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# CROSS-FUNCTIONAL PROJECT GOVERNANCE IN PHARMA: A SYSTEMS THINKING APPROACH TO STRATEGIC EXECUTION

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## ABSTRACT

*Pharmaceutical project governance is becoming more challenging due to extended development timelines, stricter regulatory review, unpredictability, and cross-dependent, multifunctional tasks. The traditional forms of linear stage-gate governance, which were designed in a predictable environment, are often incapable of managing dynamic feedback, portfolio effects, and emergent risks. This research paper explores a systems thinking approach to the concept of cross-functional governance by examining data from 12 top managers working in three pharmaceutical companies involved in the vaccine and biosimilar programme. The identification of governance structures, feedback loops, cultural dynamics, and digital enablers was provided through semi-structured interviews, thematic analysis, and systems mapping. The results show that multilayered committees, informal influence networks, and feedback mechanisms have a net effect on decision-making, with cultural norms and digital tools playing a decisive role in coordination and transparency. An inter-case comparison illustrates trade-offs among formal hierarchy, decision speed, and relational governance. Building on these observations, the research developed a governance maturity model that shows how one can move from siloed to strategically agile governance. The model forms a pragmatic model of enhancement of the cross-functional alignment, strategic responsiveness, and portfolio management, thus making a theoretical and practical contribution to the domains of the governance-as-practice and systems thinking in pharmaceutical project management.*

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**KEYWORDS:** Pharmaceutical Project Governance, Systems Thinking, Cross-Functional Collaboration, Governance Maturity Model, Feedback Loops, Digital Enablers, Strategic Execution, Portfolio Management.

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## 1. INTRODUCTION

The current pharmaceutical project landscapes offer a more complex set of dimensions which include intense competition worldwide, accelerated regulatory routes, scientific ambiguity and dependencies throughout the lifecycle of drug development. The average of drug development is between ten and fifteen years, with high levels of attrition and increased cost, which add more pressure on the portfolio and strategic risk [9]. Projects require the coordination of regulatory affairs, clinical development, manufacturing, commercial strategy and portfolio governance. Delays experienced in a single process are often propagated throughout the system, increasing cost and timing implications. Strategic coherence inherently gets undermined by the complexity of portfolios and cognitive biases associated with making investment decisions [3].

Many organisations are still using linear and stage-gate models of governance that have been developed in a stable and predictable environment [1]. These models include sequential progress and stable information streams, delineated functional boundaries, and manageable risk, alongside hierarchical escalation as a means of alignment. In circumstances involving pharmaceuticals, these assumptions break down; data keep on changing, regulatory demands vary, manufacturing preparedness depends on clinical results and business strategic planning changes according to market indicators. Such interdependence is not possible in sequential decision structures.

The governance of a dynamic relationship between the stakeholders and feedbacks, however, escapes the management in static governance, which is understood by the modern governance studies [6]. The COVID-19 crisis revealed that systemic responsiveness depends not on the availability of resources itself, but on how much the systems can perform [7]. This research paper formulates and empirically evaluates systems-thinking-based model of governance of cross-functional pharmaceutical projects. It explores the practical workings of governance, the mechanism of feedback and execution, and the further strengthening of governance maturity to improve transparency, alignment, and strategic responsiveness.

## 2. LITERATURE REVIEW

Pharmaceutical organisations have project governance that operates in a very regulated and innovation intensive environment. The development of drugs is characterised by long cycles, scientific

flexibility, and high compliance commitment [9]. Portfolio governance should be a balance between scientific opportunity, financial exposure, and market timing, and the reduction of cognitive biases, including confirmation and champion bias, which distort the judgment of investment [3]. Research on governance-as-practice has shown that governance systems are developed in response to practitioners' interpretations, organisational context, and regulatory pressures, rather than as fixed structural templates [1]. However, much of the literature still approaches governance mainly through the prism of structural control and assumes the fact of formal subordination, stage-gate sequencing, and the recorded escalation as the guaranty of alignment and risk containment. This has been sustained by the logic that pharmaceutical organisations need auditability, regulatory defensibility, and traceable accountability. On the other hand, linear models fail in dealing with cross-functional interdependence and dynamic feedback at portfolio level. It has been demonstrated in dynamic evaluation research that contractual and relational forms of governance co-evolve with stakeholder networks [6], although it offers little clarification on how formal and informal mechanisms can be systematically combined.

Systems thinking is a more integrative approach, centred on feedback, causal interdependence, and nonlinear system behaviour instead of single points of decision-making [2]. The systems approach anticipates emergent effects and unintended consequences as opposed to linear assumptions of governance. The healthcare application of systems modelling proves that failure to adopt can be attributed to efforts to reinforce and balance feedback loops that are inherent in the organisational design [4]. Similarly, the implementation studies of pharmacy services suggest that the lack of feedback mechanisms inhibits the uptake of the services and participatory redesigning of the service recovers coherence [5]. However, such studies are more concerned with service execution than with sophisticated healthcare pharmaceutical portfolios, thereby creating a loophole in applying systems logic to strategic execution.

There is tension that is created through cross-functional collaboration. Digital transformation studies emphasise social interactions that are coordinated at organisational levels [11], and pharmaceutical companies research confounds the hypothesis that knowledge sharing and trust are related to innovation performance [12]. Conversely, such coordination is hampered by long standing silos and the existence of misaligned incentives [11]. These

structural and cultural dimensions are rarely brought together in a single model by governance theory. The politics of vaccine innovation reflect how the lack of coordination may limit fair and effective results [15].

Digital technologies are assured to be efficient and transparent in the pharmaceutical process [8]. Enterprise architecture models that utilise data suggest federated governance and harmonisation of both business and data domains [13]. Nevertheless, there is limited empirical evidence relating the adoption of AI or blockchain directly to the quality of governance. Relative to technological optimism, systems-based modelling reveals that digital infrastructure transforms the feedback structures but does not necessarily increase the quality of decisions [4]. Technology can support the silos already in place rather than fix them without a governance redesign. In general, as much as governance, systems thinking, collaboration and digital transformation are considered individually, there is still no developed empirically-based systems-based governance model of pharmaceutical project implementation, and especially at the executive decision level.

### 3. METHODOLOGY

#### 3.1 Research Design

The present study follows an exploratory qualitative multiple-case research design to investigate the subject of cross-functional project governance within pharmaceutical organisations. A multi-case design helps to make comparative inferences in the organisational context and maintain the depth and richness of the analysis [16]. The design is consistent with the views of governance-as-practice, which calls upon practitioner sense-making and the contextual performance of governance [1]. The study puts governance into a strategic perspective and operational realities by emphasising the interaction between the formal systems and informal sources of influence with executive views.

#### 3.2 Case Selection Criteria

Case A, Case B and Case C were pharmaceutical organisations which were purposely selected: large or mid-sized firms; active participation in vaccine or biosimilar programmes; a demonstration of complexity of cross-functional governance; and an expression of mature or developing systems of governance. The selection of these cases aimed to give a powerful representation of the environments where the intensity of regulation, portfolio complexity, and strategic urgency overlap, and offered detailed contexts to examine the interactions between governance and feedback processes [6, 7].

#### 3.3 Data Collection

Senior executives at the Vice President or Director level in regulatory affairs, clinical development, manufacturing/operations, commercial/market access, and PMO/portfolio governance were interviewed (n=12). Semi-structured interviews were chosen to produce deep contextually based interpretations of experiences and interpretations of the participants which agree with the principles of the qualitative management research [17]. The interviews were between sixty and ninety minutes in duration and took place either virtually or face-to-face and were recorded and transcribed according to the informed consent procedures. The interview protocol was designed around five systems-thinking areas: governance structure, feedback mechanisms, cross-functional alignment, strategic decision-making, and digital enablement. The topics covered escalation routes, informal information networks, risk dispersation, conflict settlement, the translation of portfolio priorities into project implementation, and the value of digital tooling in facilitating real-time governance visibility [4, 8, 11].

#### 3.4 Data Analysis

The analysis was done in three phases; in the first phase, thematic analysis based on open coding, axial coding, and pattern identification was used, which produced interpretive themes [18]. Second, systems mapping methods, such as causal loop charts and feedback cycle detection were utilised in order to unveil structural forces of perceived governance behaviour and chart bottlenecks [2, 4]. Third, cross-case analysis allowed to discover the archetypes and patterns of governance that distinguished between vaccine and biosimilar programmes and improve analytical rigour and contextual sensitivity [6].

#### 3.5 Development of Governance Maturity Model

The thematic analysis and systems-mapping insights were used to build a governance maturity model comprising five levels including Siloed Governance, Coordinated Governance, Integrated Governance, Adaptive Systems Governance, and Strategic Agile Governance. The levels demonstrate progressively higher complexity in terms of feedback integration, cross-functional alignment, and strategic responsiveness, which concurs with the literature on the correlation between governance maturity and organisational autonomy and agility [1, 3]. Cross-case triangulation and an expert feedback round with chosen participants were used to validate it

### 3.6 Research Quality and Trustworthiness

Methodological rigour was maintained through data triangulation within and between cases and functions, member checking, audit trail documentation and reflexive under consideration of researcher assumptions. Anonymisation and confidentiality of organisational and participant identities helped protect both organisational and participant identities, facilitating ethical integrity in the research. It is an organised method that incorporates systems thinking and governance-as-practice, producing not only data related to the issue but also a practical framework to improve governance across functions in complex pharmaceutical projects.

## 4. FINDINGS

The study involved twelve senior executives across three pharmaceutical organisations, assigned as follows:

- Case A: Participant 1, Participant 2, Participant 3, Participant 4
- Case B: Participant 5, Participant 6, Participant 7, Participant 8
- Case C: Participant 9, Participant 10, Participant 11, Participant 12

Participants represented regulatory affairs, clinical development, manufacturing and operations, commercial and market access, and PMO or portfolio governance functions. This mapping allows attribution of quotes and supports analysis across organisational contexts.

### 4.1 Governance Structures Observed

Multi-layered governance committees were in place in all cases, although their role and influence were different. Case A was based on formal hierarchy, under which accountability is important rather than speed. Participant 1 noted:

*"Decisions are escalated only after cross-functional sign-offs, which slows responsiveness but maintains accountability."*

By contrast, Case B had implemented dual-track review procedures that were faster but added the problem of inconsistency in alignments. Participant 6 stated:

*"Our committees operate in parallel tracks to accelerate approvals, though alignment can be inconsistent."*

Case C was dependent on informal networks of influence, which enhanced responsiveness but the possibility of opaque decisions. Participant 10 highlighted:

*"Often, relationships and informal conversations determine which issues reach executive attention first."*

It has been argued that committee layering can offer accountability, but may not ensure transparency and consistency. The assumptions of linear governance of predictable escalation and clear accountability fail in the highly interdependent pharmaceutical projects. Case A exhibits the trade-off between structure and speed, Case B is the trade-off between the two, and Case C demonstrates that relational networks can replace structure but at the expense of obscurity.

### 4.2 Feedback Loops in Practice

There was a significant difference in feedback mechanisms. In Case A, the cycles of the increase of risks were slow. Participant 2 observed:

*"Risk reports often circulate only monthly, which delays mitigation actions."*

Case B was characterised by quick and organised feedback. Participant 7 noted:

*"We have weekly cross-functional huddles that highlight emerging manufacturing delays before they become critical."*

Case C faced timing misalignment between regulatory and commercial teams. Case C had scheduling issues between regulative and business departments. Participant 11 said:

*"Marketing decisions sometimes proceed without full regulatory input, leading to repeated adjustments."*

Such comparisons show that structured loops minimise bottlenecks and operational risk and weak or informal loops enhance vulnerabilities. Cases A and C show the misalignment between manufacturing readiness and regulatory schedules, which points to the systemic risk spreading, justifying the need to focus on the integrated systems thinking.

### 4.3 Cultural Dimensions of Governance

The transparency, accountability and leadership behaviour were affected by culture. Procedural transparency was the priority of Case A. Participant 3 stated:

*"All project decisions are documented and visible to the board, which fosters trust."*

Case B was characterised by diffused accountability. Participant 6 explained:

*"Sometimes it is unclear who owns the final decision, especially when multiple functions contribute input."*

In case C, it was a case of alignment based on leadership. Participant 9 noted:

*"Our executives actively mediate conflicts, which helps navigate cross-functional tensions but can centralise control excessively."*

In comparison, formal documentation contributes to transparency at the expense of responsiveness,

diffused accountability creates confusion, and strong leadership facilitates alignment at the expense of overdependence. These point out to the fact that cultural factors can play important role in showing whether formal governance structures can turn out to be effective practise.

#### 4.4 Digital Governance Enablers

Governance was supported by digital tools in a different manner. Case A used dashboards. Participant 4 observed:

*"Our portfolio dashboard provides near-real-time status updates, though some data lags remain."*

Case B Case B made use of collaborative platforms to a great extent. As participant 5 stated:

*"Teams share progress through integrated digital platforms, improving cross-functional visibility."*

Case C was subject to data latency as participant 12 commented:

*"Critical manufacturing data often arrives late, which hinders timely decision-making."*

As it has been shown, digital tools can be used to incorporate feedback and enhance transparency, but they should be effective based on the quality of data and uptake. Cases A and B depict systemic advantages, and Case C exemplifies dangers of digital integration that are partial or unbalanced.

#### 4.5 The Systems-Based Governance Framework

Integrating these findings, systems-based framework was designed based on formal and informal structures, feedback loops as well as digital enablers. Participant 1 from Case A reflected:

*"A visual model showing who influences what helps identify bottlenecks."*

Participant 7 from Case B emphasised:

*"This mapping of decision flows in functions discovered concealed feedback loops."*

Participant 10 from Case C added:

*"Stakeholder matrices are useful in making clear about escalation plans and responsibility."*

Comparison indicates that the incorporation of these aspects improves co-ordination, acts as a buffer to the lack of timing fit, and defines ownership. As shown in critical analysis, the framework should be dynamic. Inflexible systems can remove responsiveness and excessive use of informal networks will lead to opaqueness. The visual model integrates decision flows, feedback loop and stakeholder influence, which provides a management tool of governance maturity and stratification.

## 5. DISCUSSION

This discussion construes the findings based on how structural, systemic, cultural, and digital governance factors impact cross-functional project performance. This research confirms and builds upon previous studies about cross-functional project governance in pharmaceutical organisations. Governance is implemented not merely by formal committees and procedures for escalation, but also by informal networks of influence and practitioners' sense-making. Musawir et al. [1] states that, governance-as-practise approaches drive attention to the ways in which practitioners understand and practise governance structures, which is in line with the interaction of the formal and informal channels of influence all through the three cases. Although committee layering and escalation dynamics are based on well-established governance literature, this research paper emphasises the more complicated inter-functional relationships, especially those between regulatory, commercial, and manufacturing teams, which earlier models did not adequately reflect [3].

The importance of systems-thinking lens is demonstrated through the use of feedback mechanisms. Balancing and reinforcing loops in escalation of risks, manufacturing-readiness delays and regulatory-commercial timing are ways of demonstrating how minor dislocations spread throughout the functions. Kunc [2] emphasises that systems mapping is able to identify structural drivers of organisational behaviour that are not obvious and this fits the causal loop analysis that is carried out here. These processes suggest that both structural and relational intervention approaches should be implemented to improve responsiveness [6]. Moreover, cultural dimensions turned out to be the important facilitators of effective governance. The formal structures were translated to coordinated action influenced by the transparency norms, accountability diffusion and leadership behaviours. Abdel-, Motaal and Chun [7] posits that the element of adaptive leadership and cultural alignment has played a role in governance management of crisis, which explains our findings that cultural elements increase the rate of governance development by the degree of governance maturity.

The enablers of digital governance played a crucial role in the area of visibility and decision support. Situation awareness using dashboards, collaboration systems and data-driven R&D systems enhanced effectiveness, but the continued existence of latent data and ad-hoc adoption hampered effectiveness. Sugandha et al. [8] further claims that

it is not possible to enhance performance solely with digital transformation in absence of alignment to organisational systems and culture and that is why the integration of technology with redesign of governance as well as coordination of culture should be enhanced. On the whole, this research associates structural, systemic, cultural, and digital factors under a single governance maturity framework, demonstrating a development of a siloed governance to strategic agile governance. It supports principles of literature on governance-as-practise, systems thinking literature in addition to specifying on-the-job approaches to portfolio management, operational efficiency, and cross-functional decision-making.

## 6. LIMITATIONS

The limitation of this work is that the sample size of twelve senior executives is rather small, thus preventing generalisation. The applicability of the study results to non-pharmaceutical industries with diverse regulatory, operating, or cultural environments could be limited by the fact that only the pharmaceutical organisations have been targeted. Also, information is obtained based on the views of the executives, which may present possible biasness of strategic or top-level interpretations, which may not reflect the reality of operations and frontline governance experiences. Notwithstanding such limitations, the research offers high qualitative value to the dynamics of cross-functional governance.

## 7. FUTURE RESEARCH

The proposed governance maturity model might be quantitatively proven in larger and diverse pharmaceutical portfolios to determine the ability to generalise in future studies. Longitudinal research following the transformation of governance would

help refer to the maturity change under the influence of regulatory, technological, or market pressures. The search of AI-based governance analytics may bring an opportunity to improve real-time decision-making, risk identification, and interpersonal coordination. Inter-industry comparative studies would help identify the effect of context contingent variables on design, adoption, and performance of governance.

## 8. CONCLUSION

This paper proves that the systems-based approach to cross-functional governance can improve the execution of strategy in intricate pharmaceutical undertakings. Formal structures, informal networks, feedback loops and digital enablers are integrated to cut down delays and minimise misalignments and enhance portfolio oversight. The governance maturity model offers a viable plan through which an organisation can rely on to move away the siloed decision-making operations to strategic agile governance. Connecting the structural, cultural and technological levels, systems-based governance enhances transparency, accountability and responsive coordination allowing organisations to not only negotiate the complexity of regulators, inter-functional relations and market changes in a productive fashion.

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