Constraints;

The application of each one of these tools is complimentary and may contribute to the consensual definition of the strategic priorities of the organization. The SWOT analysis is widely used by companies of all sizes and industries. SWOT represents strengths, weaknesses, opportunities, and threats. The first two dimensions, strengths and weaknesses, characterize the firm from within. The objective is to identify the company's strengths to better exploit them, and identify its weaknesses to define improvement initiatives that could mitigate or eliminate them. The latter two, Opportunities and Threats, characterize the external elements present in the environment in which the company operates. Opportunities (sometimes overlooked) should be exploited to the maximum, while threats should be protected against.

Lambin and Schuiling (2012) characterizes it as a multifactorial analysis, purely qualitative and not based on objective measures, and argues that the SWOT analysis gives a sense of the market attractiveness (external factors) in relation to the competitiveness of the firm (internal factors). The SWOT analysis indicates a strategic direction for the firm, and contributes to the development of the strategic planning, as managers use it to evaluate the relationship between the organizational characteristics and the environmental conditions of the market.

Porter (1979) introduced the concept of analyzing an industry by describing the five forces that shape competition. In particular industries, the forces may be stronger, which make the sector more competitive and reduces profit for the companies operating in it. When forces are weaker, companies are usually more profitable (Porter, 1979). The five forces are:

- (1) bargaining power of suppliers;
- (2) threats from new entrants;
- (3) threats from substitute products or services;
- (4) bargaining power of customers; and
- (5) competition between existing competitors.

The comprehension of the industry structure is essential for effective strategic positioning. It is one of the first steps for strategy development. The forces reveal the most significant aspects of the competitive environment. It is crucial for their performance that companies defend themselves against competitive forces in their industries (Porter, 1979).

Zott *et al.* (2011) argue that the business model concept is multifaceted. They conclude that: the business model is emerging as a new unit of analysis in the literature; business models emphasize a system-level, holistic approach to explaining how firms "do business"; firm activities play an important role in the various conceptualizations of business models that have been proposed; and business models seek to explain how value is created, not just how it is captured (Zott *et al.*, 2011). Osterwelder and Pigneur (2010) introduced the

Business Model Canvas, which is used to understand the business model by describing the logic of how the organization creates, delivers and captures value. The model is composed of nine “building blocks” that represent the organization. The business model is a “blueprint” for the implementation of strategy (Osterwelder and Pigneur, 2010). The Canvas can be used to identify opportunities for improvements to the organization, including the identification of the value proposition delivered to each stakeholder, and it complements the tools presented previously.

The CRT of the Theory of Constraints is yet another effective strategic tool, but less known than the previous tools presented. Hence, the CRT is better described in the following section.

2.4 Current reality tree (CRT), of the Theory of Constraints (TOC)

According to Rahman (2002), managers may use the Theory of Constraints tools to develop growth strategies for their organizations. The CRT is a logical structure that can be built to describe the current reality of any given system to be analyzed. It is one of the tools of this theory, developed by E. Goldratt. The Theory of Constraints is based on a logical “Thinking Process” composed by tools, which support the representation of current and future realities of an organization or business process. It contributes to the definition of strategic goals and to the identification of appropriate projects and solutions to achieve those goals (Scoggin *et al.*, 2003).

The CRT can help identify complex relationships between organizational problems or dysfunctions (called undesirable effects (UEs)) and their root causes, and it may be used as a first step in the TOC Thinking Process in order to obtain desirable changes in complex systems (Dettmer, 1997, p. 66).

The TOC tools aim to answer the following basic questions (Rahman, 2002):

- What to change?
- Change it to what?
- How to promote this change?

The CRT aims specifically at answering the question “what to change?” It allows managers to identify the root causes of the perceived problems of their organizations. The CRT starts with the identification of the relationships between probable causes and perceived UEs in the organization, forming a base for the comprehension of complex systems. Figure 6 represents the structure of a CRT, as illustrated by Pádua *et al.* (2014).

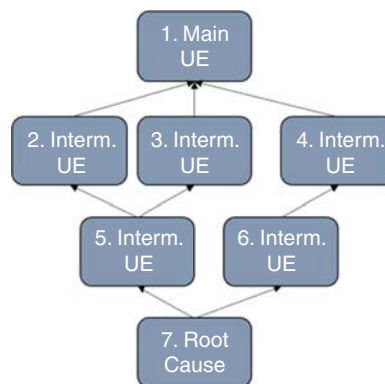


Figure 6.
Example of a Current
reality tree (CRT)

Source: Pádua *et al.* (2014, p. 252)

The CRT aims to reach the following objectives (Dettmer, 1997, p. 64):

- identify evident UEs in a system;
- establish relationships between UEs by cause-effect logic until a root cause is detected;
- identify, whenever possible, a core problem that represents 70% or more of the UEs in the system;
- determine when root causes and core problems are outside the sphere of influence of managers;
- isolate the restrictions that must be addressed for performance enhancement of the system; and
- identify the changes that will most positively impact the whole system.

Gupta *et al.* (2004) argue that the CRT and other tools of the “Thinking Process” of the Theory of Constraints may be useful in strategic planning. The CRT is an ideal tool for developing consensual mental models of the organization or process being analyzed. If adequately used, all members participating in the development and validation of the CRT understand the system, and are likely to commit to achieving the desired results (Gupta *et al.*, 2004).

The next section contextualizes the clinical trials industry, and the environment in which the organization in focus for this study operates. This contextualization, coupled with the comprehension of the tools previously described, further prepared the authors for the action research project to take place.

2.5 Clinical trials management

The National Institutes of Health, in the USA, defines clinical research as any research that directly involves a person, or group of persons, or research that utilizes materials from humans, such as behaviors or tissue samples (National Institutes of Health, US Department of Health and Human Services, Health Information, 2015). A clinical trial is a specific type of clinical research that follows a pre-defined plan or protocol (NIH, 2015). Clinical trials are conducted in phases, usually three or four phases per study. Each phase of the trials tests safety and efficacy of the study medication on a progressively targeted population, and the biopharmaceutical firm must seek final approval from agencies such as the Food and Drug Administration (FDA), before introducing the product in the market (Huckman and Zinner, 2008). Figure 7, by Huckman and Zinner (2008), presents a schematic of the main activities in clinical trials, comparing them with activities in traditional patient care. BPM programs promoted at CRCs should contemplate improvements in the processes involved in these (and other) steps.

Glickman *et al.* (2009) highlight the recent process of globalization of clinical trials, and argue that there are, among others, two relevant factors in this process: the costs for conducting procedures of protocols of the pharmaceutical companies and of academia are significantly lower in developing countries than the ones in developed countries; and protocols are becoming more complex over time, and that demands a greater number of patients in each study, in order to obtain statistically reliable conclusions for each protocol. This demands a geographical expansion of the conduction of the studies.

Even though there are significant similarities across sites worldwide, with respect to the terms and requirements of any given trial, their organizational structure differs significantly (Huckman and Zinner, 2008). Each trial is overseen by a detailed study protocol, which is developed by the sponsoring firm, sometimes in partnership with outside physicians. The protocol stipulates patient eligibility for the trial through specific inclusion criteria, as well as the clinical procedures and tests that must be performed, including the data that must be gathered (Huckman and Zinner, 2008). The protocol contains the specifications of the product, which are identical across all research sites participating in a given trial around the world.

	Traditional Patient Care	Clinical Trials
Preparation		<ul style="list-style-type: none"> • Seek or Respond to New Project • Review Protocol-Discuss w/ Staff • Investigators' Meeting • IRB Review Approval • Sponsor's Site Qualification Visit • Subject Recruitment
Evaluation	<ul style="list-style-type: none"> • Patient Scheduling • Patient Evaluation 	<ul style="list-style-type: none"> • Subject Scheduling • Subject Screening
Treatment	<ul style="list-style-type: none"> • Follow-up Visits • Insurance, Billing • Testing and Re-Evaluation 	<ul style="list-style-type: none"> • Visit 1 • Visit 2 • ... • Visit N • Case Report Forms • Laboratory Shipments • Data Queries • Sponsor Payment

Not shown: sponsor visits, ongoing sponsor contact, protocol amendments

Source: Adapted from Huckman and Zinner (2008, p. 176)

Figure 7.
Typical activities
involved in patient
care and clinical trials

Each site, however, is responsible for making its own operational and management decisions concerning aspects such as finding potential study subjects, allocation of activities (i.e. between investigator, study coordinator, and other administrative or clinical employees), and operational performance (i.e. enrolling and processing subjects) (Huckman and Zinner, 2008). This implies that each center is responsible for optimizing its operations, namely identifying areas where costs can be reduced without compromising scientific validity.

According to Daudelin *et al.* (2015), there is a growing consideration that process improvement initiatives hold promise for enhancing quality and efficiency in clinical and translational research. Efforts are in progress to promote high quality and efficient clinical trials, yet the systematic application of evidence-informed improvement methods to clinical and translational research has been restricted, at least in the published scientific literature (Daudelin *et al.*, 2015). Eisenstein *et al.* (2008) highlight the need for better alignment between the operational processes involved in clinical trials and the achievement of its scientific objectives, emphasizing the value of improvement initiatives for the common practices employed in the conduct of large-scale clinical trials. This suggests a promising opportunity for the use of BPM in CRCs.

Schweikhart and Dembe (2009) describe a few applications of Lean-Six Sigma techniques at clinical and translational research sites, and conclude that because traditional research practices at CRCs often suffer from poor coordination, inefficient use of resources, and burdensome administrative requirements, there is considerable potential for process improvement initiatives. Schweikhart and Dembe (2009), however, observe that mere application of Lean Six Sigma or other techniques for process improvements, are generally not, in themselves, sufficient to ensure a successful process improvement project. Achieving better efficiency and process flow also requires other factors, such as a receptive organizational climate, active management support and engagement, sufficient financial and other resources, and clear communications channels within the organization about the need for change (Schweikhart and Dembe, 2009). This reiterates the importance of factors such as alignment between strategic planning and BPM. The action research described in the next sections demonstrates this important aspect of BPM promotion, illustrating how alignment between strategic planning and process improvements may be obtained.

The method used in the research is presented in the next section. Each activity in the method is detailed, as well as their expected outcomes. Other research centers might emulate the steps described here to successfully start a BPM program.

3. Method

This section describes the method used, and is divided into two parts. First, the methodological approach is presented, and the phases of the project are broadly defined. Action research was chosen as the methodological approach for this work, as it aims to solve practical problems while generating scientific knowledge simultaneously. In the second section, the phases are detailed, including the presentation of specific steps taken in each phase.

3.1 Action research

Coughlan and Coughlan (2002) define action research as an approach that aims for: action towards solving a specific problem, and the development of knowledge or theory regarding the action taken. In action research, a real problem must be present, and the problem must be of practical and research importance. Additionally, projects that use this method of research must be conducted in partnership between managers of the organization in focus and the outside researchers and analysts (Coughlan and Coughlan, 2009).

Action research recognizes that the researcher influences the problem he or she is investigating, and, thus, the environment surrounding it. Additionally, this method is frequently used to explore complex and dynamic problems, and because of that, the learning process about the situation in question is intrinsically related with the actions undertaken to transform this situation or reality (Zuber-Skerritt and Perry, 2002).

Action research comprises the enactment of iterative cycles, each of which is composed by phases. Figure 8 illustrates the phases of a typical cycle of action research.

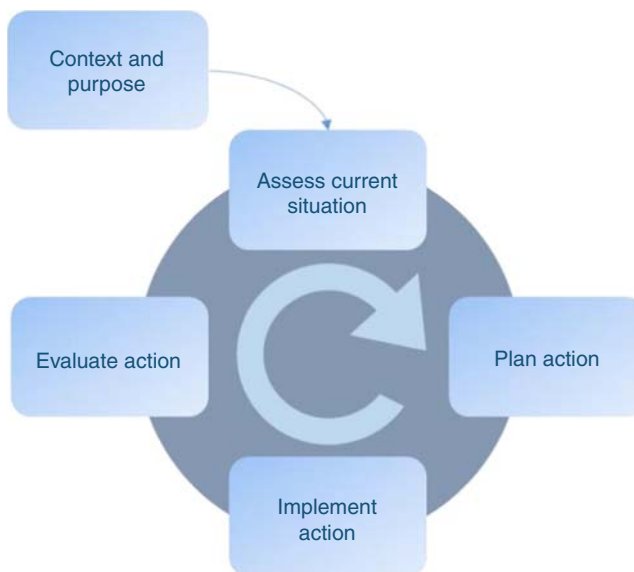


Figure 8.
Cycle of action
research

Source: Based on Coughlan and Coughlan (2002, p. 230)

The phases of the cycle of action research are (Coughlan and Coughlan, 2002):

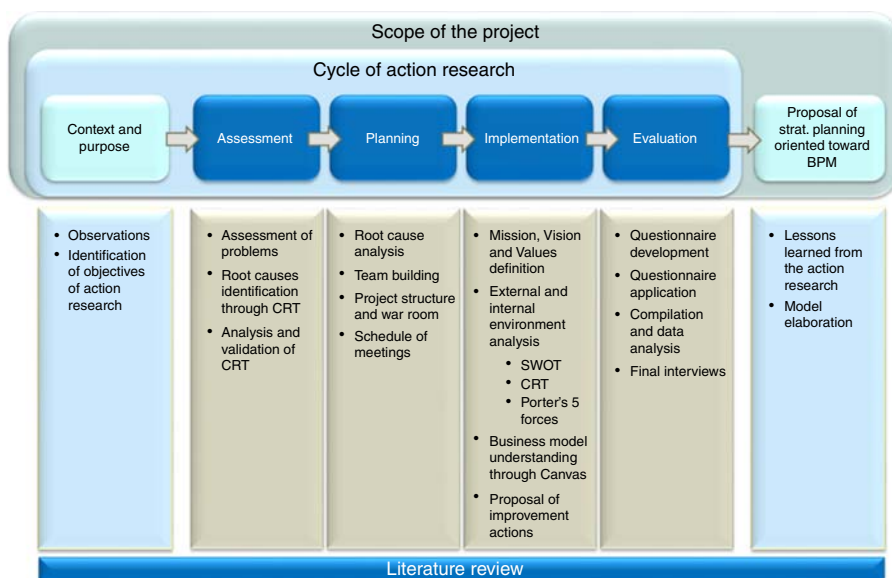
- (1) Context and purpose: the prerequisite for an action research project is knowledge of the business and the organization in focus, such as its history. This phase is characterized by two questions:
 - What is the reason for action?
 - What is the reason for research?
- (2) Assess current situation: in this phase main problems are identified. Activities must be conducted in a collaborative way. The researcher must include all relevant members of the organization and of the processes in question.
- (3) Plan action: this phase is developed upon the analysis of the context, purpose and assessment. It is characterized by key questions:
 - What needs to be changed?
 - In which part of the organization?
 - What types of changes are needed?
 - Who must support the change?
 - How to establish commitment?
 - How to manage resistance?
- (4) Implement action: in this phase, the changes are made according to the action plan, in close collaboration with relevant managers of the organization in focus.
- (5) Evaluate action: phase of reflection and analysis of the results of the actions taken. Additionally, the cycle is revised for its next execution, if the project requires additional cycles. Lessons learned in the first cycle may contribute to the execution of future cycles. Key questions in this phase:
 - Was the initial assessment correct?
 - Were the actions taken correctly?
 - Were the actions taken correctly?
 - What must be the input for the next cycle of assessment, planning and action, if needed?

3.2 Phases of the research

This section presents the details of each phase of the cycle of action research undertaken in the project. Figure 9 shows the steps and activities of each phase. In the next sections, each phase is further detailed.

3.2.1 Context and purpose. In this first step, observations were made in the organization in focus. From the start, the work was conducted in partnership with the managers of the organization in focus, as suggested by Coughlan and Coughlan (2009). The researchers were presented to the daily routine of the organization and learned the context in which it operated. From these observations and conversations with top management, the objectives of the action research project were established. The next step was to perform a broad assessment of the organization's processes using the CRT.

3.2.2 Assessment. The identification of the management dysfunctions or undesirable effects (UEs) of the CRC was done using the CRT, which followed a set of steps. Firstly, 21 semi-structured interviews were carried with healthcare professionals that worked in



Source: Authors

Figure 9.
Steps of the research

the CRC or had significant interactions with it inside the University Hospital. The objective was to detect dysfunctions they perceived in their daily routines. Each interview lasted about 30 minutes and was openly guided. The interviewees were encouraged to report as many problems as possible, and it was assured from the start of the interview that the interviewees would not be associated with the dysfunctions they reported. After the interviews were carried, the researchers, with collaboration with one of the managers, established the cause and effect relationships between all of the dysfunction, creating thus the CRT. The undesirable effects (UEs) were categorized according to their content. Bardin (2011) proposes two ways in which to categorize a set of qualitative data: in the first, there is a pre-defined set of categories that must be used in the classification of units of registered data. In the second, there are no pre-defined categories, but they are defined during the data analysis, in a bottom-up strategy. The process itself of analyzing the data generates categories that become apparent to the researchers. This second way to categorize the information was chosen for the analysis. The CRT was validated with top management, and the root causes for the UEs were identified.

3.2.3 Planning. The project team was then defined, as well as the location in which the meetings would take place. The frequency of meetings was also determined. The meeting room could fit the entire Clinical Research Center (CRC) team. The dynamics for each activity were defined. In most of them, the CRC team would be sub-divided into smaller groups to analyze a particular issue, such as the dimensions of the SWOT analysis. The sub-groups would then report their analysis to the whole team, and a compilation of the results was made.

3.2.4 Implementation. In this step, the strategic planning tools were applied in the organization in focus. As mentioned, the entire team of the CRC was involved. The first activity was the definition of mission, vision and values. The steps of the activity are described as follows:

- all employees were present in the meeting and were divided into groups of four or five members;

- each group came up with their version of the statements; and
- after each group's presentation, the whole team discussed (with the leadership of the center's director) and reached a consensus version for the statements.

The second activity was the SWOT analysis, conducted similarly as the first activity, following the same steps. It is noteworthy that many qualitative aspects in Weaknesses dimension of the SWOT overlapped with the UEs of the CRT. The external analysis was conducted using Porter's five forces, and was performed with top management, and complemented the results of the SWOT analysis. The fourth activity was the comprehension of the business model of the organization. The Canvas was used as the tool for this activity, and only top management was involved. The results were later presented to the whole organization. The last activity was the formulation of punctual quick-wins improvement initiatives. The strategic goals and priorities were determined by top management, but the solutions were designed by sub-groups designated for each improvement initiative. In parallel to these improvement projects, a formal BPM program was started by additional external researchers, using traditional modeling techniques, but the content of their work is out of the scope of this project. The next section presents the evaluation of the work.

3.2.5 Evaluation. As previously mentioned, after the implementation phase of this study, an external group of researchers promoted a first cycle of BPM in the organization in focus, aiming to improve operational efficiency of its main processes. After the conclusion of the first cycle of the BPM program, the perceptions of the managers regarding the activities of the strategic planning process (i.e. the activities within the scope of this action research project) were evaluated and analyzed in relation to their benefits for the organization and for the subsequent BPM program with its process improvements using traditional modeling techniques.

The evaluation was conducted in two ways:

- (1) application of structured questionnaires with questions regarding the steps, or activities, of the strategic planning process; and
- (2) application of semi-structured interviews, with the objective to identify the benefits of the initial strategic planning activities for the subsequent BPM program.

The questionnaire was composed by the following questions:

- (1) How satisfied are you with the procedure used to obtain the initial diagnosis (CRT)?
- (2) How useful was the initial diagnosis (CRT) to the organization?
- (3) How satisfied are you with the procedure used to in the strategic planning process activities?
- (4) How useful was the strategic planning for the organization?
- (5) How useful was the construction of the business model to the organization?
- (6) How satisfied are you with the procedure used to obtain the improvement projects proposed?
- (7) How useful were the improvement projects proposed to the organization?

The possible answers varied from 1 (completely unsatisfactory) to 10 (completely satisfactory). Seven (7) "judges" were selected to answer the questionnaire, anonymously. The judges were employees of the Clinical Research Center (CRC) and participated in all activities performed. The evaluation of the answers to questions above was based on the within-group interrater method applied in a satisfaction questionnaire, proposed by

James *et al.* (1984). The method aims to assess the level of agreement among judgments made by a single group of judges on a single variable in regard to a single target. The method contemplates the degree of alignment and similarity between responses. The degree varies between zero and one: the closer to one, the stronger the concordance index, i.e. the more consistent the opinions of the respondents are. The following equation is used to calculate the within-group interrater (wgi), where i denotes each grade of the respondents ($i = 1, 2, \dots, i$):

$$r_{wg(i)} = 1 - (SD/\sigma_i^2)$$

where SD is the standard deviation of the given scores by the respondents for each question in the questionnaire, while the expected variance is due to random error. The variance is calculated assuming that grades granted to each question have an uniform distribution, i.e. the grades have the same probability. Variance is then calculated according to the following equation (James *et al.*, 1984):

$$\sigma^2 = (A^2 - 1)/12$$

where A is the number of possible answers for each question, with discrete numbers. In this work case, $A = 10$ (answers varying from 1 to 10). Studies have concluded that $A = 7$ (plus or minus 2) is optimal for values of variance (James *et al.*, 1984). The results of this analysis are discussed in Section 4.5.1.

After the application of the questionnaires, the semi-structured interviews were conducted, in order to better understand if and how the strategic planning activities contributed to the process improvement initiative that followed (formal BPM program). Two managers were interviewed. They were encouraged to speak freely about the contributions and limitations of this work. A qualitative analysis of the open responses of the managers interviewed was then conducted for the development of the discussion.

3.2.6 Model proposal for strategic planning process oriented towards BPM. After analyzing the managers' perception, reflecting upon the results of each of the activities carried throughout the action research project, and considering the concepts found in the literature, a model was conceived for strategic planning process oriented towards the promotion of BPM. The model construction followed recommendations given by Bandara *et al.* (2009), shown in Section 2.2:

- the assessment of corporate goals, objectives and KPIs should be outlined;
- BPM initiative objectives should be selected based on organizational strategic objectives;
- in the formulation of strategy, the process capabilities should be considered – consonant with Adamides (2015);
- understanding organization's process capability should contribute to strategic goals and objectives;
- major corporate processes that support the business objectives and goals should be identified;
- stakeholders' requirements should be considered in the prioritization of the processes (this is one of the contributions given by the Canvas); and
- strategic objectives should be considered in prioritization of process improvement initiatives.

The detailed results of each stage of the method used, including the final model conceived, are presented in the next sections.

4. Results

The results are presented in the same sequence of phases contemplated in the method section. Each phase yielded different results. The combination of results leads to the overall output of the action research.

4.1 Context and purpose

The first step of the project was to understand the context and purpose of the work. There was an observation *in loco* of the operations of the organization in focus, and the research objectives were determined.

Since 2005, the University Hospital in question has had a Clinical Research Center (CRC) dedicated to managing and supporting clinical research. The center employs 37 people (at the time of the research), and is considered among the best in Brazil. The center supports projects of interest to the national healthcare system (SUS), and is sponsored by the Hospital's foundation for the support to teaching, research and assistance, in partnership with national research funding agencies. It also works in collaboration with multinational pharmaceutical companies, other research centers in Brazil and abroad, as well as regulatory agencies such as Brazilian Health Regulatory Agency (ANVISA), European Agency for the Evaluation of Medical Products (EMEA) and Food & Drug Administration (FDA).

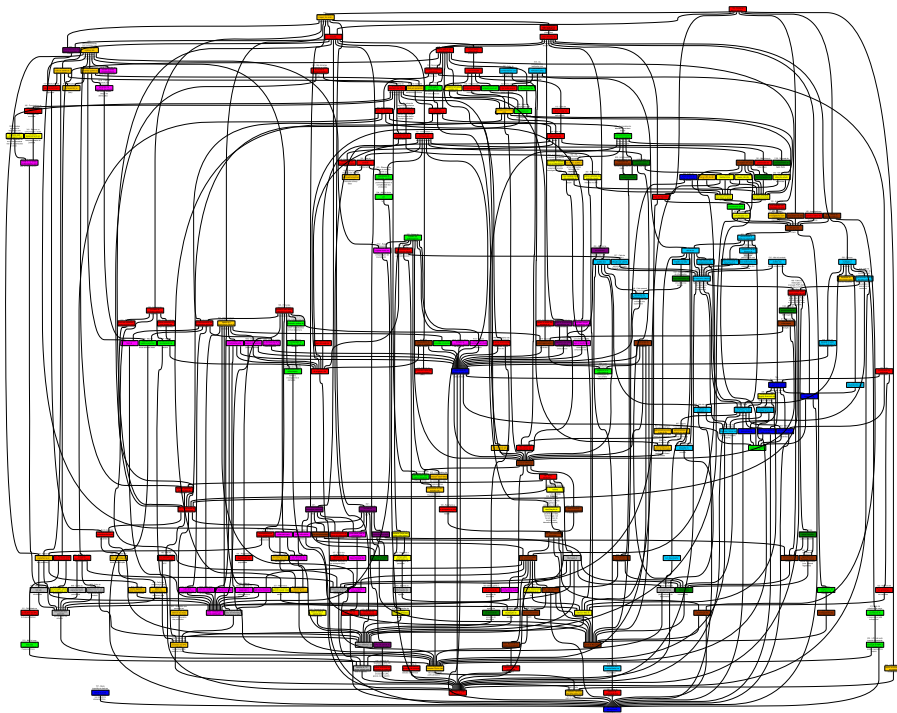
The managers of the CRC wanted to improve the performance of their organization and streamline its processes. Thus the research started with the objective to promote BPM and to contribute to the literature with the development of knowledge on promoting BPM in a CRC environment.

4.2 Assessment

After the initial contextualization, the overall management dysfunctions of the CRC were identified, through the use of the current reality tree (CRT). The identification of undesirable effects (UEs) was done through 21 semi-structured interviews, and around 260 UEs were detected. These were associated in cause-and-effect relationships and grouped into 11 categories, as follows:

- (1) service performance/processes;
- (2) organizational structure;
- (3) internal communication;
- (4) regulatory norms;
- (5) financial and judicial;
- (6) external relations;
- (7) strategic planning;
- (8) human resources;
- (9) IT systems;
- (10) infrastructure; and
- (11) knowledge management.

An image of the CRT is presented in Figure 10. Details are deliberately unreadable as it contains sensitive information. The CRT was validated by top management, and hung on the wall of the Clinical Research Center (CRC), where everyone could see. The CRT evidenced the relationship of cause and effect of the UEs as reported by the team members, and this generated consensus around the main problems faced by the organization, as well as their root causes.



Source: Authors

Figure 10.
CRT of the clinical
research center

4.3 Planning

In this step, the root causes in the CRT were discussed. One of the root causes detected was the lack of a formal strategic planning process. This identification determined the content of the rest of the action research project to be carried. Instead of “validating strategy,” as most BPM life cycle models propose, the research sought to formulate strategy. In this step, the project team was defined. The center’s director was designated as project leader and sponsor. The tools to be used were defined, based on strategic planning processes present in the literature, such as the ones presented in Section 2.2. The place where meetings would take place was also designated, as were the structure of the work and frequency of meetings. The whole team would assemble in strategic planning meetings, on a weekly basis, and for most activities, the whole group would be divided into smaller sub-groups. The whole process lasted six months.

4.4 Implementation

The first activity in this step was the definition of mission, vision and values of the organization in focus. This activity was conducted in 1 afternoon, following the method presented in Section 3.4. The statements are not presented here, since no authorization for its disclosure was given. The next activity was the use of the SWOT analysis. Once again, the whole team participated in the meeting. Half of the team discussed internal factors (strengths and weaknesses) and the other half analyzed external factors (opportunities and threats). The results were discussed afterwards, and consensus was reached. As previously mentioned, much of the results of the internal analysis were similar to the previous

assessment performed using the CRT. The results of the SWOT analysis are also not presented in this work, since it contains sensitive information to the organization.

After the SWOT analysis, the external environment was further analyzed using Porter's five forces. The meetings were conducted with top management. The objective was to identify external opportunities to be explored by the center, and also detect and devise ways to minimize external threats.

Finally, a meeting with top management was conducted to comprehend the business model of the CRC using the Canvas, proposed by Osterwelder and Pigneur (2010). During this activity, the value proposition for each stakeholder was identified, and that contributed to the definition of the strategic priorities of the organization. Figure 11 is a photo of the Canvas used to comprehend the business model of the Clinical Research Center (CRC). The information is purposefully illegible, as it contains sensitive information.

After the use of the strategic planning tools, including the initial in-depth assessment with the current reality tree (CRT), top management of the organization subjectively defined the strategic initiatives of the CRC. The following areas were considered strategic and defined as priorities for improvement:

- implementation of an IT system and implementation of electronic medical records;
- development of better communication channels with different stakeholders, including the hospital itself;
- implementation of formal internal training;
- standardization of work for executing clinical research protocols; and
- standardization of flow of financial information.

For each priority topic, an improvement project was proposed. Again, the whole team was sub-divided into smaller groups, and each group became responsible for designing solutions to the problems at hand. The projects were meant to be quickly implemented, and to be conducted in parallel to a subsequent traditional BPM program, that incorporated customary modeling techniques for process improvements.

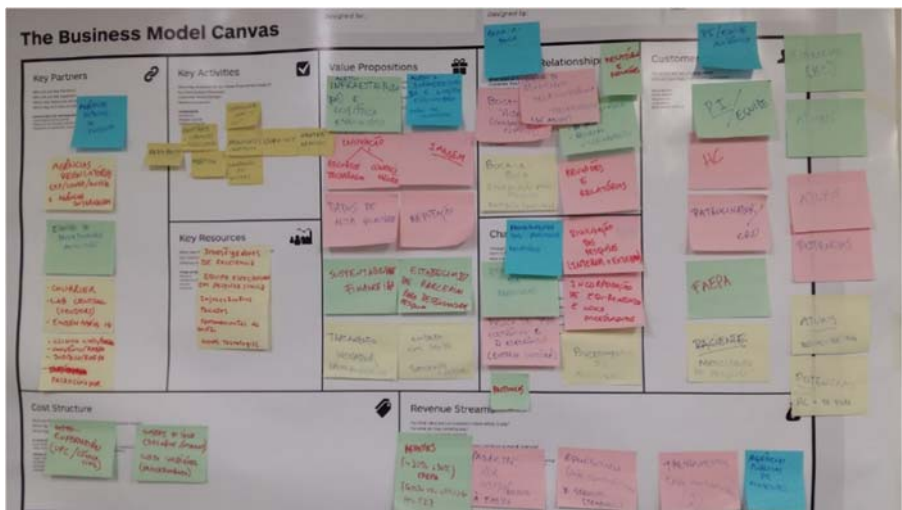


Figure 11.
Business model
canvas of the CRC

Source: Authors

4.5 Evaluation

The evaluation step in this work was conducted after the cycle of BPM performed by external researchers, and the goal was to assess the importance of the strategic planning process for the organization and for BPM promotion. The evaluation followed the method presented in Section 3.2.5.

4.5.1 Questionnaires. The scores for each question (presented in Section 3.2.5) varied from 1 (extremely unsatisfactory) to 10 (extremely satisfactory). Seven members of the organization answered the questionnaire, which corresponds to 16 percent of the whole organization. Table I illustrates the average score for each question, as well as the standard deviation, variance and the within-group agreement (wga).

The wga, as proposed by James *et al.* (1984), and described in Section 3.2.5, were calculated. For all questions included in the questionnaire, the wga resulted in a high score (close to 1). Except for question 3 (where wga = 0.86) and question 5 (wga = 0.88), all other questions have a wga greater than or equal to 0.9. That indicates a high level of agreement between the respondents, and, thus, high level of satisfaction with the overall project.

4.5.2 Semi-structured interviews. After the questionnaires were applied, two semi-structured interviews were conducted with top management, in order to further verify what were the benefits and the limitations brought by the strategic planning process for the organization and for the posterior BPM life cycle. The opinion of these managers helped corroborate the model proposed in Section 5 of this paper. The presentation of these statements is intended to give a qualitative and generic exemplification of two important stakeholders in the project (managers). In the previous section, a more systematic evaluation was carried out using structured questionnaires. The open answers are presented as quotes:

Manager A: Initiating the work with the assessment (CRT – current reality tree) was the basis for consensus in the project. The identification of management problems of the centre, through the anonymous interviews with people involved in our operations, reflected empathy, that is, it involved everyone right from the start. We first listened to what people had to say, and then designed solutions. That was very important. If that wasn't done before the BPM cycle started, it probably wouldn't have worked. Also, the team became more mature with the participation in the strategic planning activities. The centre developed valuable management practices, such as weekly coordination meetings. The priority areas identified in the strategic planning process were important for the cycle of BPM. The use of the Business Model Canvas was particularly very valuable to us. Before its construction, it wasn't very clear how the research centre related to each of its partners. The Canvas identified the value proposition for each stakeholder, and that was very useful.

Manager B: The CRT was very important for the identification of the real needs of the organization. The participation of the whole team was fundamental to generate consensus. When we constructed the Canvas I was able to really understand our business model. That was of real importance, as we

Question	Answers per respondent							Mean	SD	σ^2	wga
	1	2	3	4	5	6	7				
1	8	8	10	8	9	9	8	8.57	0.79	8.25	0.90
2	10	8	10	9	9	9	10	9.29	0.76	8.25	0.91
3	10	7	8	10	8	8	8	8.43	1.13	8.25	0.86
4	10	8	10	9	8	9	9	9.00	0.82	8.25	0.90
5	10	9	7	8	9	9	9	8.71	0.95	8.25	0.88
6	10	9	8	8	8	9	9	8.71	0.76	8.25	0.91
7	10	8	10	9	8	9	9	9.00	0.82	8.25	0.90
Mean	9.71	8.14	9.00	8.71	8.43	8.86	8.86				
SD	0.756	0.69	1.291	0.756	0.535	0.378	0.69				

Source: Authors

Table I.
Answers to
questionnaires

identified the value proposition for each stakeholder. Today I can communicate much better with each stakeholder, knowing what it is they expect from us. Today, we are able to see the research center as a whole. The improvement project proposals identified the problems to be addressed. That was valuable. The whole process generated consensus around our real problems. It empowered our whole team to be proactive. This initial work, prior to the BPM life cycle, was fundamental to prepare the organization. It was essential to understand our priorities and needs beforehand. I do not think the BPM program would have worked if we did not conduct this prior planning that involved the whole team.

The managers' quotes support the logic behind the model proposed at the end of the action research, and substantiate its importance for practitioners and researchers. The next section presents discussion of the results, including analysis of the managers' quotes, model proposal for strategic planning process oriented towards BPM and its comparison with existing approaches.

5. Discussion, model proposal and comparison with existing approaches

5.1 Discussion

Considering the evaluation of the work using the application of questionnaires and semi-structured interviews, it can be concluded that the activities carried during the strategic planning process were important for the organization and for the subsequent BPM program. When analyzing the quotes presented in Section 4.5.2, it is possible to conclude that the current reality tree (CRT) played a pivotal role in the process. It was responsible for generating consensus around the problems faced by the organization, and around the need for change, in consonance with Gupta *et al.* (2004), as discussed in Section 2.4. This consensus was considered vital for the subsequent BPM program: "the whole process generated consensus around our real problems. It empowered our whole team to be proactive. This initial work, prior to the BPM life cycle, was fundamental to prepare the organization" (Manager B).

According to both managers' quotes, the comprehension of the CRC's business model with use of the Canvas was also important. It provided a means for dialogue between managers regarding each element of the business model. As stated by Osterwelder and Pigneur (2010), the tool may be used to understand the business model by describing the logic of how the organization creates, delivers and captures value. This tool demonstrated the organization's logic of value creation, delivery and capture. It was also helpful in identification of strategic opportunities for improvements in the organization, to be addressed by process improvement initiatives during the following BPM program.

At the start of the project, the organization in focus of this study was managed through a functional perspective. One of the quotes of the managers interviewed highlights that the inclusion of the whole team in the strategic planning process provided common realization of the importance of process-oriented perspective. The external and internal analysis performed with the use of these complementary tools (SWOT, Porter's five forces, CRT and Business Model Canvas), involving the whole organization, resulted in a consensus of the organization's main problems and their root causes, including its lack of a process-oriented perspective. According to the RBV, the valuable strategic resources of the Clinical Research Center (CRC) determine its performance in the competitive and dynamic environment in which it operates (Collis and Montgomery, 2008). The internal and external analysis, using the tools previously mentioned, contributed significantly to the identification of valuable strategic resources to be exploited or developed for market competitiveness, and thus strategic priorities were defined to be addressed by a BPM program.

The current reality tree (CRT), in particular, proved to be an excellent tool to detect problems and root causes. It can be used for in-depth internal analysis of the organization, complementing the SWOT analysis. The CRT investigates the internal problems of the organization in a much deeper level of comprehension than the SWOT analysis.

It provides a consensual mental model of the organization. All members participating in the development and validation of the CRT understand the system and are likely to commit to achieving the desired results (Gupta *et al.*, 2004).

Furthermore, the effective implementation of strategy was due the ability of top management to decompose it to lower managerial levels, in consonance with Gębczyńska (2016). The identification of key concerns to be addressed, done by top management with the use of the CRT, as well as the design of improvement projects, to be carried by lower level management, exemplified the decomposition of strategy as described by Gębczyńska (2016). Based on these considerations, a model was proposed for strategic planning process oriented towards BPM.

5.2 Model proposal

The proposed model for strategic planning process oriented towards BPM is illustrated in Figure 12. It is based on the initial proposal by Morais *et al.* (2014), but it advances the model by contemplating strategic planning in alignment with BPM.

According to this model, a strategic planning process, with detailed activities, must be integrated to a BPM program. First, a general assessment may be conducted using Theory of Constraints' current reality tree (CRT). This tool is important for generating consensus regarding the need for change in the organization. The objects of investigation are the organization's business processes. The CRT starts with the design of a semi-structured

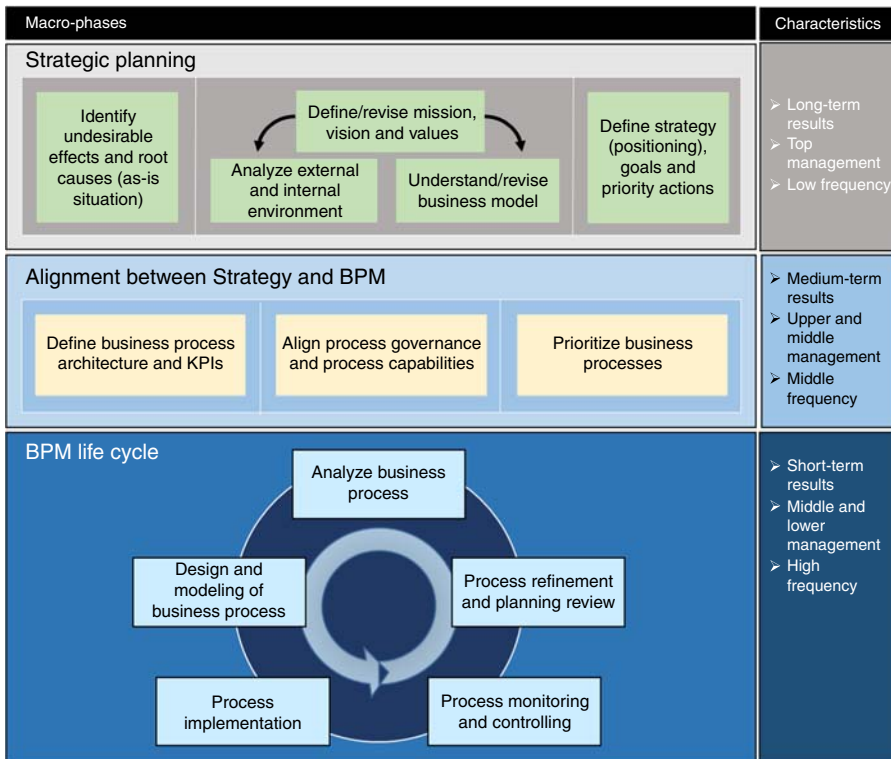


Figure 12. Model for strategic planning process oriented towards BPM

Source: Authors, based on Morais *et al.* (2014, p. 427)

questionnaire to serve as a guide for interviewing managers of all levels and functions in the organization. The results of the interviews are analyzed, and they are the source of the identification of UEs. The UEs are connected through cause-and-effect relationships resulting in the CRT. The CRT should be validated by top management, and displayed in a place where everyone in the organization is able to see. In that way, the main UEs and their root causes are explicit to everyone and serve as an initial basis for discussion toward the design of solutions.

Next, still in the strategic planning phase, the organization's Mission, Vision and Values should be defined or revised. This is a crucial step in the transformation process because all other improvement actions should support these statements, without contradiction. That is why these statements need to be precise. The way to conceive or revise the statements will vary between organizations. However, in all cases, the opinion of members of all levels of the organization regarding these statements should be considered as much as possible, as they will reflect the work carried at all levels inside the firm.

Following, an internal/external analysis is conducted, using an assessment tool such as SWOT analysis. Again, the way to conduct this activity will vary between organizations. One way to conduct the SWOT analysis is to form separate teams to analyze external and internal factors. The main weaknesses may be represented on the CRT, but there is always the possibility to add new problems due to different point of view. Once the teams have reached a consensus within themselves, a broad discussion is conducted between all of the teams, in order to reach consensus on the main issues at hand.

After the internal/external analysis, the business model of the organization needs to be understood. Business Model Canvas may be applied to identify the main "building blocks" of the model. One particular outcome of this activity is the identification of the value proposition to each stakeholder of the organization. This identification proved to be very valuable in the action research project presented. One manager interviewed highlighted the significance of the construction of the Canvas. It "was of real importance, as we identified the value proposition for each stakeholder. Today I can communicate much better with each stakeholder."

After these activities are done, the strategic positioning of the firm is defined, the goals are set and priority actions are identified and communicated throughout the organization. When key improvement opportunities are highlighted, the following BPM program is well aligned with the company's strategy, as it will aim to solve the right issues. This alignment increases the chances of BPM programs to achieve strategic goals of the organization, and prevents efforts being wasted on non-strategic objectives. This is the model's main contribution, and in this respect it is unique among other models present in the literature.

The macro phase of strategic planning is conducted with long-term results in sight, and is carried less frequently than the other two phases. The second macro phase in the model is composed of activities that help deploy the strategic issues identified in the first phase into the subsequent process improvements to be done during the BPM life cycle execution. This second phase is composed of the definition of the process architecture and KPIs; the alignment of process governance and process capabilities; and the prioritization of business processes to be improved during the BPM life cycle. For more details on these activities, see Morais *et al.* (2014). The model is consonant with Rosemann and Bruin (2005), who emphasize the importance of the process architecture, which captures the relationships between key business processes and support processes and the alignment with strategy, goals and organization policies (Rosemann and Bruin, 2005). This macro phase aims to achieve mid-term results, and is carried more frequently than the previous phase, yet less frequently so than the next phase.

The final macro phase is comprised of the typical activities present in most BPM life cycles. The model here presented uses the steps defined by Morais *et al.* (2014). As previously presented, Morais *et al.* (2014) reviewed the literature on BPM life cycles and

identified these steps as common ground: analyze business process; design and modeling of business process; process implementation; process modeling and controlling; and process refinement and planning review. This macro phase may be conducted as frequently as possible, and it seeks to achieve short term results.

5.3 Comparison with existing approaches

When comparing the model proposed in this work with other models present in the literature, it is possible to identify similarities and differences. Kachaner *et al.* (2016) discern strategic planning and implementation between three different time horizons: long term, medium term and short term. The model incorporates this view, as each macro-phase focuses on one of these time horizons. The tools included in the model produce results for strategic planning in different time horizons. For example, innovations of the organization's business model may occur in a longer time horizon, while specific improvements to business processes may happen in the short term. By using this model, companies are following recommendations made by Kachaner *et al.* (2016).

Leu and Huang (2011) presented a successful BPM case implemented at a hospital, which resulted in improvements in some of the performance measurements defined. However, the research does not deal with the long term benefits of the program, or how the hospital will balance long-term with short-term results. Leu and Huang (2011) do not demonstrate if this process improvement program contributed to the hospital's long-term strategic goals. By optimizing specific processes without establishing the relationship of the initiative with the hospital's strategy, the probability for longer-term success of the BPM program is hampered. In contrast, the model proposed here contemplates the dichotomy between long and short-term priorities, and appropriately aligns strategic goals with processes improvement initiatives. The model assures that process improvement efforts will enable strategy deployment.

Yarmohammadian *et al.* (2014) propose a simple method for selection of processes to be analyzed, as well as steps to promote improvements. The reported case communicates positive results, but it does not reveal how the organization plans on sustaining the practices shown. It also does not delve into strategic issues, such as positioning in their market, nor does it explore the time horizons for the actions taken. Similar to the case presented by Leu and Huang (2011), there is emphasis on short term results for the hospital. Our model proposal differentiates in this sense, by determining the strategic valuable resources required for market competitiveness, and translating these requirements into a BPM program, using an outside-in view. The model presented here serves as a reference for sustaining the improvement initiative through different time horizons, by designating tools and responsibilities within the company.

Yarmohammadian *et al.* (2014) state that healthcare processes are very complex, involving clinical and administrative tasks, large volumes of data, and a large number of patients and personnel. Hence, healthcare processes improvements require the cooperation of different organizational functions and medical disciplines. This resonates with the action research presented in this paper. The model presented in Figure 12 was the result of the close collaboration between professionals in the healthcare sector, specialized in clinical trials, and external business and process analysts. The co-design approach for the model's development was indispensable for its success.

Griffith and White (2005) present the case of St Luke's Hospital's (SLH) strategic planning process, which unfolds into specific process improvement initiatives. Their model does not contemplate BPM life cycle. Therefore, the model presented here is an improvement upon SLH comprehensive system, as presented by Griffith and White (2005).

All of the proposals from the literature reviewed have elements in common with the model proposed in this work. However, they do not entirely integrate strategic planning with BPM. In contrast, the model proposed here bridges this gap by identifying the

necessary activities for alignment between strategy and BPM. It explicitly describes the steps to be carried, and tools to be used, in order to align strategic planning with process improvement, and this is a novelty in the literature. The characteristics of this proposal are broad and the model may be applied/tested in other contexts without major modifications. Companies operating in other industries may benefit from the model, as Figure 12 does not restrict the use of the model to CRC management.

One of the differentials of this proposal, in relation to the existing literature, is the integrated use of a holistic assessment of the organization's management dysfunctions (and the identification of the cause-effect relationships between these dysfunctions) as a starting point for the project. Many organizations address specific problems related to business processes, achieving short-term results, but these initiatives often lack analysis of other perspectives of the business (e.g. human factors), which may result in discontinuity of BPM initiatives or failure to achieve strategic goals.

The final remarks are made in the next section, including the summary of the main contributions of this work, the acknowledgment of its limitations and identification of opportunities for future research.

6. Final remarks

The promotion of BPM is not a novelty in many sectors. However, no significant references on comprehensive BPM programs at Clinical Research Centers (CRCs) were found in the literature. The need for operational improvements in CRCs was highlighted, and the organization in focus for this action research project reflected such need. This work bridged important gaps found in the literature, granting significant contributions. The first one is specific to the literature on process improvement initiatives designed for CRCs. The detailed action research project may be replicated in other research centers, as the results were positively evaluated by the CRC's managers. As before mentioned, there are many benefits to the implementation of process improvements techniques to clinical research. The specificities of clinical trials pose significant challenges for operations management in CRCs, and managers need a comprehensive model to help them integrate strategic and operations management inside their research centers to assure the success of process optimization efforts. This research meets this requirement by presenting a model that details the integration of complimentary methods and approaches, typically lacking in research in the field of CRC management.

The second – and most important – contribution of this work is to the BPM literature, with the proposal of a model that contemplates the alignment of strategic planning with BPM. The model includes best practices for integrating strategic planning with BPM and identifies specific activities to be carried, which are typically absent in other publications. The work is consistent with existing literature, as it highlights the importance of strategic planning for BPM. Yet, it delves deeper into the topic by describing an action research project and presenting detailed steps taken. The results for each step are discussed and analyzed. As previously mentioned, alignment between strategy and BPM is considered one of the main success factors for BPM, and this work describes specific steps and activities that may be emulated by managers in other contexts. The implications of this work contribute to strategic level analysis, resulting in directives for strategy deployment into operations management and improvement. This strengthens probability of success for BPM programs, by endorsing the work of process improvement teams inside the company, and fostering consensus towards the importance of BPM as an incremental effort for reaching corporate objectives. CRC management literature does not include BPM as an approach to achieve strategic goals, although BPM does represent promising opportunities for clinical research operations management. Additionally, the inclusion of a holistic diagnosis (using the current reality tree – CRT) of the organization supports the BPM initiative in CRC management, since this technique results in the representation of the cause-effect

relationship of the main problems and dysfunctions as an alternative to the traditional modeling of the as-is situation. This kind of representation aligns strategic planning with BPM, and, therefore, has implications at the strategic level. The CRC's goals for the next period (normally a year) might include actions to eliminate the main undesired effects (UEs) and even root causes represented in the CRT. In the deployment of the strategy, the problems identified can lead to process improvement projects. Hence, this is an implication for the operational level.

The work was carried in close collaboration with the CRC managers, and the solutions were conceived and implemented iteratively and cooperatively. The partnership between the multidisciplinary teams proved pivotal for the research's end result (the model proposed). Importantly, the model is of significant relevance to both researchers and practitioners, and the reproduction of this work in other contexts may yield interesting results, both theoretical and practical. The project was sponsored and lead by the CRC director, and this leadership proved to be a key factor to the project's success. It generated essential inside credibility to the changing efforts and team motivation.

From a theoretical perspective and according to logical deductive reasoning, the research method adopted does not allow immediate validation of the proposal's applicability to other contexts. The model is promising for organizations of different sizes and outside the CRC context, and may yield positive results for companies in other industries, but additional applications must be conducted for validation of the proposal's general applicability. Further testing through applications may add valuable information for improving the model. This represents an encouraging opportunity for future research, as different organizations will present different needs. Moreover, analyses of process architecture and performance measurement systems were not included in this work. These concepts represent impending research opportunity, as they play an essential role in the alignment between strategy and BPM.

Note

1. For more details on the Baldrige National Quality Award in Healthcare, see Griffith and White (2005)

References

- Adamides, E. (2015), "Linking operations strategy to the corporate strategy process: a practice perspective", *Business Process Management Journal*, Vol. 21 No. 2, pp. 267-287.
- Armistead, C., Pritchard, J.P. and Machin, S. (1999), "Strategic business process management for organizational effectiveness", *Long Range Planning*, Vol. 32 No. 1, pp. 96-106.
- Association of Business Process Management Professionals (ABPMP) (2013), *Guide to the Business Process Management Common Body of Knowledge – BPM CBOK*, 3rd ed., Version 3.0, CreateSpace Independent Publishing Platform, p. 446.
- Bandara, W., Alibabaei, A. and Aghdasi, M. (2009), "Means of achieving business process management success factors", *Proceedings of the 4th Mediterranean Conference on Information Systems, Athens University of Economics and Business, Athens, September 25-27*.
- Bardin, L. (2011), *Content analysis*, Vol. 70, Edições, São Paulo, p. 229 (in Portuguese).
- Collis, D. and Montgomery, C. (2008), "Competing on resources", *Harvard Business Review*, Vol. 86 Nos 7-8, pp. 140-150.
- Coughlan, P. and Coughlan, D. (2002), "Action research for operations management", *International Journal of Operations and Production Management*, Vol. 22 No. 2, pp. 220-240.
- Coughlan, P. and Coughlan, D. (2009), in Karlsson, C. (Ed.), *Researching Operations Management*, Chapter 7, 1st ed., Routledge, New York, NY, pp. 236-262.

- Daudelin, D., Selker, H. and Leslie, L. (2015), "Applying process improvement methods to clinical and translational research: conceptual framework and case examples", *Clinical and Translational Science*, Vol. 8 No. 6, pp. 779-786, doi: 10.1111/cts.12326.
- Dettmer, H.W. (1997), *Goldratt's Theory of Constraints: A Systems Approach to Continuous Improvement*, ASQ Quality Press, Milwaukee, WI.
- Eisenstein, E.L., Collins, R., Cracknell, B.S., Podesta, O., Reid, E.D., Sandercock, P., Shakhov, Y., Terrin, M.L., Sellers, M.A., Califf, R.M., Granger, C.B. and Diaz, R. (2008), "Sensible approaches for reducing clinical trial costs", *Clinical Trials*, Vol. 5, pp. 75-84, doi: 10.1177/1740774507087551.
- Gębczyńska, A. (2016), "Strategy implementation efficiency on the process level", *Business Process Management Journal*, Vol. 22 No. 6, pp. 1079-1098.
- Glickman, S.W., McHutchison, J.G., Peterson, E.D., Cairns, C.B., Harrington, R.A., Califf, R.M. and Schulman, K.A. (2009), "Ethical and scientific implications of the globalization of clinical research", *The New England Journal of Medicine*, Vol. 360 No. 8, pp. 816-823.
- Griffith, J.R. and White, K.R. (2005), "The revolution in hospital management", *Journal of Health Management*, Vol. 50 No. 3, pp. 170-189.
- Gupta, M., Boyd, L. and Sussman, L. (2004), "To better maps: a TOC primer for strategic planning", *Business Horizons*, Vol. 47 No. 2, pp. 15-26.
- Harmon, P. (2007), *Business Process Change: A Guide for Business Managers and BPM and Six Sigma Professionals*, 2nd ed., Morgan Kaufmann, San Francisco, CA.
- Hernaus, T., Vuksic, V.B. and Stemberger, M.I. (2016), "How to go from strategy to results? Institutionalising BPM governance within organisations", *Business Process Management Journal*, Vol. 22 No. 1, pp. 173-195.
- Huckman, R.E. and Zinner, D. (2008), "Does focus improve operational performance? Lessons from the management of clinical trials", *Strategic Management Journal*, Vol. 29 No. 2, pp. 173-193, doi: 10.1002/smj.
- James, L.R., Demaree, R.G. and Woolf, G. (1984), "Estimating within-group interrater reliability with and without response bias", *Journal of Applied Psychology*, Vol. 69 No. 1, pp. 85-98.
- Kachaner, N., King, K. and Stewart, S. (2016), "Four best practices for strategic planning", *Strategy & Leadership*, Vol. 44 No. 4, pp. 26-31, doi: 10.1108/SL-06-2016-0046.
- Kaplan, R. and Norton, D. (2008), "Mastering the management system", *Harvard Business Review*, Vol. 86 No. 1, pp. 62-77.
- Lambin, J. and Schuiling, I. (2012), *Market-Driven Management: Strategic and Operational Marketing*, 3rd ed., Palgrave Macmillan, New York, NY.
- Lederer, M., Kurz, M. and Lazarov, P. (2017), "Making strategy work: a comprehensive analysis of methods for aligning strategy and business processes", *International Journal of Business Performance Management*, Vol. 18 No. 3, pp. 274-292.
- Leu, J.D. and Huang, Y.T. (2011), "An application of business process method to the clinical efficiency of hospital", *Journal of Medical Systems*, Vol. 35, pp. 409-421, doi: 10.1007/s10916-009-9376-4.
- Magretta, J. (2002), "Why business models matter", *Harvard Business Review*, Vol. 80 No. 5, pp. 86-92, 133.
- Minonne, C. and Turner, G. (2012), "Business process management – are you ready for the future?", *Knowledge and Process Management*, Vol. 19 No. 3, pp. 111-120.
- Morais, R., Kazan, S., Pádua, S. and Costa, A. (2014), "An analysis of BPM lifecycles: from a literature review to a framework proposal", *Business Process Management Journal*, Vol. 20 No. 3, pp. 412-432.
- National Institutes of Health, US Department of Health and Human Services, Health Information (2015), "NIH clinical research trials and you", available at: www.nih.gov/health-information/nih-clinical-research-trials-you/basics
- Niehaves, B., Poepelbuss, B., Plattfaut, R. and Becker, J. (2013), "BPM capability development – a matter of contingencies", *Business Process Management Journal*, Vol. 20 No. 1, pp. 90-106.

- Osterwelder, A. and Pigneur, Y. (2010), *Business Model Generation: A Handbook for Visionaries, Game Changers and Challengers*, John Wileys and Sons, Inc., Hoboken, NJ.
- Pádua, S., Costa, J., Segatto, M., Souza, M. and Chiapetta-Jabbour, C. (2014), "BPM for change management: two process diagnosis techniques", *Business Process Management Journal*, Vol. 20 No. 2, pp. 247-271.
- Paim, R., Caulliraux, H.M. and Cardoso, R. (2008), "Process management tasks: a conceptual and practical view", *Business Process Management Journal*, Vol. 14 No. 15, pp. 694-723.
- Porter, M. (1979), "How competitive forces shape strategy", *Harvard Business Review*, Vol. 57 No. 2, pp. 137-145.
- Porter, M.E. (1996), "What is strategy?", *Harvard Business Review*, Vol. 74 No. 6, pp. 61-78.
- Rahman, S. (2002), "The theory of constraints' thinking process approach to developing strategies in supply chains", *International Journal of Physical Distribution & Logistics Management*, Vol. 32 No. 10, pp. 809-828.
- Rosemann, M. and Bruin, T. (2005), "Application of a Holistic model for determining BPM maturity", *BPTrends*.
- Scoggin, J.M., Segelhorst, R.J. and Reid, R.A. (2003), "Applying the TOC thinking process in manufacturing: a case study", *International Journal of Production Research*, Vol. 41 No. 4, pp. 767-797.
- Schweikhart, S.A. and Dembe, A.E. (2009), "The applicability of Lean and Six Sigma techniques to clinical and translational research", *Journal of Investigative Medicine*, Vol. 57 No. 7, pp. 748-755, doi: 10.2310/JIM.0b013e3181b91b3a.
- Trkman, P. (2010), "The critical success factors of business process management", *International Journal of Information Management*, Vol. 30 No. 2, pp. 125-134.
- Trkman, P., Mertens, W., Viaene, S. and Gemmel, P. (2015), "From business process management to customer process management", *Business Process Management Journal*, Vol. 21 No. 2, pp. 250-266.
- Yarmohammadian, M.H., Ebrahimpour, H. and Doosty, F. (2014), "Improvement of hospital processes through business process management in Qaem teaching hospital: a work in progress", *Journal of Education and Health Promotion*, Vol. 3, p. 111, doi: 10.4103/2277-9531.145902.
- Zott, C., Amit, R. and Massa, L. (2011), "The business model: recent developments and future research", *Journal of Management*, Vol. 37 No. 4, pp. 1019-1042.
- Zuber-Skerritt, O. and Perry, C. (2002), "Action research within organisations and university thesis writing", *The Learning Organization*, Vol. 9 No. 4, pp. 171-179.

Corresponding author

Victor Cattani Rentes can be contacted at: vcrentes@gmail.com

For instructions on how to order reprints of this article, please visit our website:

www.emeraldgroupublishing.com/licensing/reprints.htm

Or contact us for further details: permissions@emeraldinsight.com

Reproduced with permission of copyright owner. Further reproduction prohibited without permission.