Revista Review Index Journal of Multidisciplinary 2022; 2(4):15-21
e-ISSN: 2583-0031
Double-blind peer-reviewed | Refereed Quarterly Online Journal

RESEARCH PAPER

A study on Institutional oversight and the effectiveness of clinical trial strategic alliances

*Nisha R Rijhwani

Research Scholar, Saurashtra University, Rajkot, Gujarat

Abstract

This research seeks to evaluate the efficacy and efficiency of clinical-trial strategic partnerships by examining their connections to the country's regulatory agencies. The country's formal institutions, i.e. its defined norms, are what ultimately govern the behaviour of social actors. A strategic alliance is a voluntary, long-term cooperation arrangement between two or more independent businesses with complementary strengths and objectives in order to gain a market advantage. Organizational effectiveness and efficiency are reflected in the performance of clinical-trial strategic alliances, which are structured according to the contractual relationship and the relational capabilities of the parties to overcome challenges in the partnership's activities and ensure intercompany cooperation. This research built on a previous critical literature assessment by proposing new hypotheses on the connections between national regulatory bodies and international partnerships for testing experimental pharmaceuticals in humans.

Keywords: *regulation, formal institution, interorganizational relationships, relational capability*

Article Publication

Published Online: 31-Dec-2022

***Author's Correspondence**

Nisha R Rijhwani

Research Scholar, Saurashtra University, Rajkot, Gujarat.

nishar.rijhwani72@gmail.com

10.31305/rrijm2022.v02.n04.004

Scan and access Online

Introduction

The current theoretical development research was carried out with the intention of analysing the links that exist between formal regulatory institutions on a country-by-country basis, as well as the relational capabilities and performance of clinical-trial strategic alliances. In each nation, the formal institutions may be considered to be the codified norms that include the constitutions, the legal systems, the regulations of regulatory bodies, the statutes, and the social contracts (Raza, Muffatto & Saeed, 2019; Williamson, 2000). On the other side, the term "relational competence" refers to the actions involved in alliance management.

The regulatory institutions of the nations have been investigated with reference to their interaction with international investment capital. On the other hand, there are no studies that examine their link with the operational capabilities and performance of enterprises operating in a particular sector of the economy, which is what the current study proposes. As a result, the primary objective of this study was to evaluate the relationship between the formal regulatory institutions of the

country and the growth of the operational activities of companies operating within a particular economic sector, specifically the subset of the pharmaceutical industry that is concerned with conducting clinical trials.

In the pharmaceutical industry, a company that specialises in providing research and development (R&D) services is known as a contract research organisation, or CRO for short. CROs play an important part in the process of conducting clinical trials of new drugs through the use of contractual strategic alliances. The phase of the research and development process that corresponds to the testing of novel medications on humans is known as clinical trials. In 2018, the pharmaceutical sector made a global investment in research and development that was expected to be worth USD 172 billion. This represents an average yearly growth of 4.4% between 2013 and 2018. (Association of the Pharmaceutical Research Industry - INTERFARMA, 2019). Alliances between CROs and pharmaceutical companies enable a decrease in the research expenses incurred by the business, which in turn promotes improved economic efficiency (De Pinho Gomes, Pimentel, Landim & Pieroni, 2012).

Through a contractual relationship that exemplifies the organisational form of alliance, independent companies, such as pharmaceuticals and CROs, are brought together in the process of developing new drugs as a result of conducting clinical trials as part of collaborative research and development arrangements (Williamson, 1991; Howard, Steensma, Lyles & Dhanaraj, 2016).

In light of this information, the following research question presents itself: How do formal regulatory institutions at the country analysis level relate to the relational capability and performance of contractual strategic alliances to carry out clinical trials of new medicines in the pharmaceutical industry?

The response to this question is found in the method of approaching the country's formal regulatory institutions, such as the legal system, the Constitution, the regulatory rules of government agencies, the statutes, and social contracts (North, 1990; Williamson, 2000), as well as the organisational form of strategic alliance (Ménard, 2006) that is utilised in the pharmaceutical industry for the research and development phases of new drugs.

The purpose of the current investigation is to deductively expand the theory by conducting a critical literature research with the intention of suggesting the conceptual linkages that are involved between the constructs that are of interest. It is important to highlight that the propositions that were developed regarding formal regulatory institutions and strategic alliances are only hypotheses at this point. These propositions are the result of critical thinking, and they will need to be tested in the future using empirical data.

Literature Review

Formal institutions, alliance management capability (or relational capability), and strategic alliance performance were the topics of this investigation. The New Institutional Economics framework was used to the study of formal institutions and strategic alliances. As part of an effort to address the capability approach in Strategic Management, the concept of relational capability was explored.

Formal Regulatory Institutions

Definition: Institutions are a society's set of norms and expectations for how things should be done. These limitations are imposed by humans and have an effect on how people interact (North, 1990). North argues that institutions have effects on people's actions because of the function they play in society. The Constitution, courts, laws, and regulations all fall under the category of formal institutions, whereas social norms and contracts fall under the category of informal institutions (North, 1990; Raza et al., 2019; Preusler, da Costa, Crespi & Porto, 2020).

There are a number of ways in which informal institutions diverge from their more formal counterparts. The political, economic, and social relations of a society are governed by informal institutions, which are only the results of human restrictions (North, 1991). They are seen as barriers to transformation, with their cultural origins forming an informal

boundary. They also stand for recognised social patterns of cohabitation, such as traditions and customs, which are the impromptu shifts linked with a society's cultural history and historical experience (North, 1991; Williamson, 2000).

Notable examples of informal institutions are customs and norms of behaviour. Due to their organic nature, these institutions are indicative of natural inertia, or the gradual evolution of societies over long periods of time (Williamson, 2000; Boudreaux, Nikolaev & Klein, 2018). As a result, there is not much leeway for these organisations to adapt to alterations made by formal institutions, such as the principles of law. In spite of this, as Holmes Jr. et al. (2013) noted, formal institutions have the power to mould informal ones over time via the collective cultural characteristics of a given society. The social norms codified in formal organisations include written codes. Williamson (2000) says. According to North's institutional theory (1990), established institutions are based on the consolidation of informal institution parts that have co-evolved and proven useful to a society.

This paves the way for the government and its agencies to set up official regulatory processes for the growth of activities across economic sectors (Gomes-Casseres, 1996; Fuentelsaz, González, & Maicas, 2018). They are describing mechanisms that underpin monetary exchanges and are put to use in a realistic sense to standardise and govern market operations. They can impede or boost productivity in businesses, slow down or speed up positive development, and mitigate the effects of unfavourable market conditions (North, 1991).

Countries' institutional regulatory environments are made up of regulatory, political, and economic institutions having national scope (Holmes Jr. et al., 2013). Institutions charged with regulation create norms on the conduct of businesses and other social actors, such as the extent to which multinational corporations can participate in an economy, the acceptance of technological obstacles, corporate governance, and the prevention of corruption. The laws that govern a country are developed in a political institution, and its primary concern is the norms that regulate how social actors can and should be involved in that process. Last but not least, economic institutions coordinate the interactions between various social players in a country's economy (Boudreaux et al., 2018; Raza et al., 2019).

Harmony between formal and informal institutions has been demonstrated through an analysis of formal regulatory institutions through the lens of the rules of the formal game. These rules represent the development of legal processes within states and the normative improvement of the rules encoded within the constitutions, laws, and property rights of each country (Williamson, 1991). However, an appropriate institutional setting is where compatibility begins (Williamson, 2000).

Contract research organisation (CRO) agreements with pharmaceutical companies to produce novel treatments are the subject of this research. The following sections provide a synthesis of the literature on alliances.

Strategic alliances and relational capability

In order to arrange and carry out combined long-term manufacturing, distribution, or marketing operations, businesses may form strategic alliances (Ménard, 2006; Almeida & Costa, 2017). Cooperative relational contracts provide interdependencies and consensus among the parts in this economic transaction (Leischnig & Geigenmüller, 2018).

These kinds of systems are known as hybrids because they combine features of market and hierarchical control (Williamson, 1991; Ménard, 2006). Similar to the decentralised nature of a market-based governance structure, alliances are distinguished by its members' individual freedom within the context of shared decision-making and information on operational and strategic goals (Howard et al., 2016).

Successful strategic alliances rely on relational competence, which is the capacity to manage the inter-organizational links between its constituent members. In addition to the relational contract between the parties, it acts as an interorganizational coordinating mechanism (Ménard, 2006; Lima Nogueira & Bataglia, 2018). Alliance actions, integration procedures,

operational interfaces, and dispute resolution are all guided by these governance structures, which dictate how alliance activities are produced and distributed among participants.

The capacity of a business to manage alliances, or its "relational aptitude," is a dynamic capability with the potential to develop, grow, or adjust the resource bases of partners with the essential goal of acquiring competitive advantages (Helfat et al., 2009). As such, it is employed to amass or transfer resources, as well as to make advantage of synergies between them (Yoona, Rosalesb & Tallurib, 2018).

Strategic partnerships between contract research organisations (CROs) and pharmaceutical companies have enabled the conduct of clinical studies of potential new medications. The R&D process for novel medications includes stages like the ones described below (De Pinho Gomes et al., 2012; Shakeri & Radfar, 2017).

It attempts to conduct human trials of synthetic and semi-synthetic compounds containing active components with the ultimate goal of developing them into novel therapeutics for widespread usage in society.

Relational capacity procedures are used by CROs and pharmaceuticals to manage and steer a variety of alliance management operations that are distinct from one another but are interconnected (Almeida & Costa, 2017; Hoang & Rothaermel, 2016). Interdepartmental and portfolio coordination, as well as organisational learning, proactiveness, and alliance transformation are examples of such practises (Schilke & Goerzen, 2010). The term "inter-organizational coordination" is used to describe the process of planning, dividing, and integrating the efforts of many entities to create a single whole. Managing the ties across alliances is a key part of alliance portfolio coordination, which aims to maximise the value of the partnerships your company has formed. Capturing and storing insights gained via collaborative activity is an integral aspect of management, and hence an integral part of the organisational learning process. Tasks connected to scanning the external world for new possible partners and opportunities make up the proactive routine. When an alliance has become irrelevant, it is time to evaluate it and make any necessary adjustments, which is what the alliance transition procedure entails.

The development of practises for managing new alliances is informed by the knowledge gained from managing existing ones (Rothaermel & Deeds, 2016; Almeida & Costa, 2017). Thus, it is essential that there be a system in place for overseeing coalitions (Schilke & Goerzen, 2010).

Countries' formal institutions (regulatory, political, and economic) can boost or hinder the relational capability of partners in clinical trial strategic alliances by altering their outlook on business opportunities, increasing or decreasing the number and complexity of alliance management activities, and removing or erecting barriers to the communication that guides specific goals and results over a given time period (Fuentelsaz et al., 2018).

Alliance Performance

According to Aguinis (2013), the effectiveness of strategic partnerships may be evaluated based on their capacity to deliver outcomes within a company or within a consortium of companies. As a consequence, it is vital to monitor and manage the entire process, which includes creating goals and targets in a continuous way, evaluating the results, and offering and receiving training and feedback in a sequence, apparently without gaps. This ongoing process demonstrates that the dynamics of performance management are constantly present in the actions that align objectives, develop relationships between the results and goals of strategic partnerships, and represent people' contributions to the overall effort. Coordinating behaviours is an essential part of managing performance due to the correlation between performance and purposeful practises, both of which have an impact on the efficiency of a company (Aguinis, 2013).

According to Cordeiro and Bataglia (2015) and Schilke and Goerzen (2010), the performance of alliances is typically measured by their manager's perception of how well the alliance achieved its initial strategic objectives, interorganizational learning, general satisfaction, and profitability with the alliance.

The cooperation between Bayer HealthCare and the German Cancer Research Center is a good illustration of how beneficial strategic alliances can be in the pharmaceutical business (Deutsches Krebs for schungszentrum [DKFZ], 2019). The participation of both parties in joint research was a crucial component of the partnership, as it paved the way for the development and application of innovative concepts. The level of collaboration that took place between the companies had an impact on the standard of the outcomes. It made it possible to do more in-depth research on the mechanisms behind cancer, to adjust the outcomes of idea creation, and to discover new ideas for potential targets (Walsh, Lee & Nagaoka, 2016). Additionally, it had an impact on the investigation of hypotheses throughout the process of carrying out research in newly developing cancer-related fields. Because of the interactions between partners, the German Cancer Research Center was able to increase 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 developing 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. All of these areas are important for the pharmaceutical industry (DKFZ, 2019).

Because of this partnership, the partners were able to share risks and finance for all of the projects that were carried out (Serrat, 2017). The relationship resulted in the formation of project teams, and it also encouraged the participation of businesses in various events, including scientific conferences, site visits, and seminars. This strategic R&D partnership produced a partner licencing option and made it feasible for partner firms to benefit from each other's licences, even if the partner companies participated in other alliances at the same time (Walsh et al., 2016; DKFZ, 2019). In this particular illustration, Bayer offered a licence choice for collaboration outcomes that aided in the creation of initiatives for prosperous commercial items. In this scenario, the German Cancer Research Center gained monetarily from Bayer's success in achieving its financial goals through the operation of this firm.

The collaboration between Bayer HealthCare and the German Cancer Research Center resulted in the establishment of a committee for the management of the budget as well as a commission for the joint assessment of research. Both the committee and the commission were tasked with the duty of making recommendations about the projects in which the coalition should take part (Otte-Trojel at al., 2017). The seats in the committees that were constituted by the partners were reserved specifically for the alliance management. According to the administration of this strategic relationship, it has been successful throughout the course of the years.

As a result of the evaluation of this alliance, it was possible to identify key success factors such as the following: collaboration at the same level, promoting interactions; the 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; an increase in the amount of information shared between the various projects; an increase in the amount of information available (Martins, 2016; Preusler et al., 2020). Lastly, the incentive that was effectively used was the success factor in the performance of the evaluated strategic alliance. This incentive permitted the attainment of stated goals through the issurance of the appropriate reports, as well as through managing the alliance itself.

Connections Between Traditional Regulatory Bodies and Business Partnerships Dedicated to Developing Innovative Medications

Whether in the political, economic, or regulatory spheres (Holmes et al., 2013), formal institutions take the shape of rules, regulations, and codified processes, which are then implemented by government agencies to ensure that businesses are in line with these standards (Gomes-Casseres, 1996). Organizational actions, such as clinical-trial partnerships, can be impacted positively or negatively by these factors (North, 1991; Holmes et al., 2013).

Time and speed are affected by factors such as the ease with which drugs or other substances needed in clinical trials may be imported and utilised, and the number of red tape hoops that must be jumped through. These procedures reduce the amount of work that must be done by the partners in order to share data, complete paperwork, get goods through customs, and plan and execute the processes in which the imported materials will be used.

Another case in point is when a clinical trial plan is deemed to be outside the scope of regulation by the relevant authorities. Sending emails, picking up the phone, and setting up clarification meetings with the regulatory body are all examples of new activities related to relational capability that may be required, as is, if necessary, articulating the partners to obtain the required information for the response to the agency.

A higher or fewer number of alliance management activities may be necessary depending on the nature of the formal institution used as a reference in developing routines for relational competence, i.e. for managing the operational activities of the clinical-trial alliance.

When formal institutions ensure that the clinical trial's operational operations adhere to preexisting standards defined by government authorities (Holmes et al., 2013), they add unnecessary expenses and reduce the alliance's performance. Regulatory procedures that enhance bureaucracy in imports, for instance, can encourage the loss in efficiency and efficacy of the clinical study by slowing down the trial and increasing the time it takes to complete.

Government agencies may be another source of unpredictability due to their hierarchical structure, which is made up of units and subunits. At the community level, decisions are made centrally, whereas at the subunit level, authority is delegated to local agents (Raza et al, 2019). The problem here is that authority must be divided within unitary agencies, and this is achieved by the establishment of local institutions inside those organisations. As a result, the unit cannot alter the regulations and policies that govern clinical trial facilitation without the consent of the subunits (Gomes-Casseres, 1996). The approval procedure establishes a web of interdependence among the various levels of government. This is a difficult task for government agencies and has the potential to reduce the efficiency of clinical trials.

On the one hand, relational capability positively affects alliance performance due to its association with value creation via knowledge sharing activities, dependence management on complementary resources, and joint activity development aimed at lowering regulatory, market, and technological uncertainty (Shakeri & Radfar, 2017; Martins, 2016; Yoona et al., 2018; Preusler et al., 2020).

In this case, too, one may appeal to the identical example of importation control offered in favour of Proposition 1. There would be less need for relationship management efforts to reduce the dysfunctional impact of the bureaucratic process on the alliance's performance if it were easier to import drugs and other substances for use in clinical trials.

On the other hand, formal institutions serve as pointers in the development of relational capability activities, i.e., for managing clinical trial activities, and may call for more or fewer alliance management activities depending on their nature, increasing alliance management costs and thereby negatively affecting alliance performance. Proposition 1's reasoning about a rejected clinical trial proposal illustrates how this might happen: the partners have to come up with new relational capability activities to respond to the agency, which drives up costs and reduces alliance performance.

Final Considerations

In this study, we analysed formal institutions' connections to one another, their capacity for partnerships, and the impact they have on clinical trials.

This paper's model has important conceptual implications for public health and public administration literatures because it suggests that formal institutions can affect clinical trial performance at the level of the country analysis by either encouraging or discouraging investment in new clinical trials in countries, which in turn affects the availability of new medicines and, by extension, the quality of life for populations.

Although the existing literature focuses on the connection between formal institutions and the inward foreign direct investment in countries, limiting the analysis of their impact by economic sector, the model proposed in this paper indicates the need to define a research agenda on the role of formal regulatory institutions at economic sector levels.

Investment in relational capability activities is vital to minimise the uncertainty of alliances, boosting their performance, in general and to clinical-trial alliances, which is another conceptual contribution of this research to the alliance literature in the administration domain.

On the one hand, this paper makes a practical contribution to public health managers by drawing attention to the importance of assessing the impact of their decisions, given the legal weight afforded to them by the discretionary authority typically accorded to them by constitutions, on day-to-day operations and the conduct of clinical trials. This paper's findings also highlight the importance to public managers of establishing and following clear democratic procedures in the regulation of government agencies, which would allow all agents to participate in the discussion of new rule decisions and ensure that all relevant perspectives and interests in the regulated markets would be taken into account.

On the other hand, this article recommends that, before investing in the development of pharmaceuticals in other countries, pharmaceutical firms and their executives conduct a comparative review of the nations' rules and the influence on clinical trials.

References

[1] Almeida, J. D., & Costa, P. D. (2017). Development of relational capability in technology-based companies in the information and communication technology sector. International Journal of Managerial Studies and Research, 5(4), 119-126.

[2] De Pinho Gomes, R. D. P., Pimentel, V. P., Landim, A. B., & Pieroni, J. P. (2012). Clinical trials in Brazil: international competitiveness and challenges. BNDES Sectorial, 36, set. 2012, 45-84.

[3] Gofredo, T. R., & Bataglia, W. (2015). The synchronization mechanisms in strategic alliances. Administration Journal of the Federal University of Santa Maria, 8 (4), 633-649.

[4] Hoang, H., & Rothaermel, F. T. (2016). How to manage alliances strategically. MIT Sloan Management Review, 58(1), 69-76.

[5] Holmes Jr, R. M., Miller, T., Hitt, M. A., & Salmador, M. P. (2013). The interrelationships among informal institutions, formal institutions, and inward foreign direct investment. Journal of Management, 39(2), 531-566.

[6] Leischnig, A., & Geigenmüller, A. (2020). Examining alliance management capabilities in university-industry collaboration. The Journal of Technology Transfer, 45(1), 9-30.

[7] Otte-Trojel, T., Rundall, T. G., de Bont, A., & van de Klundert, J. (2017). Can relational coordination help inter-organizational networks overcome challenges to coordination in patient portals? International Journal of Healthcare Management, 10(2), 75-83.

[8] Schilke, O., & Goerzen, A. (2010). Alliance management capability: an investigation of the construct and its measurement. Journal of management, 36(5), 1192-1219.

[9] Shakeri, R., & Radfar, R. (2017). Antecedents of strategic alliances performance in biopharmaceutical industry: A comprehensive model Technological Forecasting and Social Change, 122, 289-302.

[10] Williamson, O. E. (1991). Comparative economic organization: The analysis of discrete structural alternatives. Administrative Science Quarterly, 269-296.

[11] Yoon, J., Rosales, C., & Talluri, S. (2018). Inter-firm partnerships–strategic alliances in the pharmaceutical industry. International Journal of Production Research, 56(1-2), 862-881.

How Cite this article?

Rijhwani, N. R. (2022). A study on Institutional oversight and the effectiveness of clinical trial strategic alliances. *Revista Review Index Journal of Multidisciplinary*, *2*(4), 15–21. https://doi.org/10.31305/rrijm2022.v02.n04.004