Institutional regulation and performance of clinical-trial strategic alliances

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Abstract: The goal of this study is to assess the relationships between the country's regulatory institutions and the relational capability and performance of clinical-trial strategic alliances. The country's regulation is made up of a set of formal institutions, i. e. codified rules, which aim to determine social actors' practices. Strategic alliances are long-term cooperative relationships voluntarily established between two or more autonomous companies with shared interests and goals to create competitive advantage. Clinical-trial strategic alliances are organized according to the contractual relationship and parties' relational capabilities that aim to overcome difficulties in the partnership activities and ensure intercompany cooperation, reflecting on organizational efficiency and effectiveness, and impacting on alliance performance. This work developed a critical review of the literature and expanded it through the establishment of novel relational propositions regarding the relationship between formal regulatory institution of countries and strategic alliances for clinical trial of new medicines.

Keywords: formal institution, regulation, relational capability, interorganizational relationships, strategic alliance performance.

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The present theoretical development study was conducted to assess the relationships between formal regulatory institutions at the country analysis level, the relational capability and performance of clinical-trial strategic alliances. Formal institutions are understood as the codified rules that encompass the constitutions, the legal systems, the rules of regulatory agencies, the statutes, and social contracts in each country (Raza, Muffatto & Saeed, 2019; Williamson, 2000). On the other hand, relational capability refers to alliance management activities.

The countries' regulatory institutions have been studied regarding their relationship with foreign capital investment. However, there are no studies that address their relationship with the operational capabilities and performance of companies in a specific sector of the economy as proposed in the present study. Therefore, the focus here was to evaluate the relationship of the country's formal regulatory institutions with the development of the operational activities of companies in a specific economic sector, that is, the segment of clinical trials in the pharmaceutical industry.

A contract research organization (CRO) is a company specialized in providing research and development (R&D) services in the pharmaceutical industry, which plays an important role conducting clinical trials of new drugs through contractual strategic alliances. Clinical trials are tests of new drugs in humans, corresponding to a phase of the R&D process of new medicines. The pharmaceutical industry made a global investment in R&D estimated at USD 172 billion in 2018, presenting an average annual growth of 4.4% between 2013 and 2018 (Association of the Pharmaceutical Research Industry - INTERFARMA, 2019). CRO's alliances with the pharmaceuticals enable the reduction of industry's research costs, promoting greater economic efficiency (De Pinho Gomes, Pimentel, Landim & Pieroni, 2012).

Conducting clinical trials through collaborative R&D arrangements unites autonomous companies, the pharmaceuticals and CROs, in the drug innovation process through a contractual relationship that characterizes the organizational form of alliance (Williamson, 1991; Howard, Steensma, Lyles & Dhanaraj, 2016).

In this context, the following research question arises: How do formal regulatory institutions at the country analysis level relate to relational capability and performance of contractual strategic alliances to conduct clinical trials of new medicines in the pharmaceutical industry?

The answer to this question involves the approach to the country formal regulatory institutions, i.e., the legal system, the Constitution, the regulatory rules of government agencies, the statutes, and social contracts (North, 1990; Williamson, 2000), and the organizational form of strategic alliance (Ménard, 2006) used in the pharmaceutical industry for the R&D phases of new drugs.

The goal of the present study is to extend the theory deductively, through a critical literature review, proposing the conceptual relationships involved between the constructs of interest. It is noteworthy that the propositions generated involving formal regulatory institutions and strategic alliances are tentative propositions, the product of critical reflection, and require future empirical tests.

Literature Review

The constructs addressed in the present study were formal institutions, alliance management capability or relational capability, and strategic alliance performance. Strategic alliance and formal institutions were considered from New Institutional Economics perspective. The relational capability was considered addressing the capability approach in Strategic Management.

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Formal regulatory institutions

Institutions are defined as the rules of the game in a society. They are restrictions of human origin that shape interactions in society (North, 1990). According to North, institutions play a role that directly links them to the behavior of individuals. They are divided into formal institutions represented by the Constitution, legal system, rules of regulatory agencies and contracts; and informal institutions that refer to rules or codes of conduct created in society and without legal frameworks (North, 1990; Raza et al., 2019; Preusler, da Costa, Crespi & Porto, 2020).

Informal institutions differ from formal institutions in several ways. Informal institutions are human constraints designed to structure political, economic, and social interactions (North, 1991). They are perceived as restrictions on change, informally circumscribed by aspects derived from culture. They also represent traditions and customs, the spontaneous changes associated with cultural heritage and historical experience that guide the paths followed by society, representing accepted patterns of social coexistence (North, 1991; Williamson, 2000).

It is worth mentioning that informal institutions are traditions and the code of conduct. As these institutions are spontaneous, they represent natural inertia, that is, the slow changes that have taken place over centuries or millennia (Williamson, 2000; Boudreaux, Nikolaev & Klein, 2018). Therefore, these institutions have little flexibility in relation to changes made through formal institutions, that is, legal rules. Although, Holmes Jr. et al. (2013) pointed out that informal institutions can be shaped by formal institutions through collective cultural dimensions through the time.

Formal institutions are the coded social rules, such as through written codes. (Williamson, 2000). In this sense, North's institutional theory (1990) explains that formal institutions are the result of the solidification of the components of informal institutions that co-evolve over time, proving to be effective for a social group.

In this way, they allow government and its agencies to structure formal regulatory procedures for the development of activities in the sectors of the economy (Gomes-Casseres, 1996; Fuentelsaz, González & Maicas, 2018). They are outlining tools that support economic transactions and are used in a pragmatic dimension to regulate and standardize market activities. They have the potential to undermine or optimize the performance of organizations, delay or catalyze positive changes, and limit the impacts of negative market factors (North, 1991).

The institutional regulatory environment of countries is constituted by formal institutions with national coverage which are classified as regulatory, political, and economic (Holmes Jr. et al., 2013). Regulatory institutions establish rules that refer to the role and relationship of social actors, such as the forms of participation of foreign companies in the economy, adoption of barriers to technology, corporate governance, and corruption. Political institutions focus on the norms relating to the participation of the social actors in the formulation process of rules that govern the country. Finally, economic institutions organize the economic activity and relationship of social actors through economic transactions in countries (Boudreaux et al., 2018; Raza et al., 2019).

The assessment of formal regulatory institutions, from the perspective of the rules of the formal game, which represents the evolution of legal processes of states, the normative improvement of the rules encoded in the constitutions, laws, and property right of the countries, has indicated the existence of harmony between formal and informal institutions (Williamson, 1991). However, the origin of compatibility lies in the adequacy of the institutional environment (Williamson, 2000).

The focus of the present study is on formal regulatory institutions of countries and its impact on activities of contract research organisations (CRO)'s alliances with the pharmaceuticals for developing new medicines. In the next sections, we review synthetically the literature on alliances.

Strategic alliances and relational capability

Strategic alliance is a voluntary cooperative agreement between two or more companies to organize and carry out joint long-term production, distribution or marketing activities (Ménard, 2006; Almeida & Costa, 2017). This economic transaction between partners is based on cooperation, using relational contracts that generate interdependencies and consensus between parts (Leischnig & Geigenmüller, 2018).

Those arrangements are hybrids, characterized by combining elements of governance structures of market and hierarchical (Williamson, 1991; Ménard, 2006). Alliances are characterized by the parties' autonomy as in the market governance structure, and by the integration and knowledge of the parties involved regarding the operational and strategic plans as in hierarchical governance structure (Howard et al., 2016).

Relational capability guarantees the functioning of strategic alliances, managing the inter-organizational relationship between the parties involved. It constitutes an additional interorganizational coordination mechanism to the relational contract between the parties (Ménard, 2006; Lima Nogueira & Bataglia, 2018). These governance structures determine activities developed in the alliance and their distribution among the partners, guide the development of actions in the parties, the integration mechanisms, the operational interfaces, and the resolution of eventual conflicts.

Relational capability is the organizational capability to manage alliances, which can be considered a dynamic capability with the potential to deliberately create, expand or modify the resource bases of partners with the vital objective of obtaining competitive advantages (Helfat et al., 2009). In this way, it is used to obtain complementary resources, in order to use synergies and gather or transfer resources (Yoona, Rosalesb & Tallurib, 2018).

CROs and pharmaceuticals have been conducting clinical trials of new medicines through contractual strategic alliances. This activity organized together constitutes one stage in the R&D process for new drugs (De Pinho Gomes et al., 2012; Shakeri & Radfar, 2017).

It aims to test molecules with synthetic and semi-synthetic active ingredients, associated or not, in humans for conversion into new medicines to be used in society.

CROs and the pharmaceuticals use relational capability routines to manage and guide several alliance management different and interrelated activities (Almeida & Costa, 2017; Hoang & Rothaermel, 2016). These routines are interorganizational and portfolio coordination, organizational learning, proactiveness and alliance transformation (Schilke & Goerzen, 2010). Inter-organizational coordination refers to organizing, dividing and integrating the activities that will be developed by the partners. Coordination of the alliance portfolio focuses on optimizing the organization's alliance portfolio by managing the relationships between alliances. The organizational learning routine is related to the management activities of capturing and retaining knowledge from activities developed jointly with partners. The proactive routine is composed of activities related to the scaning of the external environment in order to identify new potential partners and opportunities. Finally, the alliance transformation routine refers to activities of evaluating and implementing changes when an alliance is obsolete.

Knowledge acquired through the experience in managing previous partnerships influences the creation of routines to manage new alliances (Rothaermel & Deeds, 2016; Almeida & Costa, 2017). In this sense, the existence of an organizational structure for managing alliances becomes critical (Schilke & Goerzen, 2010).

The formal institutions of countries (regulatory, political, and economic) may facilitate or undermine the relational capability of partners in strategic alliances for clinical trials, influencing the perception of business opportunities, amplifying, or reducing the number and complexity of activities necessary to manage the alliances, and eliminating or creating barriers in the communication that guides specific goals and results for a given period (Fuentelsaz et al., 2018).

Alliance performance

According to Aguinis (2013), the performance of strategic alliances is measured by the ability to produce results in the organization or in a group of organizations. Therefore, it is essential to monitor and manage the entire process that involves setting goals and objectives in a continuous manner, observing the results, and giving and receiving training and feedback in a sequence, apparently without intervals. This continuous process indicates that the dynamics of performance management is always present in the activities that align objectives, create links between results and goals of strategic alliances, and express individuals' contribution. Managing performance means coordinating behaviors, because performance and deliberate practices are related and influence organizational effectiveness (Aguinis, 2013).

According to Cordeiro and Bataglia (2015) and Schilke and Goerzen (2010) the performance of alliances is usually measured by their manager's perception of the following dimensions: general satisfaction, interorganizational learning, achievement of initial strategic objectives, and profitability with the alliance.

An example of the effectiveness of strategic alliances in the pharmaceutical industry is the partnership between Bayer HealthCare and the German Cancer Research Center (*Deutsches Krebsforschungszentrum* [DKFZ], 2019). The important factor in the alliance was the collaboration in research, which allowed the generation and implementation of new ideas. The cooperation between the organizations affected the quality of the results. It allowed deepening investigations on the mechanism of cancer, modifying the results of idea generation, and developing new target ideas (Walsh, Lee & Nagaoka, 2016). It also influenced the exploration of the ideas during the implementation of emerging areas of cancer-related research. The interactions between partners made the German Cancer Research Center raise the standard of clinical research in high-quality scientific work, perform the recombination of knowledge and tacit knowledge flows (Walsh et al., 2016), and concentrate on new mechanistic tests. On the other hand, Bayer improved its expertise in drug development, regulatory approvals from agencies, sales and marketing, the development of pre-clinical drugs and trials through high-throughput screening, medicinal chemistry, and a compound library (DKFZ, 2019).

This alliance allowed the partners to share financing and risks in all implemented projects (Serrat, 2017). The collaboration created project teams in conjunction with the involvement of companies in activities such as scientific conferences, visits, and seminars. This strategic R&D alliance created a partner licensing option, made it possible for partner companies to benefit from each other's licenses, even if they had other alliances (Walsh et al., 2016; DKFZ, 2019). In this example, Bayer had a licensing option for partnership results that helped in the development of projects for successful commercial products. In this context, the German Cancer Research Center benefited from the financial income that Bayer obtained through this business.

The alliance between Bayer HealthCare and the German Cancer Research Center allowed creating a budget managing committee and a joint research review commission. The committee and the commission were responsible for recommending the projects in which the coalition should participate (Otte-Trojel at al., 2017). Alliance managers were guaranteed a seat in the committees formed by the partners. Thus, this strategic alliance has been successful over the years based on management.

The assessment of this alliance made it possible to determine key success factors such as: collaboration at the same level, promoting interactions; exchange of experiences with a long-term view; scientific cooperation with theoretical development, based on the comparison of studies conducted by individual partners; reduction of management and decision-making obstacles; reduction in the bureaucratic level, given that the same individuals worked in the various projects; and reduction of expenses and improvement in the investments (Martins, 2016; Preusler et al., 2020). Finally, the success factor in the performance of the assessed strategic alliance was the incentive successfully applied, which enabled the achievement of defined goals through the issurance of the necessary reports, as well as by managing the alliance.

Relationships Between Formal Regulatory Institutions and Strategic Alliances for New Medicines

The following propositions explain the relationship between the constructs under analysis in the domain of contractual strategic alliances for clinical trials (Figure 1).

Formal institutions, i.e., rules, laws, and codified procedures, whether in the economic, political, or regulatory field (Holmes et al., 2013), are transformed into regulatory procedures carried out by governmental agencies that monitor compliance of companies (Gomes-Casseres, 1996). They can enhance positive or negative aspects for carrying out the activities of organizations (North, 1991; Holmes et al., 2013), such as those linked to clinical-trial alliances.

For example, regulatory mechanisms that allow faster importation and less bureaucracy for medicines or substances that will be used in clinical trial affect its speed and time. These mechanisms require less coordination and integration activities performed by the partners to provide information, fill out and distribute documents, clear products at customs, and organize and carry out the activities in which the imported components will be applied.

Another example is when a clinical trial proposal is assessed by the regulatory agency as non-regulatory. In this case, new activities related to relational capability are necessary, increasing the number of activities such as sending e-mails, making phone calls and scheduling clarification meetings with the regulatory body; and if necessary, articulating the partners to obtain the necessary information for the response to the agency.

Formal institutions are references in the development of routines for relational capability, i.e., for managing the operational activities of the clinical-trial alliance and may require a greater or lesser number of alliance management activities according to their nature.

Following these lines, we argue:

> **Proposition 1:** Formal regulatory institutions influence the incidence of relational capability activities within the scope of clinical-trial strategic alliances.

Formal institutions relate to the performance of clinical-trial strategic alliances once they enforce the compliance of the operational activities of the clinical trial with existing rules set by governmental agencies (Holmes et al., 2013), thus increasing costs and therefore decreasing the alliance performance.

For example, regulatory mechanisms that increase bureaucracy in imports can promote the decrease of efficiency and effectiveness of the clinical trial, through reducing its speed and amplifying its time, therefore compromising its performance.

The instability of the rules can also have an impact on the performance of strategic alliances by increasing uncertainties (North, 1990) and costs, as in the example of the importation regulation used in the argument supporting Proposition 1 that can generate increases in storage costs.

The organizational structure of governmental agencies can also generate uncertainty when they are composed of units and subunits. The units centralize the decision-making process, whereas subunits delegate the process to local agents at the community level (Raza et al, 2019). In this case, the challenge is the existence of local institutions within unitary agencies, ensuring the division of power. Thus, the unit cannot change the rules and procedures for facilitating activities of clinical trials without the approval of the subunits (Gomes-Casseres, 1996). The approval process creates an interdependence between the various governmental levels involved. For governmental agencies, this is a complex challenge that can result in decreasing of clinical trial performance.

Based on the reasoning developed in the previous paragraphs, the new proposition arises:

> **Proposition 2:** Formal regulatory institutions influence the performance of clinical-trial strategic contractual alliances.

By one hand, relational capability influences positively the alliance performance because it is associated with value creation through activities to share knowledge between partners (Shakeri & Radfar, 2017); management of the dependence on complementary resources (Martins, 2016; Yoona et al., 2018; Preusler et al., 2020); and the development joint activities, aimed to reduce uncertainties related to issues on the regulation, market and technology (Schilke & Goerzen, 2010; Shakeri & Radfar, 2017; Leischnige & Geigenmüller, 2018).

The same example of importation regulation used in the argument supporting Proposition 1 can be used here. If we have less bureaucracy for importing medicines or substances that will be used in a clinical trial, this generates less relational management activities aimed to minimize the dysfunctional influence of the bureaucratic process, reducing costs and therefore increasing the alliance performance.

By the other hand, formal institutions are references in the development of activities of the relational capability, i.e., are references for managing activities of the clinical trial, and may require a greater or lesser number of alliance management activities according to their nature, increasing alliance management costs, and therefore negatively influencing the alliance performance. As in the example used in the argument of the Proposition 1 on clinical trial proposal refused by the regulatory agency, in which new activities related to relational capability had to be developed by partners to respond to the agency, increasing costs and therefore decreasing the alliance performance.

Consequently, the following proposition enunciated and tested by Schilke and Goerzen (2010) arises:

> **Proposition 3:** Relational capability influences the performance of strategic alliances in the clinical trial sector.

The relationship of relational capability to the performance of clinical-trial alliances is related to alliance management activities that

optimize the allocation of resources, the assignment of tasks, and the synchronization of alliance operational activities developed by partners to maximize the alliance performance (Schilke and Goerzen, 2010; Goffredo & Battaglia, 2015). The rules and procedures defined by the governmental agencies establish the order in which companies operate and face unforeseen changes in the market (Holmes Jr. et al., 2013). Therefore, relational capability activities manage the development of operational activities in the clinical trial, guarantying the compliance between them and the regulatory matrix of the market.

However, the improvement in performance is limited by regulation given the condition of enforcement of existing rules that cannot be changed. This establish limits to what can be done to optimize the alliance operational activities, leading to a reduction on the influence of the relational capability into the performance.

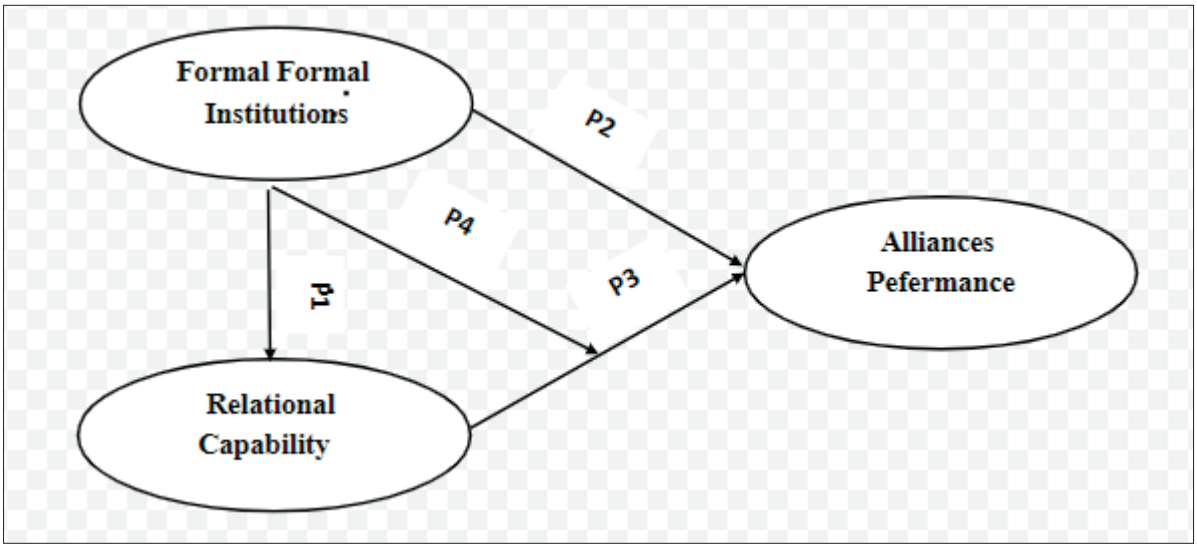
For example, it is not possible to expedite customs clearance of an imported item that is required to carry out the clinical trial if partners do not follow the legal procedures established in the institutional matrix for testing of new medicines in the pharmaceutical market of the country in which they are operating, limiting the ability of the relational capability activities for increasing speed, time, and therefore the alliance performance.

Following these lines, we argue:

> **Proposition 4:** Formal institutions moderate the relationship between relational capability and the performance of clinical-trial strategic alliances.

Summing up, the relationship between the constructs involved generated three novel propositions in the context of strategic alliances (P1, P2 and P4), according to the conceptual model proposed in Figure 1. Proposition 3 had been proposed by Shilke and Goergen (2010).

Figure 1. Proposed model of the relationship between the constructs.



Source: Prepared by the authors based on the relationships assessed.

Final Considerations

The present study assessed the relationships between formal institutions at the country analysis level, relational capability, and performance of clinical-trial strategic alliances.

The main conceptual implication of the model presented in this paper to the public health and public administration literatures is that formal institutions, at the country analysis level, can influence clinical trials performance, promoting or restricting the investment in new clinical trials in countries, directly impacting the availability of new medicines, and therefore the life quality of populations.

Another conceptual contribution of this paper to the organizational economics literature in administration and economics areas is that the model proposed indicates the need to define a research agenda on the role of formal regulatory institutions at economic sector levels, once the existing research is focused on the relationship between formal institutions and the inward foreign direct investment in countries, preventing the analysis of their impact by economic sector.

Other conceptual contribution of this paper to the alliance literature in the administration area is that the investment in relational capability activities is important to reduce the uncertainty of alliances, increasing their performance, in general and to clinical-trial alliances.

From the practical point of view, by one hand, this paper contributes to public health managers by highlighting the need to evaluate the impact of their decisions, with force of law by the discretionary power usually attributed to them by constitutions, in the operational

activities and performance of clinical trials. It is also noteworthy to public managers as a consequence of this paper the need to establish and practice clear democratic procedures in the regulation of governmental agencies permitting the participation of all agents in the discussion of new rule decisions for guaranteeing the access to different points of view and interests involved in the markets regulated.

By the other hand, this paper suggests that pharmaceutical companies and their executives consider the comparative analysis of the countries' regulations and their impact in clinical trials before new investments in their development in different countries.

It is worth highlighting that the presented model is constituted of tentative propositions that must be tested in future empirical tests.

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