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An Orchestration Framework for Digital Innovation: Lessons from the Healthcare Industry¹

Abhijeet Satwekar, Tiziano Volpentesta, Paolo Spagnoletti, Mara Rossi

Abstract— The healthcare industry is continuously evolving with innovative discoveries and therapies, and at the same time, there is a decline in the research and development productivity leading to an increased cost for payers, providers, and patients. Despite the benefits that digital technologies can have on healthcare innovation, such a highly regulated industry often relies on proven-established technologies and organizational procedures that can be at odds with the new logics of digital innovation. In this paper, we will be introducing a Digital Innovation Management (DIM) framework that guides the pursuit of digital innovations in a phase-appropriate and incremental set-up (e.g., scale, costs, risks, value evaluations, policies, and resources). The framework is designed and validated through an iterative process of continuous adaptation with local practices in a biopharmaceutical company. DIM provides practical guidance to drive digital innovations that entail different logics compared to traditional innovations, by improving the visibility of the digital innovation process and increasing organizational confidence in pursuing digital innovations and enhancing decision-making effectiveness.

I. INTRODUCTION

THE healthcare sector is characterized by a complex ecosystem of individuals, organizations and public authorities [1]–[4], functioning responsibly, interdependently and coherently as a process towards the well-being of the individuals. The enhancement of the complex multifaced process with digital technologies that create value, trigger disruptions, bring strategic, cultural and structural changes, elevate organizational barriers and drive better organizational performance is contemplated as digital transformation [5]–[8]. Digital transformation in the healthcare industry encompasses a radical change in the value creation for a multi-stakeholder audience which involves patients, physicians, pharmacies, hospitals, regulatory agencies, pharmaceutical & biopharmaceutical companies, non-government bodies, insurance companies and many more. Pharmaceutical and biopharmaceutical companies are an integral part of the healthcare ecosystem and operate collectively with the multi-stakeholders of the healthcare sector with the responsibility to discover, develop,

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manufacture, and distribute medications and therapies towards the underlying health conditions of individuals and improve their quality of life. Pharmaceutical and biopharmaceutical products differ in complexity [9] leading to a wide gap in production costs [10]. Specifically for biopharmaceutical companies, there has been a decrease in research and development productivity, leading to increased costs within the past few decades [11], [12]. To bring a new biopharmaceutical drug to a patient, the costs have increased from \$1.2 billion in 2007, \$1.8 billion in 2010, \$2.8 billion in 2016; with a drop in the success rates (Phase 1 to approval) from 30% to 12% between 2007 to 2016 [11], [13]–[15]. Currently, there is a continuous discovery and development of innovative modalities as therapies for better healthcare outcomes [16], and consequently, the pressure on costs is increasing for payers, providers, and patients [17]. When dealing with the cost pressures, biopharmaceutical companies undertake digital transformation programs to increase the productivity and efficiency of the Chemistry, Manufacturing, and Controls (CMC) activities, which represents the process development and manufacturing of the therapeutic medicines [16]. However, achieving digital transformation in biopharmaceutical companies can be challenging, due to the tension between the new logics of digital innovation [18] and the norms regulating the healthcare sector. In fact, biopharmaceutical companies must follow strict guidelines, and rely on proven-established technologies and organizational procedures to develop new products. In contrast, digital innovation is based on new technologies and characterized by a more uncertain and flexible innovation process [19]–[22] and traditional methodologies may not be well suited. Therefore, biopharmaceutical companies provide an ideal setting in order to investigate the organizational conditions for successful adoption of the new logics of digital innovation [18] in the healthcare sector.

The capability to orchestrate resources is a fundamental aspect of digital innovation management [23]. It is a necessary capability for organizations to continuously adapt to the fluidity and emergence of digital innovations by managing and coordinating resources in accordance with the arising needs from different actors and stakeholders [24] [25], [26]. Therefore, orchestrating digital innovation management in the healthcare sector - characterized by the aforementioned characteristics- is critical to deploy digital innovations for successfully achieving digital transformation. Grounded on the above literature relevance, our study addresses the following research question: “How can digital innovation be effectively orchestrated in the highly regulated healthcare industry?”

In this paper, we report the results of an Action Design Research study [27], [28] aimed at designing and validating a Digital Innovation Management (DIM) framework in the context of a biopharmaceutical company. We also show the applicability of the DIM framework in a real-world scenario through an expository instantiation on an Artificial-Intelligence based solution. The framework guides the pursuit of digital innovations in a phase-appropriate and incremental set-up (e.g., scale, costs, risks, value evaluations, policies, and resources). Through reflection and learning on the framework design, we developed a nuanced view on the role of orchestration in the digital transformation within the healthcare sector. Moreover, we provide an effective practical managerial tool for managing digital innovation in biopharmaceutical companies.

II. THEORETICAL BACKGROUND

Digital transformation is an emerging, complex and multifaced phenomenon [29] that radically transforms organizational business models, processes, and products [5]. In recent years, many scholars and practitioners have engaged in research pertaining to the digital transformation in healthcare [1], [30]–[32], and a recent systematic literature review [31] points the state-of-the-art of digital transformation in healthcare literature which consists of clusters made up of operational efficiency by healthcare providers, patient-centered approaches, organizational factors and managerial implications, workforce practices, and socio-economic aspects, thereby suggesting a need for further research on business model transformation and implications for the management of different interest groups towards the holistic transformation across the healthcare ecosystem [31]. The digital transformation in healthcare research has been mainly focused on technology, and sparsely highlights the managerial and business impacts at the multistakeholder level [31], [33].

Oftentimes, the process of introducing innovations in healthcare is accomplished by stage-gated linear process models, entailing the early setting of and adherence to rigid plans, boundaries and features on the deliverable benefits [18], [34], [35]. Furthermore, the pursuit of digital transformation is threatened at the organizational level of incumbents by established IT and Finance operating models and procedures. First, most of the corporate IT budget is allocated to run business operations, maintenance, and regulatory compliance rather than strategic investments thus, leaving little room for pursuing digital transformation [36]. Then, the traditional financial assessments are less reliable with digital [37], strategic, and innovative investments as it is difficult to project estimated cash flows due to intangible, interdependent, and not immediate benefits, and the relevance is difficult to quantify [38], [39].

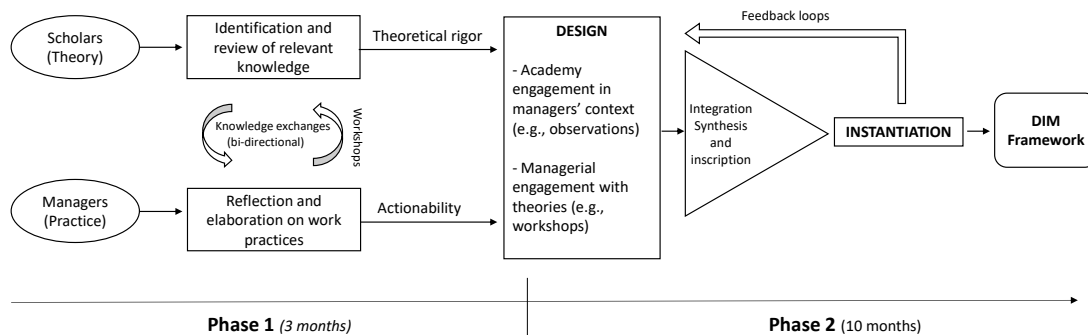
In comparison to other industries such as retail, finance, media and insurance, healthcare ranks lowest for the use and adoption of digital technologies [32]. Therefore, there is a stringent need for radical and incremental innovations in the healthcare sector to depart from the established legacy processes [40], [41].

Academic scholars have widely elaborated the theories, processes, challenges, and solutions to build, deploy and manage innovations for achieving the digital transformation goals within the organizations [18], [31], [50], [42]–[49]. A recent survey within the Danish Biotech industry on “the current state and perceived future obstacles in implementing digitalization concepts in biotech production processes”, revealed that adequate business cases value propositions, and organizational readiness were critical hurdles [51]. Furthermore, the insights from a U.S. Food and Drug Administration (FDA) survey report aimed to understand “a manufacturer’s decision to invest in and adopt digital technologies by illuminating both perceived and demonstrated barriers” indicated that the key barriers to adopt digital technologies are due to lack of business cases, tight timelines constraining digital technology implementation, and challenging global regulatory environment constraining implementation [52]. Therefore, biopharmaceutical companies are on the verge of managerial challenges for driving the digital transformation ambitions within the healthcare sector. This ushers a need to develop managerial frameworks to build incremental digital innovations in the rapidly changing environment for cost-competitiveness and ensuring steady supply of high-quality medications and therapies.

Digital innovations are an inherently socio-technical phenomenon [53] in a continuous state of flux entailing an unprecedented level of “unpredictability and dynamism” [18] that is extended and appropriately differentiated from

heterogenous and distributed actors and organizations [42]. Digital technologies underlying digital innovations [53] are malleable, editable, open, and transferable [43] and have ambivalent ontologies [50]. Therefore, digital innovations are laden with three key characteristics: generativity, affordance, and convergence. Generativity refers to the ability of digital innovations to create unplanned and unprompted change through their editable features; while affordance is a disposition of technology to offer an action potential and represents- what a specific set of users in a use case “are” or “are not” able to do, through the set of available features. It includes both material (technological features) and human (use case of users) constrains. Lastly, converge refers to bring-together the digital and physical aspects, along with the convergence of actors and users from different organizations [43], [53]. The above-mentioned characteristics require new logics for digital Innovation, postulated as 1) Dynamic problem–solution design pairing, 2) Socio-cognitive sensemaking, 3) Technology affordances and constraints and 4) Orchestration. These are theoretical elements to construct a more accurate innovation process and outcome in the digital world [18]. These logics provide general guidance to build digital innovations with a process that is closely connected, less predefined and dynamically evolving for the scope and outcomes according to the changing conditions of the business.

Fig. 1 Representation of the engagement process between scholars and practitioners



Generally, the management of innovation is a complex process entailing high uncertainty. There are several innovation management models in literature, each focusing on different aspects of managing the complexity of the innovation process [54]. Stage-gated models are one of the most adopted by organizations and are considered to be rigid [55],

[56], as they are based on the assumptions of defining objectives and adherence to specification through a planning process already defined from the front-end of the innovation process. Instead, digital innovations are characterized by a fluid innovation process, that frequently changes by developing complex paths. These characteristics limit the application of traditional stage-gate models towards the management of digital innovation. To accommodate such changes, the stage-gate model has been discussed with agile methods and design thinking practices to better support changing requirements and iterative testing [55]–[58]. The regulatory framework and bureaucratization of established healthcare organizations have an impact on innovation efforts [59], [60]. There is a tendency to favour the status quo, resulting into constraints for the adoption of emerging technologies within the stringent regulatory context [61], [62]. Within these established healthcare organizations, the challenges from organisational barriers in terms of characteristics and complexities to drive digital innovations are overlooked by current research, albeit being a useful context to contribute to both theory and practice. Little research has investigated the organizational arrangements and models appropriate for managing digital innovation in healthcare. Orchestration of a managerial framework is fundamental for successful digital innovation management in established and complex organizations [24], [26]. The capability to orchestrate digital innovations, entail building and maintaining coordination across and within the firm’s assets, and bridging different pools of knowledge and resources [23]. Digital innovation necessitates the repeated engagement, interaction, and coordination of multiple audiences, actors (internal and external stakeholders) to share and collaborate for co-creating digital solutions [25]. Hereafter, it is important to design a framework to effectively manage digital innovation within organizations operating within the highly regulated healthcare sector.

III. METHODOLOGY

The DIM framework is designed from an engaged research approach entailing the collaboration between scholars and practitioners, through an in-depth understanding of the practical process and the challenges in the organizations [63]. A longitudinal iterative exchange as “Dialogical sensemaking” [64] was essential to thoroughly examine the complex established organizational processes in a continuous mode for capturing the relevant dynamically evolving information for the delivery of a pragmatic solution. We have applied a qualitative research method, involving close collaboration between management practitioners from the industry and academic scholars [65]–[67]. The interactions involved thorough discussions on the existing organizational challenges in pursuing digital innovations in the healthcare industry – a biopharmaceutical company. Academic scholars were engaged as observers in project review meetings within the ongoing projects and interacted with project leaders, team members and sponsors. Following the observations, workshops were conducted between practitioners and scholars to elaborate on the findings and discuss potential remedies to resolve the ongoing challenges. Academic scholars contributed with theoretical and methodological rigours to refine the existing management process and proposed areas to bring actionability through management practitioners. Overall, the process was accomplished in two phases (Figure 1).

Phase 1 of the methodology was focused on *identifying the relevant academic knowledge and better understand the issues and difficulties faced by practitioners*. Academic scholars followed up to 8 ongoing projects by participating to project review meetings at a frequency of at least 1 review meeting per project in a month. The projects were selected

as purposeful and convenience representatives [68] to include diverse scenarios of the biopharmaceutical operations encompassing the need for business value propositions, adherence to internal and external policies and compliance across the global stakeholders, senior management endorsements and decision-making, and prospects of scale-up with a life cycle plan. Additionally, bi-weekly workshops were conducted with management practitioners from the biopharmaceutical company to analyze and validate the findings and observations. Thus, academic scholars were able to observe a real-time progression of digital innovation projects, to understand the underlying challenges through a first-hand lens. This established the knowledge base for the opportunities, problems and challenges as drawn from the real world and reflects *Practice-inspired research* to allow the capturing of up-to-date information [69]. A knowledge base was established within Phase 1 over a 3-month period of interactions. This was further extended to Phase 2, *for bringing the actionability and iterative testing of remedies in a real-world scenario*. Phase 2 interactions between the practitioners and academic scholars involved similar frequency and set-up of interactions as that of Phase 1. Distinctively, Phase 2 focused on knowledge synthesis into actions by deeper brainstorming sessions and other decision support processes. This led to the exploration of the literature to identify academic theories for building an initial *theory ingrained artifact* [69] - the Digital Innovation Management (DIM) framework. Through the iterative optimization and evaluation, the artifact was *reciprocally shaped* [69] to adapt with the organizational processes and elevate the challenges by the continuous engagement between academic scholars and practitioners with *mutually influential roles* [69]. Thus, allowing a specialized knowledge contribution to additionally tune the artifact. Academic scholars and practitioners were closely associated within the 8 ongoing digital innovation projects and the observations were captured spontaneously from the real-world progression of the projects. This provided immediate visibility of the challenges and facilitated the discussions to evaluate and define interventions as prompt actions to introduce the appropriate changes to the artifact by *authentic and concurrent evaluation* [69]. This approach facilitated a *guided emergence* [69] to develop and implement a finely tuned artifact within the dynamic real-world scenario as expository instantiation. The final artifact was developed according to the observations, feedback and evaluations into a widely applicable framework as a *Generalized outcome* [69]. Thus, we have defined the DIM framework aligned to the 7 principles of the Action Design Research (ADR) [69]. The model emerged from an abductive [64] approach in which both, theory and practice have been continuously revisited, to reach a level of information saturation, and until the model described all the relevant peculiarities of introducing the digital innovations in the biopharmaceutical company. Emerging from the interactions and discussions between the management practitioners and academic scholars, the findings were synthesized in a highly pragmatic research endeavour in that we aimed to elaborate concepts that prompt and support actions. [64], [68]. Phase 2 resulted in a 10-month period and facilitated an in-depth immersion in the digital innovation management process over a long real-time period [70], [71] with an enhanced level of understanding of real-world challenges in their natural day-to-day context [72], [73]. The research methodology provided an improved understanding of the existing situations and the observations or findings were consistently validated and triangulated with biopharmaceutical company management practitioners that had over 5+ years of experience in the healthcare industry and its operational processes to increase the trustworthiness of the research as adhered to the Lincoln and Guba criteria (credibility, transferability, dependability and confirmability) [74]. The observations and evaluations

from the empirical - 8 digital innovation projects were considered valid, if they were observed in more than one project, and confirmed by the biopharmaceutical company management practitioners. To this purpose, data from observations were equally reliable as other data sources [73], and further facilitated contextualizing [72] the underlying knowledge. To conclude, the prolonged observations and close interactions between academic scholars and management practitioners, and the subsequent discussions on Digital innovation management theories allowed better scoping of the organizational challenges and to define remedies with iterative testing and validating an actionable DIM framework as facilitated by the Action Design Research (ADR) methodology [27], [28] through an engaged research approach [63]. We further provided the basis of the theoretical logics from the Nambisan et al. [18] seminal article as the kernel theory, and applied the DIM framework on a project involving an AI-based solution in the subsequent sections.

IV. DESIGNING DIGITAL INNOVATION MANAGEMENT FRAMEWORK

A. Digital Innovation Logics as a Kernel Theory

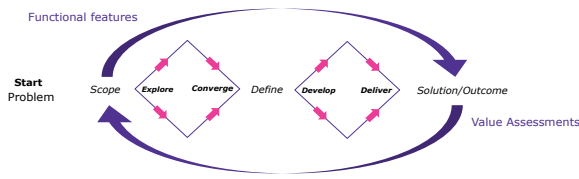
We draw on the Nambisan et al., 2017 seminal paper as the kernel theory to derive the DIM framework. Thus, our DIM framework is grounded and applies the characteristics of digital innovations i.e., a) Dynamic problem–solution design pairing, b) Technology affordances and constraints, c) Socio-cognitive sensemaking and d) Orchestration as discussed in the next sections. A detailed elaboration is provided in Table I, highlighting the key assumptions of the Innovation Management Theories, as challenged by the Digital Innovations, and connecting the synergies from the theoretical new logics of Digital Innovation [18] with our DIM framework. A visual representation of the practical use of the theoretical new logics within the DIM framework is shown in Figure 2.

The DIM framework envisions the management process of the digital innovation into three gated phases of *Proof of Concept (PoC) – Proof of Feasibility (PoF) and Proof of Value (PoV)*, where the Go/No-Go decision is determined by the successful evaluation of a phase-specific Business Case (Figure 3, Table II). The phase-appropriate set-up aligns expectations and deliverable objectives so that managers can gain confidence to drive digital innovations with high success rates and improved decision-making at the project and portfolio level [75]. The incrementality allows initiatives to fail fast and cheap, decreasing the risk as resource engagement increases across the phases (until the PoF phase). Moreover, the uncertainty linked to the financial evaluation is decreased, that facilitates to minimize the tension generated by the co-existence between the status quo and digital innovations. These characteristics alleviate the resistance of traditional IT and Finance procedures outlined in the previous section, as the adoption of digital innovation proceeds gradually. Based on emerging experimental evidence from these phases, the adoption of the framework results in higher visibility of the digital innovation process, improved decision-making, and confidence in the value.

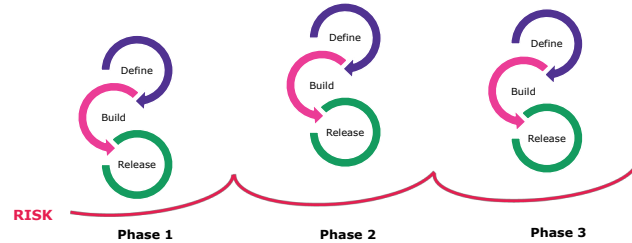
TABLE I
CONNECTING THEORETICAL LOGICS OF DIGITAL INNOVATION WITH DIM FRAMEWORK

Key Assumptions of Innovation Management Theories	Assumptions of Innovation Management Theories challenged by Digital Innovation	New Logics of Theorizing about Digitization of Innovation	Addressing the new logics about Digital Innovations	Synergies with our DIM framework
Adapted from Nambisan et al., 2017		Connecting the New Logics (Nambisan et al., 2017) with our DIM framework		
<p>1) Innovation is a well-bound phenomenon focused on fixed products.</p> <p>2) The nature of innovation agency is centralized, with stakeholders organizing for innovations.</p> <p>3) Innovation process and outcomes are two distinct phenomena, allowing the nature and organization of innovations to be explicitly theorized.</p>	<p>a) less bounded by boundaries to allow continuous shifting of outcomes</p> <p>b) less predefined & evolving for goals, motives, capabilities, and outcome</p> <p>c) having fewer boundaries between the innovation process and outcome to have complex and dynamic interactions between the process and outcomes.</p>	1) Dynamic problem-solution design pairing.	Dynamic problem-solution design pairing that outlines the opportunity creation path until the development of a value-generating digital innovation (product/process/service). Throughout the digital innovation journey, there is frequent navigation between divergence and convergence of digital innovation opportunities. Thus, leading to the iterative reshaping of scope and functionalities of the digital innovation.	1) Dynamic problem-solution design pairing is practically placed in a phase-appropriate framework, allowing leaner - quick experimentation to adoption, with a phase-specific definition of objectives that are consistently evolving concerning the benefits focus and opportunity areas. Thus, the link between the innovation process and outcome is dynamic and constantly evolved to increase benefit value.
		2) Socio-cognitive sensemaking.	Socio-cognitive sensemaking reflects the roles of actors to define and discover new opportunities around the digital innovations and construct other extended benefit use case scenarios, that are further required to be negotiated and justified meaningfully for stable adoptions within the organizations	The use of phase-appropriate business case as a technique to elaborate the benefits, fits with the logic of using divergence and convergence. We apply a phase-appropriate business case evaluation approach, wherein the initial phase a broader vision for prospective benefits (divergence) is set. And then in the subsequent phase, a focused business case on selective attainable benefits is defined to have an immediate value plan for the organization (convergence). Later phases are directed to cover the forecast benefits as well as explore extended benefits by continuous monitoring.
		3) Technology affordances and constraints	The use of IT systems and infrastructure as enablers or their limitations within the digital innovation journey is considered in Technology affordances and constraints. It further relates to the potential need for new digital technologies & capabilities to facilitate the digital innovation building and adoption. The approach would also involve repurposing the same technology for different benefit outcomes in other contexts. Thus, showcasing an influence on the digital innovation journey concerning changing outcomes.	The 3) Technology affordances and constraints are aligned to our framework, as phase-appropriate progression is leaner, gated, and builds the necessary IT systems & architecture on the need basis. This allows step by step experience-based evaluation and building of digital technologies or capabilities and repositioning them for extended benefits.
		4) Orchestration	Orchestration reflects the matching of problem/opportunity with the digital innovation solution. It involves collective structuring of the digital innovation by digital technologies, to enable, constrict, and shape the digital value. This further requires the integration of all interacting stakeholders (internal and external) to mix fluidly and distribute within the organization as per the value purpose of digital innovation.	4) Orchestration is synergistic to our framework structure on roles and responsibilities, that showcases the need for an enabling role to drive the integration of various stakeholders, tackle any systemic barriers to bring a smoother transition of the digital innovation into adoption.

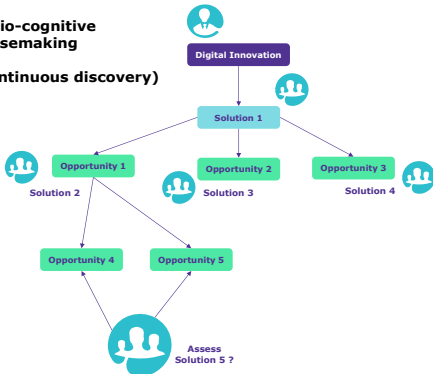
Dynamic problem-solution design pairing



Technology affordances and constraints (Iterative and AGILE)



Socio-cognitive sensemaking (continuous discovery)



Orchestration

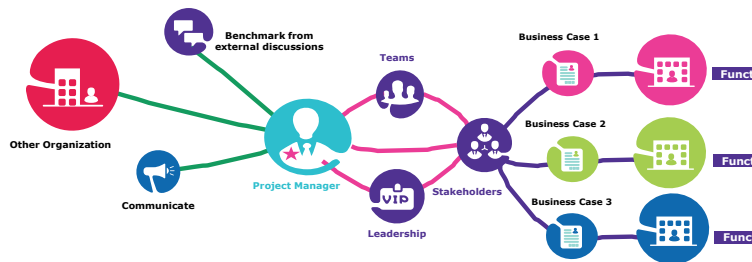


Fig. 2 Visual representation of practical use of the theoretical new logics within DIM framework

Aligning with the a) dynamic problem-solution design pairing [18], our DIM framework adopts a phase-appropriate opportunity creation and benefit/solution development in a divergent and convergent mode, for iteratively shaping the

scope and functionalities towards enhanced value. The initial scope of the problem/opportunity is explored in a divergent manner to better understand the broad benefit/solution scenario in PoC. Then, the PoF phase converges the benefits/solutions to prioritize the quick-win opportunities. Transitioning between the PoC-PoF-PoV phases follows an agile method (define, build and release) by decreasing risks and targeting benefits iteratively and modularly. Our phase-appropriate agile structuring of the PoC-PoF-PoV phases, with the incremental resource engagement, aligns with the b) Technology affordances and constraints logic [18]. Organizations are often challenged to meet the enabling IT needs for building Digital Innovations. Therefore, a strategy of re-purposing IT technologies for different benefit outcomes is ideal. Within the Phase-appropriate progression of the PoC-PoF-PoV phases, the IT systems and architecture are built by using a step-by-step experience-based evaluation and are repositioned for extended benefits, depending on the need and scope from the different stakeholders leading to reduced costs and risks. Moreover, it allows a flexible approach when negotiating with decision-makers to incrementally request IT budgets with a justified risk-based approach.

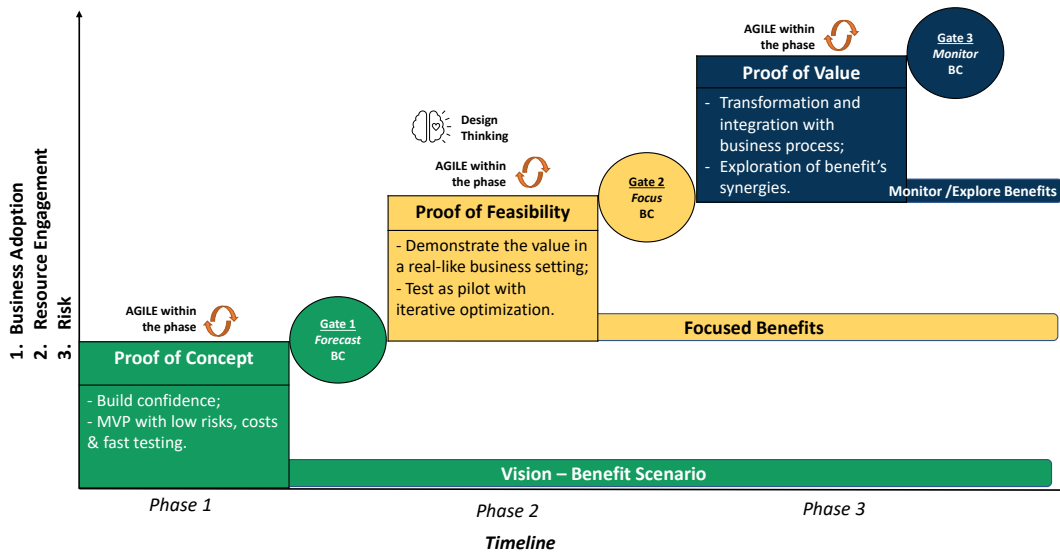


Fig. 3 DIM Framework

TABLE II

Description of PoC, PoF, and PoV phases

	Proof of Concept (PoC)	Forecast BC GATE 1				Focused BC GATE 2	
		Vision - Benefit Scenario	Proof of Feasibility (PoF)	Focused Benefits	Proof of Value (PoV)	M	
SCOPE	Identify the problem or opportunity, and scout for ideas.	Predictive Forecast.	Refine the PoC and test the digital innovation as pilot.	Facilitates a Go/No-Go decision based on expected financial and non-financial benefits.	Transform the business process. And explore new benefit's synergies.	!	
OBJECTIVE	Conceptualize the idea and build confidence by demonstrating a practical business application, even with a Minimum Viable Product/Process (MVP).		Demonstrate the value in a real-like business setting.		Establish the value for the business by fully integrating the solution in the business process.		
RESOURCE ENGAGEMENT	Minimal costs and resources.	Facilitates a Go/No-Go decision based on expected financial and non-financial benefits.	Gradual increase in costs and resources to optimize and tune.	Facilitates a Go/No-Go decision based on empiric figures generated in the PoF experience.	OPEX as defined by PoF.	!	
ADOPTION TO BUSINESS	Sandbox approach.		Iterative optimization by collecting feedback from stakeholders.		Use in day-to-day operations with continuous optimization of the solution based on stakeholders feedback.		
INTELLECTUAL PROPERTY (IP)	Initial Review on Patentability & "Freedom to Operate".	Sets a visionary forecast of benefits based on early indicators.	Application for Patents.	Facilitates a Go/No-Go decision based on empiric figures generated in the PoF experience.	Tracking on IP.	!	
EXECUTION METHODOLOGY	AGILE (Define-Build-Release) PoC either as Minimal Viable Product (MVP) or confidence in the concept		AGILE (Define-Build-Release) PoF with iterative Design Thinking to empathize stakeholder, end users perspectives.		AGILE (Define-Build-Release) modularly and following organizational policies and structure		

Within the c) Socio-cognitive sensemaking [18], there is an active role of various actors to define and discover new opportunities and negotiate for adoptions within the organizations. This concept is adapted within our DIM framework, through the phase-specific business case preparation and negotiations. The PoC phase sets the benefit forecast. The PoF phase narrows it in order to focus on the selective benefits and identifies other opportunities through experience. Lastly, the PoV phase integrates the solution into core business functions. Thus, this concept continuously discovers opportunities within the organization to enhance the benefit value.

Within the d) Orchestration [18], the matching of problem/opportunity with the digital innovation solutions is promoted by enablers. Thus, collectively structuring the digital value and integrating with cross-organizational stakeholders. The enabler manages the digital innovation to fluidly mix within the organization, depending on the scale, scope, and benefit value. Our DIM framework structures the roles and responsibilities as per the need within the PoC-PoF-PoV phases. It assigns an enabling role to the digital innovation managers to drive the integration of various stakeholders, tackles systemic barriers for a smoother transition of the digital innovation into adoption, and continuously explores the opportunities.

B. Proof of Concept (PoC): Gaining Confidence

The Proof of Concept (PoC) is the first phase. In this phase, the assumptions of the digital innovation are tested with a minimum engagement of resources, which eventually reduces the consequences of failures. This phase accelerates the project start-up time and enables the organization to test multiple digital innovation concepts/ideas in a short period of time. This allows the testing of all "what if" scenarios with a lean approach and providing innovation freedom. The objective is to deliver the confidence that there is a practical business application for the digital innovation idea or concept, as well as, to assess its limitations. The end of the PoC phase results in the preparation of a business case envisioned as a forecast of benefits (i.e., value impact) as a basis to facilitate the Go/No-Go decision to the next phase. Given the uncertainty regarding the prospects of the Digital Innovations and the limited information at the PoC phase in terms of costs and benefits, the first Business Case gate is dependent on predicted costs and benefits that define

deliverables for the next phase (PoF). The execution of the PoC phase follows an agile methodology to define-build-release the deliverables in accordance with the limited scope of the PoC phase.

C. Proof of Feasibility (PoF): Demonstrate Value

Further progression from the PoC phase to the PoF phase is dependent on the Forecast Business Case assessment. The objective of the PoF phase is to demonstrate the applicability in real-like business process settings by testing the digital innovation for its feasibility as a pilot. Furthermore, within this phase, digital innovation is comprehensively elaborated through the involvement of stakeholders, by following User Requirements Specification (URS) and aligning the digital innovation with legacy processes and systems to streamline with the established business set-up as well as, adhering to regulatory policies. The PoF phase is an iterative optimization phase with a narrow focus on selective benefit areas, as defined from the PoC phase, to provide real-world metrics. This allows the creating of a Focused Business Case by lean management of resources, opportunities, and any organizational challenges. However, resource engagement is higher than the PoC phase, as Digital Innovation requires optimization in order to comply with the organizational processes. The outcome of the PoF phase results into a Focused Business Case for a Go/No-Go decision towards the next PoV phase. This gated business case evaluation reflects the validity of the Forecast Business Case from the PoC phase and builds a Focused Business Case with a time-oriented benefit plan for its adoption. Dependently, a change management plan is further defined to bring the transition from the PoF phase to the subsequent PoV phase. The execution of the PoF phase follows an agile methodology to define-build-release the deliverables as per the limited scope of the PoF phase, and employs comprehensive evaluation with interacting stakeholders using suitable tools (such as design thinking) to ensure that all needs from the interlinked stakeholders are addressed [76]. The digital innovation is iteratively optimized depending on the stakeholder and user feedback.

D. Proof of Value (PoV): Establish Value and Transformation

The PoV phase establishes the value to the business and initiates the transformation of the business processes. The digital innovation has stringently passed the earlier phases (PoC and PoF) and met the gaps and needs of the organizational processes and systems. In the PoV phase, the transformation of the business processes and a realization of the benefits in alignment with the Focused Business Case benefits are expected. This is the phase in which the digital innovation is integrated and adopted within the day-to-day operations of the business process and further benefit synergies are explored and evaluated. In this phase, the engagement of resources is defined from the PoF experience so to ensure reduced operating costs.

The transformation initiates with the PoF phase by testing the feasibility of the innovation in a real-like business setting and further optimized depending on the needs of the interrelated stakeholders for any identified uncertain gaps. Finally, the adoption is pursued within the PoV phase that transforms the existing business process, and continuously monitors and iterates the benefits during the entire lifecycle of the project.

E. A RACI Matrix for Smoother Transitions

Governance is an important factor to drive Digital Innovations, and our DIM framework structures the roles and responsibilities by providing an enabling role to the digital - innovation managers. The DIM framework institutionalizes the phase-appropriate use of the RACI matrix to set the accountabilities on the roles and responsibilities. The RACI matrix is a simple and commonly used tool by project managers to define responsibilities for the successful delivery of project tasks [77]. The RACI acronym stems for R as Responsible to Execute the activity, A as Accountable to Ensure the activity is executed, C as Consulted to Contribute to the activity in a 2-way communication, and I as Informed about the activity (1-way communication).

Within the DIM framework, the phase-appropriate structuring of the RACI matrix allows the onboarding of stakeholders with defined roles and responsibilities necessary for the execution of the DIM phases. In Table III, we have detailed a RACI matrix by elaborating the roles of the digital - innovation managers, business sponsors, idea champions, stakeholders (business functions, leadership, regulatory, strategy, finance, etc.) and intellectual property (IP) for the different phases.

Within the PoC phase, the digital - innovation manager and the idea champion drives the initial set-up by aligning with the endorsement from the stakeholders. Subsequently, in the PoF phase the digital-innovation manager shares the responsibilities with the business sponsor or potential owner and finally transitions the responsibility to the recipient business unit in the PoV phase. The role and responsibilities are defined phase-appropriately to facilitate the onboarding of the digital innovation ideas/concepts towards their smoother adoption within their relevant business units. This entails clarity regarding accountabilities.

TABLE III

Smooth Transition and Integration (RACI matrix)

Phase	Activity	Digital Innovation Manager	Business Sponsor	Idea Champion	Other Stakeholders	Legal and IP
Proof of Concept	Idea scouting and promoting	R	C	R	I	
	Stakeholder Identification	R	C	A	C	
	Cost bearing	R	A	C		
	Study design (MPV)	R	A	C		
	Resource Commitment	A	R	C		
	Contracts	R	I	I		C
Proof of Feasibility	Value Assessments	R	C	R		
	Stakeholder Identification	A	R	C	C	
	Cost bearing	A	R	C		
	Study design (Feasibility)	R	A	C	I	I
	Resource Commitment	A	R	C		
	Contracts	R	A	I		C
	User Requirement	A	A	C	R	
Proof of Value	Adoption Plan	C	R	C	C	I
	Cost bearing	I	R	C	I	I
	Resource Commitment	I	R	C	A	I
	Contracts	A	R	I		C
	Monitoring of execution	I	A	C	C	I

F. Phase-Appropriate Value Assessments

The three DIM gates assess the value brought by the digital innovation at the end of each phase. The business case is a review technique broadly adopted by organizations to represent the cost-benefits information and aid decision-making [78], [79]. Within our DIM framework, the business case is initially built on figures that are broadly estimated through various channels (e.g., within workshops involving domain experts and sponsors, literature on similar use cases, etc.), to set a scenario planning for the benefits impact value. Thus, relating to a divergent mode, where boundless applications of digital innovation are considered. From the broad and divergent vision of the PoC phase (Forecast Business case), the PoF phase prioritizes an immediate and quick win set of benefits to be pursued, to demonstrate focused value and validate the PoC estimates. Thus, relating to convergence mode, of focusing on specific benefits (SMART: Specific, Measurable, Achievable, Realistic, and Timely) as captured within the Focused Business Case. Finally, the PoV phase monitors and pursues additional benefits in alignment with the Forecast Business case. Thus, benefits are iteratively explored following the vision during the lifecycle of the digital innovation in the PoV phase by continuous monitoring. The phase-appropriate approach provides consistently evolving benefit areas, which are logically elaborated and integrated with step-by-step adoption into the business process. The approach enables increased ability to forecast in a phase-appropriate manner, in accordance with the availability of new information from the execution experience.

The benefit identification and their measurements are crucial when elaborating business cases. Typically, the benefits generated by digital innovations range from operational (e.g., increased productivity) to strategical (e.g., increased

competitiveness). Operational benefits are easier to quantify in monetary terms and can be classified as hard savings. Whereas, the strategic benefits are difficult to quantify in monetary terms and relate to soft-savings or intangibles, as they do not directly impact the bottom-line [80]–[84]. Several authors attempted to develop methodologies to quantify intangible benefits. However, no standard approach exists [85]–[88]. Digital Innovations generate intangible, not immediate benefits interlinked with other areas, and the overall strategic relevance is difficult to estimate. A metric commonly used in organizations for estimating the value of benefits is the FTE hours savings. Typically, the cost to the company of 1 FTE unit consists of base salary plus overhead 25%, general and administration 18%, and fringe 35% [89]. On average, the cost of 1 FTE is typically 1.5 to 2.5 times the average salary costs [90]. Even though, the FTE hours savings is an easy and reliable metric, any commitment to workforce reductions needs to be realistically assessed.

Expository instantiation of the DIM framework

TABLE IV

Dimension	Proof of Concept	Forecast business case	Proof of Feasibility	Focus business case	Proof of Value	Monitor business case
SCOPE	Explore if AI can automate the business process. Use cases on simple and complex process variants.		Cover most of the process variants. Optimize the solution as per requirements and policies. Real-like business scenario features and testing.		Full integration into the business process and with complementary legacy systems. Continuous development to cover additional cross areas of applicability	
PRODUCT / PROCESS STATE	Minimal Viable Product/Process (MVP).	Forecast on FTE savings. Forecast of Hard and Soft benefits.	Optimized Product/Process.	Realistic FTE savings and redeployment to value-added tasks	Fully integrated Product/Process into the business	Monitoring FTE savings and other benefits.
OBJECTIVE	Demonstrate that AI can automate complex business processes, thus building confidence in digital innovation.	NPV – includes all the direct and indirect saving ROI – payback period more relevant	Adherence to internal policies and business processes. Assess the impact on the workload of operators.	Realistic assessment with demonstrable savings. NPV – conservative focused on direct planned savings. ROI – payback period more relevant	Transfer in routine operations and continuously evolving solution.	Continuous assessment of benefits with demonstrable savings, also from scaling the solution to other areas. NPV – conservative focused on direct planned savings.
ADAPTATION TO BUSINESS	Minimal temporary set-up as plugs and play with a sandbox approach.	Costs x1 \$	Sustainable IT infrastructure and compliance with organizational policies.	Costs x2 \$	Long term IT infrastructure, and integration with other legacies IT systems.	ROI – payback period more relevant Costs x3 \$ to x4 \$
EXECUTION METHOD	AGILE to build algorithms, and demonstrate the value		AGILE and DESIGN THINKING to build a solution empathizing with stakeholder and end-users			

The financial and profitability assessment section of the business case is crucial to take informed Go/No-Go decisions granting the transition across phases. Digital innovations are evaluated on a consistent set of Capital Budgeting Techniques (CBTs) to prioritize on the expected profitability. CBTs rely on cash flow information for decision-making, and they may or may not agree on a single project choice for prioritization. This is due to the inherent limitations of these metrics. Therefore, it becomes a difficult task to choose the most viable or profitable investment (Appendix Table I reports common CBTs metrics). A possible rationalized approach would be to use a two-staged approach for evaluating digital innovation projects. In the first stage, the projects are prioritized based on NPV & IRR. The limitations from the first stage prioritization can be eliminated by assessing the projects with non-discounted CBT methods such as ROI & payback.

This second stage allows a clear direction on quick win prioritization i.e., low investments, and faster returns. Thus, discounted methods to assess the investments according to the time value of money, can be combined with the non-discounted methods for providing the evaluation based on the organizational investment strategy. Moreover, other financial aspects such as cumulative cash flow curves over the defined period may provide insights for prioritization. The digital innovation project showing the increasing curve can be regarded as positive towards improving prospects. Hence, investment curves add a qualitative view to the assessment by signifying that, if the outflow costs are increasing, the investment may pose a risk in the future.

IV. FRAMEWORK EXPOSITORY INSTANTIATION: BRINGING AI INTO ORGANIZATIONS WITH DIM

Artificial Intelligence based digital innovations are regarded as the most significant technological contributors to businesses by promising high benefit values to the organizations. Within the Biopharmaceutical Research and Development, the use of AI has shown a high potential in predicting the drug activity for higher efficacy [91], 3-D structure stimulation for better drug design [92], biomarkers discovery for specific disease states [93], [94], predicting drug responses and interactions [95]–[98], predicting risks on mortality and adverse drug events [99], [100], optimizing clinical trials [101], [102], drug discovery and development [103], [104], and many more areas.

As with other digital innovations, AI possesses tremendous benefit potential that often goes beyond its initial benefit estimation [37]. Thus, digital innovation projects involving AI are challenging to pursue and adopt within the existing legacy business processes and systems. Therefore, we present the expository instantiation of our DIM framework on a case of AI-based digital innovation. The motive of the digital innovation was to introduce AI for driving the operational process in a faster, automated, and intelligent manner. Thereby, creating a data lake for unravelling hidden insights on the data, and configuring the AI application as a competence enhancing process innovation [105]. Within our DIM framework, the project was structured consistent with the PoC-PoF-PoV phases (Table IV).

TABLE V

Phase Specific Business Cases and Benefits

Drivers	Phase	Business Case Type	Benefit						Estimate of Cos	
Efficiency	POC	Forecast Benefit	Reduction in data processing timelines	Peak time accommodation	Reduction in human error	Increased adherence to standards	Auditability of the process	Improved quality of output	50-60	
	POF	Focused Benefits	Operator time saving (or overtime) calculated as AS-IS minus TO BE hours.		Historical frequency of errors in AS-IS process minus TO BE process					
		Dependent Data	Operator hrs. (or overtime) for AS-IS and TO-BE process		Standard Cost for rework & mitigation process					
Innovation & Technology	POC	Forecast Benefit	Boosting innovation – new business area	Agility and forward-looking focus	Fostering an innovation and data culture	Improved data maturity	Competitive advantage from improved operations		10-15	
	POF	Focused Benefits				Time savings by reusing existing data				
		Dependent Data				Reduction in time for starting new projects				
People	POC	Forecast Benefit	Up-skilling of workforce with digital skills	Codify human knowledge into digital labour (available 24/7)	Redeploy operators to high-value tasks and Boosting engagement by focusing on creative, intellectual, and social tasks		Improved training and knowledge documentation		10%	
	POF	Focused Benefits						Reduction in training time from AS-IS process minus TO BE process		
		Dependent Data						AS-IS training hours		
Sustainability	POC	Forecast Benefit	Minimize negative environmental impacts	Conserve energy and natural resources	Waste management	Improved utilization of resources by load balancing	Crisis resistant (COVID-19) favouring business continuity in operations		10%	
	POF	Focused Benefits	Reduction in Carbon footprint as contributed by AS IS minus TO BE process							
		Dependent Data	Costs on fuel and energy as linked to the AS-IS process							

Initial deliverables and success criteria were defined for the specific phases in alignment with stakeholders and business sponsors. Along with the progress within the phases, additional opportunity areas were continuously discovered and focused upon. For the cost-benefit value estimations, the first step was to define the *AS-IS* process costs, and the dependent savings were estimated by using multiple channels of information (e.g., discussions with domain experts, external collaborators, and literature data on similar use cases). The costs and resources were leanly structured to cover the dynamically defined phase-appropriate deliverables. Thus, allowing lower costs and faster outcome times in the PoC phase, and gradually increased them across the PoF phase, in order to optimize the digital innovation into the business. Eventually, onboarding it into the PoV phase with optimized operating costs in accordance with the experience gained in the PoF phase. On the timelines, the PoC phase was executed in 4 months, whereas the PoF phase required 9 months. This was due to the involvement of multiple stakeholders in defining the user requirements and optimizing the solution according to the organizational policies and processes through a comprehensive design thinking exercise in the PoF phase in order to align, with the expectations of the stakeholders and end-users. Finally, within the PoV phase, the cost and time estimates are kept on a rolling basis, as it is continuously evolving during the iterating phase. The execution was modularly performed in each of the phases through agile methodology of building the solution as per the evolving phase objectives and scope. Thus, reducing the risks and costs across the project progression.

Based on the indicators of confidence within the PoC phase, the Forecast Business Case was elaborated for tangible and intangible benefits. Benefit assessments were performed in a *diverge* mode, to extend and include all the possible value implications of the AI - digital innovation. This resulted in setting a broad vision of benefit scenario, and to

facilitate the decision-making process on prioritization and Go/No-Go decision (Table V). Upon transition into the PoF phase, the focus of the benefits was directed on a specific use case within one business unit of the organization as a pilot. Thus, as a dynamic problem-solution design pairing for iteratively shaping the scope & functionalities towards enhanced value across the phases. Thus, demonstrating the applicability of the AI-digital innovation in a selective business area and to iteratively optimize and test the AI-digital innovation in a real-like business setting in accordance with the relevant stakeholders and process necessities. This allowed the acquisition of empirical evidence concerning the associated benefits and costs. During the PoF phase, experience on the AI-digital innovation project was captured and a focused business case assessment was performed at the end of the PoF phase (Table V), to facilitate the Go/No-Go decision for the final adoption of the innovative solution into the business process (PoV phase). The difference between the Forecast and Focused business case is minor, wherein the Forecast captures the futuristic considerations on a broad estimate covering tangible and intangible benefits. Whereas the Focused Business Case is based on verified benefit metrics from the PoF phase experience.

The PoV phase reflects the adoption of the AI-digital innovation and initiates the transformation of the business process. It involves the continual monitoring of benefits from the PoF phase, in alignment with the benefit vision provided by the forecast business case (PoC phase). The continuous lifecycle monitoring of the AI-Digital Innovation provides an opportunity to keep track of competitive developments and leads continuous business transformation to leverage future benefit opportunities. It can be further extended to capture scalability and cover other areas of applicability to generate a broader valuation as predictively defined from the forecast business case during the PoC phase, or to include the not-defined benefits. With the phase-appropriate business case assessment strategy, the PoC phase sets a broader vision for prospective benefits through the forecast business case. And the focus business case provides the immediate focused benefit plan for the organization, that is to be followed through the continuous monitoring in the PoV phase. The enabling role of the digital innovation manager was instrumental for orchestration and socio-cognitive sensemaking to discover new opportunity areas and engage stakeholders for scaling it across the organization.

For the cost-benefit evaluation, the tangible benefits were calculated as elaborated in Table V. The empirical experience from PoF phase allowed to easily define the calculation methods and dependent data. The adoption of the AI-digital innovation into the business was followed with a step-by-step clear benefit plan reflecting the organization's cash flow. The PoF phase defined a realistic period-specific converged benefit plan, initiating the adoption into the business process. This approach provides a balance to pursue the forecasted benefit vision within the PoC phase and delivers reasonable, actual, accurate, period-specific benefits consistent with the dedicated timeline of the PoF phase. Thus, fostering efficient prioritization that captures the holistic view and fosters planning for accurate deliverables when transformed into PoV. Thus, the approach allowed the negotiations with decision-makers to incrementally request the IT budgets with a justified risk-based approach to tackle the IT technology constraints.

V. DISCUSSION

Taking into consideration the organizational challenges and regulatory uncertainties, we have designed our DIM framework as a phase-appropriate artifact, terming the phases as Proof of Concept (PoC), Proof of Feasibility (PoF) & Proof of Value (PoV) that – at the best of our knowledge- are used interchangeably in literature. Our DIM framework provides an approach to manage the execution plan of digital innovations by structuring phases (PoC-PoF-PoV) with initial low investments, objective, and iterative deliverables, minimized risks, and guides the managers to build phase-specific business cases to align expectations and build confidence. Thus, we propose to bring digital innovations by experimentation and transform the legacy business process through incremental benefits with an evolving portfolio based on experience and exploration. This allows the facilitating of the prioritization and the decision-making with clear expectations within the existing legacy business processes as encountered in the healthcare industry. The incrementality of building digital innovations across the phases allows to build “fit-for-purpose” evidence and gain the confidence of the regulatory expectations. Thus, balancing the uncertain risks with iteratively building digital innovations by cost-conscious incremental investments. Our framework provides a flexible approach to the practitioners in presenting to the decision-makers by proceeding progressively with few benefits at a time, and continuously monitoring and exploring to cover the benefits vision. This approach would set a good negotiation ground with decision-makers and allow practitioners to incrementally request for budgets with a justified risk-based approach. Due to the heavy reliance on proven and established technologies, any new technological changes within the operational processes of pharmaceutical & biopharmaceutical companies are highly challenging, and the notion is to “Be the First Second” in the competitive race [106]. From the recent FDA survey, “We are slow to adapt new technologies until they are proven/adopted by industry peers” was among the key findings for the manufacturing site’s approach to the adoption of promising new technologies [52]. Through our phase-appropriate DIM framework, we shift the tendency towards “Firsthand Inventiveness” by strategically dealing with the organizational barriers and regulatory uncertainties. Some preliminary indicators from the use of the DIM framework within our organization have resulted in increased stakeholder endorsements to initiate new explorative topics, leading to 3 times more projects in the portfolio, and reduction of lead-times by 40 to 60 % on the decision-making. Indeed, these are early observations on a limited set, and would vary depending on the complexity and dynamics of the digital innovation projects. Our work contributes to the extent literature on Digital Innovation Management research, by a practical translation of the digital innovation logics as defined by Nambisan et al., 2017 to apply and exemplify theory to practice [107]. Through our expository instantiation on the case of the AI-based solution, we illustrated the practice of the DIM framework to practitioners, for managing digital innovations through phase-appropriate iterative efforts, governance model, and gated assessments that are aligned to the new proposed logics a) Dynamic problem–solution design pairing, b) Technology affordances and constraints, c) Socio-cognitive sensemaking and d) Orchestration [18]. Throughout the article, we comprehensively and accurately defined the description of the widely postulated new logics on digital innovations [18] into a specific area of the healthcare sector. Understanding contextual factors is important within the Information System research [108] and this study contributes to a better understanding of the contextual differences of the digital innovation management by contextualizing within the healthcare industry and investigating how an

established biopharmaceutical organization operates and manages digital innovations. The detailed visibility of the process, from our description, will allow academic scholars to further investigate with a broader outlook and apply different methodologies, in order to identify many other influencing factors, that may be positive or negative when generalizing and refining the theoretical digital innovation logics and enriching the Digital Innovation Management research into other areas.

We contribute to the literature by investigating the orchestration of digital innovation in the healthcare industry, instrumental to illuminating the phenomenon. Orchestrating digital innovation to balance fluidity and stability is paramount for organizations to capture value [109]. In the DIM, orchestrating entails phase-appropriately defined digital innovations, adjusting to specific organizational contexts and use cases, to coordinate actors and resources iteratively and dynamically in every phase of the digital innovations process. The DIM framework neither entails rigid constraints (as stage-gate models), nor an uncontrolled path leading to non-structured processes. The fluidity, variability, and emergence of digital innovations are orchestrated in the DIM through loose couplings across phases. To this purpose, each phase has a degree of independence to embrace fluidity and generativity along the digital innovation journey. Thus, leading to the cascade of incremental effects across the phases while building stability, which allows the management, coordination, and connections of different pools of actors and resources. Moreover, DIM balances between technical and social aspects of digital innovations [110] by the phase-appropriate orchestration of actors and resources. Our work attempts to connect the Digital Innovation Management research [18] with the efforts on digital transformation in healthcare [1], [30]–[32], thus opening crossroad avenues of collaboration between these emerging areas.

The DIM framework facilitates the digital transformation within the biopharmaceutical companies with implications to generate value in terms of operational efficiencies, cost-effectiveness, and increased responsiveness to multi-stakeholders of the healthcare ecosystem. Although we have built and applied the DIM framework in the frame of digital innovation management, we foresee its broad applicability to other managerial areas with further adaptations by scholars and practitioners.

VI. CONCLUSION

Our proposed DIM framework is a further adaptation of the stage-gated models to incorporate an incremental and phase-appropriate definition of objectives and deliverables in an agile fashion. We have extended an accurate description and structuring of the emerging new digital innovation logics within the healthcare sector. Accordingly, triggering a departure from the legacy innovation management processes, and to effectively solve practitioners' challenges within the biopharmaceutical industry. Within our approach, the Nambisan et al. [18] seminal article was used as the kernel theory, along with an empirical ground (i.e., eight digital innovation projects). We showed the application of the DIM framework in a real-world scenario as an expository instantiation on a longitudinal case study of an artificial intelligence-based solution. The implication of our work aims to facilitate the digital transformation within the highly regulated pharma & biopharmaceutical companies to generate value in terms of operational efficiencies, cost-effectiveness, and increased responsiveness to multi-stakeholders of the healthcare ecosystem. We

believe that the DIM framework can be applied to many managerial areas and increase the opportunities for its exploration for both scholars and practitioners.

Appendix

Supporting information is included as Appendix Table I - Comparison of commonly used Capital Budgeting Techniques, and all the Figures and Tables from the manuscript in color.

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