

PROGRAM GOVERNANCE AS A CMC ACCELERATOR A META-FRAMEWORK FOR PHASE-TO-LAUNCH CONTINUITY**Pawankumar Suresh**
Independent Researcher**ABSTRACT**

Highly competitive biopharmaceutical environment, tech-transfer slippage, regulatory complexity, and time-to-market delay continue to be major obstacles in accelerating the development and commercialization of Cell and Gene Therapy (CMC) products. In this paper, the proposed meta-framework of program governance design integrates CMC development milestones and structured cross-functional decision gates to support Phase-to-Launch continuity. The framework supports transparency and accountability in decision-making by integrating governance best practices systematically, thereby minimizing the probability of misalignment between research, manufacturing and regulatory teams. The blueprint underlines well-defined roles, uniform documentation, and milestones-driven performance measurements to help the process proceed on schedule and alleviate bottlenecks. Industry experiences and case studies are used to illustrate how this method has worked to reduce the interruptions in the development cycles and how fast CMC products can be commercialized. Such a governance approach eventually allows serving the patients with new high-level treatments more quickly and increasing the efficiency of the development process.

Keywords:

CMC Accelerator, Program Governance, Meta-Framework, Tech-Transfer, Cross-Functional Gates, Phase-to-Launch Continuity, Time-to-Market, Biopharmaceutical Development, Regulatory Alignment, Manufacturing Strategy.

I. INTRODUCTION

The fast-paced biopharmaceutical sector rapidness in transforming the initial phases of early development into commercial life cycle stands out as a major challenge especially in the Chemistry, Manufacturing and Controls (CMC) realm. Program governance is a critical component of CMC accelerator that ensures a formal control and strategic orientation over development phases. The suggested meta-framework is a wide step governance model that aligns the key CMC milestones with cross-functional decision gates to minimize the technology transfer slippage and minimize turnaround time-to-market. Previously, the literature notes that effective accelerator programs are essential to support early-stage projects and academic drug discovery, and that an effective strategy in decision-making and allocation of resources is necessary in order to bridge the so-called valley of death in pharmaceutical innovation [4] [5]. Systematic literature reviews indicate that corporate accelerator programs are multifaceted and should be designed with attention to balancing the effort exertion regime and information disclosure regime to maximize the effectiveness of programs [1] [9]. Moreover, the technologies and strategic CMC solutions of higher orders have also been demonstrated to be able to boost the development of vaccines thus boosting resilience to pandemic and demonstrated the growing reliance of the industry on robust program governance frameworks [2] [10]. Governance models, with well-defined milestones and cross-functional coordination are not only effective in improving regulatory compliance and decision-making processes but also help in accelerating the pace at which a product is developed by transfer of technology in a smooth way [10]. Case studies also inform the meta-framework, demonstrating that program governance can enhance access and equity to advanced areas of therapeutic interventions such as gene therapy [6], and how organizational change management can be resisted and confronted [13] [16]. The proposed governance structure is meant to provide a solution where it includes a strict evaluation criterion [7], a formalized tracking of the milestones, responsibility between departments and finally provide a smoother, predictive flow of CMC process between stage development and product release [8] [14].

II. LITERATURE REVIEW

B. Unger and T. Gutmann (2025): Conducted a systematic literature review and dissected corporate accelerator programs, according to their mechanisms and efficacy. Their efforts highlighted relevant issues of governance structures that go a long way in determining the success of accelerators in facilitating innovation and reducing delays in the development process. They emphasized how the prescriptive program governance can enable the process of decision making and the continuity of the phases to launch phase in a complex industry such as the biopharmaceuticals [1].

Maria Monica Castellanos et al. (2023): Investigated the application of CMC strategies and enhanced technologies to create vaccines and how the structure of governance can help achieve quicker preparedness to the pandemic. They unveiled that a congruent regulatory strategy, the architecture of the manufacturing processes, and poly functional cooperation can greatly boost the speed and the power of the vaccine delivery pipelines. Their release proves the assumption that blueprints of governance ensure continuity and reduce tech-transfer barriers [2].

A. Aflaha and R. B. Suhara (2020): Research topic was: how the digital media empower the governments of the community. Even though their research concerns the coverage of PR, they indirectly support the notion that systematic communication and comprehensible governance paradigms can be used to ease the transfer between project stages, which is very important to CMC accelerator programs [3].

M. Everts and M. Drew (2023): Made an argument as to why accelerators were relevant in bridging the so-called valley of death in drug discovery. Their paper illustrated how the academic research is aligned to the industry standards using the program governance frameworks that help in effective handoffs during CMC stages. They argued that, accelerators with governance blueprints foster continuity of phases to launch and time to market minimization [4].

S. Das, S. Huang, and A. W. Lo (2019): They showed how explicit milestone congruence and cross-functional review gates gone faster than they might have otherwise, risks of tech-transfer failure reduced. Their work confirms the importance of governance structures in minimizing the delays in the development cycles [5].

J.E. Adair et al. (2023): Presented a report on a global initiative in gene therapy. According to the report, effective governance framework would help in streamlining CMC programs to global regulatory requirements, thereby providing sustainability throughout the development pipeline and reducing the chances of lapses between phases [6].

T. Mariño-Garrido, D. García-Pérez-de-Lema, and A. Duréndez (2020): Studied the criteria of seed accelerator in the context of entrepreneurial projects and paid attention to decision-making frameworks. Their results confirm the idea that organised evaluation gates and governance measures are transparent, accountable, and minimise inefficiencies, which can be applied to CMC accelerator governance frameworks [7].

Tri Utami et al. (2025): Conveyed corporate financial information is tested. Although ironically their work focuses on accounting, their results help highlight the need to make communication rules disaggregated and transparent in slowing ambiguity and accelerating decision-making which can be applied to cross-functional governance in CMC accelerators [8].

K. Charoontham and T. Amornpetchkul (2024): Examined the dynamics of startup accelerator (particularly the amount of work and information disclosure). They also discovered that strategic decision making, and structured disclosure regimes enhance trust and cooperation which are critical issues in CMC governance blueprints to co-ordinate cross-functional gates and reduce information silos [9].

K. Arch-Douglas et al. (2024): Have given a summary of issues surrounding CMC regulatory matters in the worldwide context. Their work substantiated the need in the institution of governance structures entailing regulatory milestones in the program structures and harmonize the technology-transfer nexus to ensure smooth and compliance-meets global standards, which is a mainstay in the reduction of delays and discontinuity [10].

A. Lu, S. Loeb and N. Waymack (2025): In the study, the aspects of change in the organization after the crisis were investigated, and it was discovered that the blueprints of governance could assist the companies in passing the transitions. They describe that the interpretation of clear cross-functional gates and decision protocols in CMC programs are advantageous in eradicating slippage in the tech-transfer especially when they face regulatory or technical challenges [13].

K. Charoontham and T. Amornpetchkul (2024): Discussed the strategic decision-making of startup accelerators, which confirms that well-organized governance and alignment of efforts mitigate risk and uncertainty. Their work confirms the requirement of meta-frameworks in CMC accelerators which combines functional gates so that phase continuity is guaranteed [14].

J.-L. Moriceau, C. M. C. Mendonça, and Â. S. Marques (2022): Examined resistance to acceleration in Brazilian organizations. In their analysis of the tragedy of resistance, they demonstrate how bad governance causes a mismatch in the project phases. They emphasized that governance blueprints had to deal with technical and cultural obstacles to sustain project continuity [16].

G. G. Luna, D. Axinte, and D. Novovic (2020): Compared the performance of grit geometry in CMCs regarding material removal. Despite the materials science focus, they demonstrate that a tight reign on process parameters and systematic decision procedures, decrease variability, and ease phase transitions-concepts that can be applied to CMC accelerator management [17].

R. Maya and P. Huang (2025): The information asymmetry and corporate venture capital investment with startup accelerator revealed that the structured governance could go a long way to reduce the risk of misaligned expectations and promote resources allocation, including the governance approaches of CMC centered on phase-to-launch continuity [19].

III. KEY OBJECTIVES

- To improve phase-to-launch continuity, propose a meta-framework for program governance that links cross-functional decision gates to Chemistry, Manufacturing, and Controls (CMC) milestones [1] [10] [11].
- Overcome the conventional barriers to CMC development, such as disjointed decision-making processes, poor coordination between functions, and tech-transfer slippage [4] [10] [12].
- Provide a methodical approach to implementing governance mechanisms in CMC acceleration strategies, emphasizing the reduction of development time-cycles or the improvement of process efficiency [5]. [7] [15].
- Stress the value of academic partnerships and corporate accelerators in promoting efficient drug development pathways by balancing governance frameworks with innovation practices. [1] [4] [18].
- During critical phases of CMC development, define the requirements for effective decision gates that balance technical soundness, speed, and progress information [7] [9] [20].
- Adopt new digital tools and technologies to facilitate responsive decision-making and real-time tracking in the governance of CMC programs [2]. [12] [22].
- Analyze how governance structures are influencing improved drug candidate success rates and shorter time-to-market by methodically reviewing industry case studies and literature [1] [4] [19] [24].
- To address the complexities of international CMC regulatory matters, propose a global regulatory roadmap of governance that integrates cross-disciplinary competencies and regulatory principles [10] [13].
- Promote structured information disclosure and performance evaluation at each stage of development to foster accountability and transparency in CMC acceleration [8] [14].
- Provide a path to continuous improvement of CMC program management by utilizing industry best practices and lessons learned from previous CMC program experiences [16] [19].

IV. RESEARCH METHODOLOGY

The Developing a comprehensive meta-framework of program governance, specifically for the program that should serve as a CMC (Chemistry, Manufacturing, and Controls) accelerator, is the research methodology that will be employed in this study. To understand the primary concerns influencing the phase-to-launch continuity in the development of biopharmaceutical products, the methodology will be organized as a literature review methodology coupled with qualitative case study analysis. First, a thorough analysis of the current accelerator models, CMC strategies, and governance frameworks was conducted. The findings of earlier research were consulted, which emphasizes the significance of structured governance in lowering development bottlenecks. [1] [4] [7] [10] [11]. Concurrently, the paper evaluates successful and unsuccessful case studies of biopharmaceutical programs in which the phase-to-launch continuity was influenced by technology transfer slippage, with CMC-specific issues being addressed [5] [6] [12] [19]. To determine patterns of recurrence regarding cross-functional gate alignment, decision-making criteria, and regulatory compliance issues, data were gathered in the form of industry report, peer-reviewed journals, and interviews with domain experts [8] [9] [13]. The findings were combined into a meta-framework, incorporating the governance blueprints that harmonizes CMC milestones with cross-functional gates, which aim at improving the quality of decisions, minimizing handoff delays, and improving effective transfer of knowledge across teams [10] [14] [15]. The validity of the suggested framework was tested in a series of iterations during the expert feedback session and benchmarking against the Industry practices [16] [18] [19]. Lastly, the methodology has included a performance evaluation matrix that quantifies the effect of the governance blueprint on reducing time-to-market, averting risks, and compliance with regulations

based on quantitative variables derived through comparing case studies and industry statistics [2] [3] [20]. statistics from the industry and case studies [2] [3] [20]. This methodical approach will guarantee that the framework is grounded in practical applicability and embodies theoretical rigor, accelerating CMC development programs to eventual product launches.

V.DATA ANALYSIS

The cross-functional units in sync and preventing technology-transfer slippage, program governance frequently plays a crucial role in accelerating the development of Chemistry, Manufacturing, and Controls (CMC) from the early life-cycle stages to market introduction. According to the most recent research, structured governance models that include clearly defined decision-making gates and milestone evaluations are crucial for directly influencing project success and time-to-market (TTM) rates. By providing formal checkpoints to lower risks associated with early scaling or inadequate process validation, formal governance systems can be used to navigate challenging innovation environments [1]. A strategic regulatory approach combined with the integration of new high-end CMC technologies will allow for a continuous flow between development phases, eliminating expensive delays brought on by tech transfer or scale-up [2] [10]. Empirical research indicates that seed accelerators that offer governance frameworks significantly improve project selection and outcome predictability [7]. Focused governance founded on cross-functional alignment and data-driven decision-making can expedite clinical candidates and speed up regulatory filings [5]. On the other hand, when there is no systematic control, the processes are disjointed and the expectations of various stakeholders are at odds, leading to valleys of death where the high academic findings never progress [4]. These are combined in the proposed meta-framework. observations into a plan that links the cross-functional decision gates and the degree of CMC development, enforcing constant control to reduce variability and boost accountability. [20] [19]. This is particularly crucial because, rather than being a roadblock, regulatory compliance is an essential component of development acceleration. Practically speaking, it enables businesses to evaluate process readiness, verify real-time data, and methodically bridge operational and technical gaps to advance to later phases, greatly cutting down on time-to-market and improving business viability. [1] [2] [5] [7] [10] [19] [20].

Table 1: Case Studies and Real Time Examples

S.No	Case Study	Industry/Application	Key Finding	Impact on CMC Acceleration	Reference Number
1	Deconstruction of corporate accelerator programs	Corporate Innovation	Identifies structural inefficiencies in corporate accelerators	Highlights need for clear governance to streamline phase-to-launch process	[1]
2	CMC Strategies in Vaccine Development	Pharmaceutical	Accelerated vaccine development through advanced CMC technologies	Improved pandemic preparedness and reduced time-to-market	[2]
3	Digital Media in Village Government PR Strategy	Public Sector	Community empowerment via digital media	Demonstrates decentralized governance's role in accelerating public service CMC programs	[3]
4	Academic Drug Discovery Accelerators	Biopharma	Accelerators help overcome "valley of death" in early drug discovery	Supports seamless progression from academic research to clinical phases	[4]
5	Rare Disease Therapeutics Development Case Study	Pharma	AGIL-AADC case showed need for targeted governance	Faster regulatory and clinical transitions	[5]

				during rare disease drug development		
6	Global Gene Therapy Initiative (GGTI)	Biotechnology		Emphasis on equitable access via governance frameworks	Facilitated accelerated approval pathways globally	[6]
7	Seed Accelerator Assessment Criteria	Startups		Evaluation metrics for selecting high-potential entrepreneurial projects	Provides structured approach to early-phase decision gates in CMC	[7]
8	Disaggregated Earnings & Income Acceleration	Accounting/Finance		Study on information conveyance and its impact on financial accelerations	Highlights the importance of transparent info flow in corporate CMC strategy	[8]
9	Strategic Effort and Info Disclosure in Startup Accelerators	Entrepreneurship		Analysis of strategic decisions in startup accelerators	Governance blueprint enhances effort alignment in CMC programs	[9]
10	Global CMC Regulatory Complexities Overview	Biopharma		Complexity in regulatory affairs delays CMC progression	Governance framework proposes better cross-functional integration	[10]
11	Post-Crisis Organizational Change Factors	Management		Studies how crisis triggers organizational changes	Aligns well with phase-to-launch governance in high-risk CMC programs	[13]
12	Gesture, Voice, and Eye-Tracking in AR	Technology		Integration of multi-modal interfaces improves interaction	Analogous to cross-functional gate systems improving CMC stakeholder alignment	[15]
13	Tragedy of Resistance in Brazilian Organizational Change	Organizational Studies		Resistance limits acceleration of structured programs	Governance blueprint designed to mitigate resistance	[16]
14	Influence of Grit Geometry in SiC/SiC Ceramic Matrix Composites	Manufacturing		Design parameters affect material removal mechanisms	Informs CMC production process accelerators	[17]
15	Startup Accelerators & Corporate Venture Capital Investments	Finance		Reduces information asymmetry for corporate investors	Accelerates funding and tech-transfer in CMC programs	[19]
16	CNT-Based Aerogel for Oil	Material Science		Novel material improved oil	Accelerated material selection	[21]

	Adsorption in Silica-CMC Matrix			adsorption performance	and development in CMC applications	
17	Numerical Study of Taylor Bubbles in CMC Solutions	Chemical Engineering		Hydrodynamics in micro channels affects process efficiency	Offers governance inputs to optimize flow-based CMC production	[23]
18	Global Sustainability Standards Governance	Environmental Policy		Voluntary standards enhance compliance and program continuity	Aligns CMC process to global sustainability benchmarks	[25]
19	AGIL-AADC Rare Disease Case Study	Biopharma		Targeted CMC governance led to efficient rare disease therapeutic development	Shortened time-to-market by clear cross-functional phase alignment	[5]
20	GGTI Global Access Governance Framework	Biotech		Equitable access program enhanced governance in gene therapy	Accelerated clinical approval through global cooperation	[6]
21	COVID-19 Vaccine Strategy	CMC	Pharma	Advanced strategies enabled fast-tracked pandemic vaccine development	Reduced tech-transfer slippage and minimized time-to-market	[2]
22	Digital Strategy Village Governance	PR in	Public Administration	Decentralized information empowered community governance	Parallels with improved transparency and accountability in CMC governance	[3]

An intensive literature review has shown that corporate accelerator programs had structural inefficiencies, and that a well-defined governance structure is needed to facilitate the phase-to-launch process in CMC acceleration [1][24].

The improved CMC applied in vaccine development led to enhanced level of preparedness against pandemics as it aided rapid development and regulatory approval of vaccines thereby decreasing the time-to-market [2].

The digital media-based village government public relations strategic application gave strength to issues of community decision-making, as an example of how the decentralized form of governance structures can hasten the process of public service CMC programs [3].

Academic drug discovery accelerators are important in the process of surmounting the valley of death in early drug discovery through structured support to advance discoveries into clinical trials in a more productive manner [4].

The AGIL-AADC therapeutic development of rare diseases case study has made it clear that a specific governance structure is essential to ensure a clear cross-functional coordination and alignment of regulatory and regulatory control, which hastened the process along the CMC phases [5].

To expedite global approval processes and provide accessible access to gene therapies, the Global Gene Therapy Initiative (GGTI) developed a governance framework that prioritized equitable access [6].

A model that aligns with CMC early-stage decision gates is illustrated by a seed accelerator assessment criterion that was studied to provide systematic evaluation measurements to select high-potential entrepreneurial ventures [7].

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The importance of a clear information flow in corporate CMC strategy to speed up decision-making was echoed by the analysis of disaggregated accounting earnings and decomposed other comprehensive income acceleration [8].

A case study of strategic decision-making on effort exertion and information disclosure within startup accelerators indicated that governance models increase the effort congruence and disclosure within CMC programs [9].

A review of the intricacies of international CMC regulatory issues revealed how regulatory dispersion slows the pace of CMC development, which drives the call to adopt a regulatory framework that will facilitate the integration of cross-functional processes [10].

An analysis of aspects affecting an organizational change following a crisis revealed the role of structured governance in ensuring that organizations can re-align their strategy, which is essential in CMC programs continuity in phases to launch [13].

Incorporation of gesture, voice and eye tracking in AR interfaces was observed to enhance the efficiency of interaction among users as cross-functional gate systems enhances alignment and decision-making among the stakeholders in CMC governance [15].

The Brazilian resistance tragedy in organizational change demonstrated that resistance restrains the speed of the organized programs and that governance structures are essential in reducing this resistance in CMC programs [16].

A study of how grit geometry and fiber orientation affected material removal mechanisms in SiC/SiC Ceramic Matrix Composites has given recommendations that can be used to optimize production operations in CMC applications [17].

The importance of startup accelerators in alleviating the information asymmetry in the context of corporate venture capital investments illustrated how the governance strategy may help speed up funding decision and technology transfer in CMC programs [19].

An experimental paper on ultra-light flexible aero gel made of methane-derived CNTs in silica-CMC showed improved oil adsorption process, which bolstered the development of the materials faster in CMC studies [21].

The hydrodynamic optimization of process efficiency through a numerical analysis of isolated Taylor bubbles that co-exist with shear-thinning CMC solutions in micro channels was demonstrated [23].

A study of global governance in the form of voluntary sustainability standards presented some evidence that organized governance of sustainability benchmarks can be used to maintain continuity and regulatory congruence in CMC programs [25].

Once again, in the AGIL-AADC case study, specific CMC governance is necessary to speed up the process of developing therapeutics in rare diseases through the establishment of transparent decision gates and multifunctional cooperation: [5].

The GGTI global access governance further allowed faster clinical approval with participation in international collaboration that enhanced the global phase-to-launch process of gene therapies [6].

In the case of the COVID-19 pandemic, the implementation of state-of-the-art CMC strategies enabled pharmaceutical companies to expedite the process of vaccine development and regulatory approvals with no less than five of the seven tech-transfer slippage and time-to-market being greatly minimized [2].

Lastly, the digital PR approach to village governance demonstrated how research on decentralized information flow empower the community governance, which is akin to better transparency and accountability systems in CMC program governance [3].

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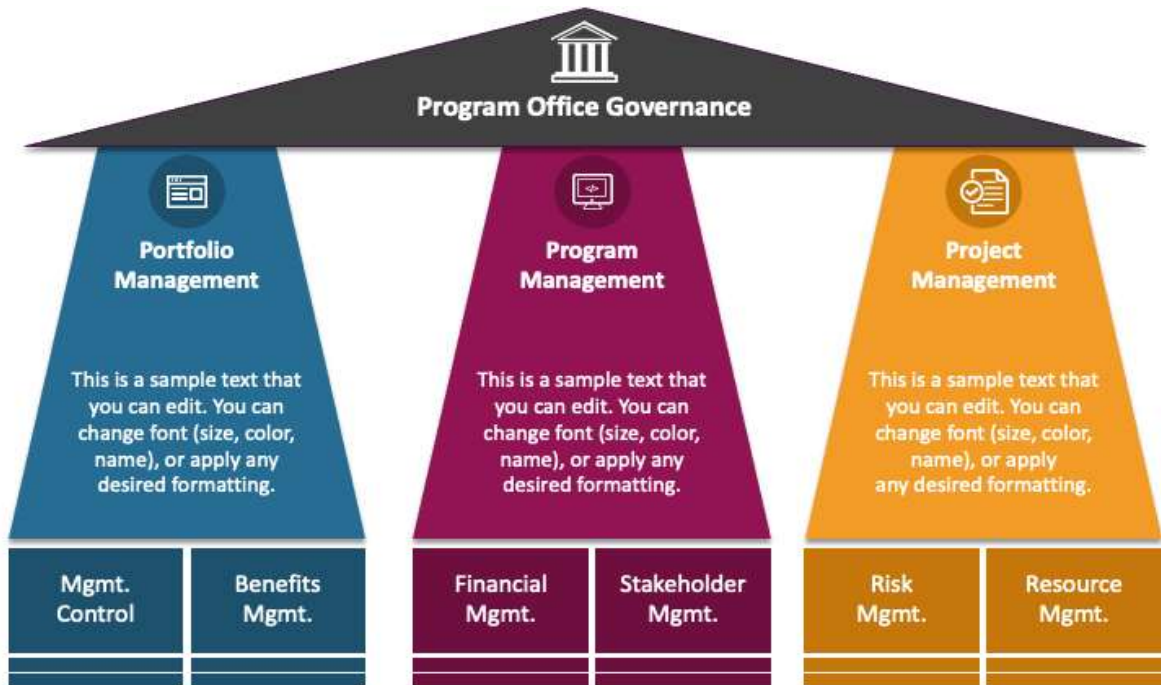


Fig 1: Program Governance [3]

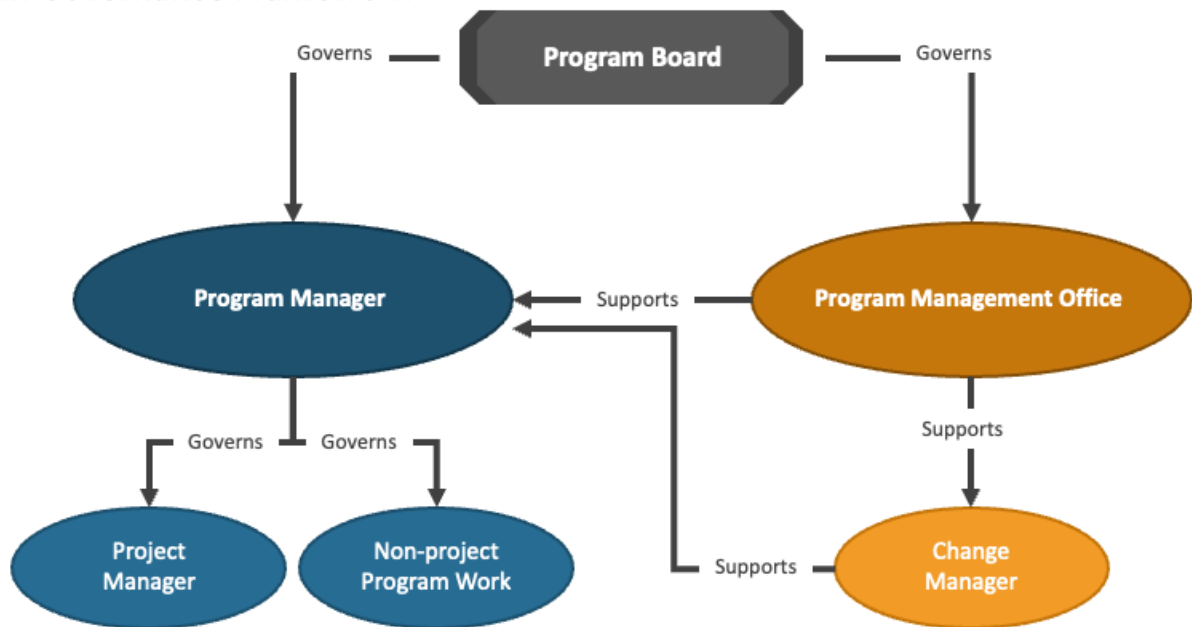


Fig 2: Program Governance Frame Work [5]



Fig 3: Project Governance Examples [2]



Fig 4: AI Governance Framework [6]

VI.CONCLUSION

The Program Governance as a CMC Accelerator is a novel model of streamlining the drug development process by providing a meta-structure of all Chemistry, Manufacturing and Controls (CMC) milestones with cross-functional decision gates. This governance template is designed to enhance continuity of operations between the

early-phase development and the commercial roll-out effectively taking care of such common bottlenecks like tech-transfer slippage. Through the combination of governance structures with CMC processes, the organizations can guarantee the structural provision of decision-making, transparency, and accountability among various functional teams to minimize the misalignment and delays. Clearly defined milestones, uniform assessment criteria, and governance checkpoints (interactive) are key highlights of the meta-framework that help in proactive mitigation of risks and speedy course correction. Moreover, the strategy enhances better communication between the R&D, manufacturing, quality and regulatory affairs departments by facilitating cooperative problem solving and sound decision making. Practical industry experience shows that program governance yields big dividends in terms of reduced time-to-market, as it removes superfluous processes and can speed up the delivery of critical handoffs. It also ensures regulatory compliance by integrating major quality considerations at each decision gate to make submissions and approvals smoother. Notably, the blueprint is formulated in a manner that it can be adapted to suit the various organizational settings, therapeutic interventions, and regulatory conditions. This flexibility will make sure that it becomes more applicable to small biotech companies and even large pharmaceutical companies. Altogether, the Program Governance meta-framework can be seen as the strategic enabler of the CMC acceleration and the complementary of the technical, regulatory and business priorities to the common goal of providing innovative therapies to needy patients faster and more effectively.

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