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Adaptive Enterprise Architecture for the Digital Healthcare Industry: A Digital Platform for Drug Development

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Abstract: Enterprise architecture (EA) is useful for effectively structuring digital platforms with digital transformation in information societies. Moreover, digital platforms in the healthcare industry accelerate and increase the efficiency of drug discovery and development processes. However, there is the lack of knowledge concerning relationships between EA and digital platforms, in spite of the needs of it. In this paper, we investigated and analyzed the process of drug design and development within the healthcare industry, together with related work in using an enterprise architecture framework for the digital era named the Adaptive Integrated Digital Architecture Framework (AIDAF), specifically supporting the design of digital platforms there. Based on this analysis, we evaluate a method and propose a new reference architecture for promoting digital platforms in the healthcare industry, with future specific aspects of them making effective use of Artificial Intelligence (AI). The practical and theoretical contributions include: (1) Streamlined processes through digital platforms in organizations. (2) Informal knowledge supply and sharing among organizational members through digital platforms. (3) Efficiency and effectiveness in planning production and business for drug development. The findings indicate that EA with digital platforms using the AIDAF contribute to digital transformation with effectiveness for new drugs in the healthcare industry.

Keywords: digital transformation; enterprise architecture; digital platform; digital healthcare; knowledge management; cloud computing; artificial intelligence

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1. Introduction

We consider new enhancements of business structure and process efficiency using digital platforms such as portals and social networking services (SNSs) among corporations in healthcare industries. We particularly expect the use of these digital platforms for drug discovery and development processes in pharmaceutical companies at the forefront of the recent utilization of digital IT technologies. However, how to properly use these digital platforms for drug discovery and development processes within pharmaceutical companies is still not well understood.

The enterprises and information societies in healthcare industries have confronted various changes, such as globalization, shifts in customer needs, and new business models with emerging technologies, whose significant changes due to recent developments in cloud computing, mobile IT, and big data technology have appeared as new information technology trends. Moreover, aforementioned technologies making advances and related processes have created a "digital IT economy," breeding business opportunities and business risks and leading enterprises to innovate or face the consequences [1]. Enterprise architecture (EA) can be useful for contributions to the design of large integrated systems, representing a substantial technical challenge toward the era of cloud, mobile IT, big data, and digital IT in digital transformation. From a comprehensive perspective, EA covers all enterprise artifacts, such as business, applications, data, infrastructure, and organizations to show the current architecture and future architecture/roadmap. In any case, EA frameworks need to accept change in ways where they take account of the emerging new paradigms and requirements affecting EA, such as cloud, mobile IT [2,3].

Likewise, considering the above background, the author of this paper proposed the "adaptive integrated EA framework," that can align with IT strategy accelerating cloud, mobile IT, and digital IT, and verified this in the case study [4]. The author has named the EA framework fitting for the digital IT era as "Adaptive Integrated Digital Architecture Framework—AIDAF" [5]. The motivation for this research paper is as follows: (1) The proposed AIDAF framework has been specifically tailored to support digital transformation with a holistic architectural perspective. (2) The AIDAF framework supports key stakeholders in architecture-based decision making, such as customers, scientists, managers, chief information officers (CIOs), and chief digital officers (CDOs). We expect that the aforementioned digital platforms for drug discovery and development can be operated and managed with the AIDAF because the above system covers big data and cloud-related aspects.

According to the latest research papers of systematic literature review on EA [6–9], these reviews have not referred to digital platforms with EA, while Pierre Hadaya et al. showed the existence of reference models covering solutions models such as platform-specific components [10]. Thus, we found that there is insufficient knowledge regarding relationships between EA and digital platforms, which will lead to effectiveness and sustainability in healthcare industries.

Therefore, this research focuses on the problem-solving process involved in promoting the efficiency and activation of processes related to drug discovery and development, and increasing effectiveness on digital platforms through the healthcare community, which is within the activities for drug discovery and development on digital platforms in pharmaceutical companies. The theoretical and practical contributions of this research arise from the following aspects: (1) Streamlining processes through digital platforms in healthcare organizations. (2) Informal knowledge supply and sharing among organizational members on digital platforms. (3) Improving efficiency and effectiveness in scheduling production and business on digital platforms for drug development.

We have organized this paper as follows: The next section presents the literature review and theoretical development of this study, followed by the description of research methodology and the descriptions and overview of the digital platform with drug discovery and development in EA. Finally, we outline our conclusions, limitations of the current study, and directions for future research.

2. Literature Review and Theoretical Development

2.1. Direction of Digital IT and Enterprise Architecture

2.1.1. Concepts of Enterprise Architecture

Enterprise architecture is a management and technology practice to improve enterprise performance, where a management program and an analytical design method are performed repeatedly at different levels of scope [11]. The essence of EA lies in building and organizing the structural context for the alignment of technology and business planning, with strategic planning as its primary driver [12,13]. Bernard [11] shows EA as a cubic representation consisting of dimensions, artifacts, segments, and levels, with six essential elements, as shown in Figure 1. We support EA analysis and design through the following six essential elements: (1) an EA framework, (2) EA components that support the drawing of (3) current and (4) future views of the architecture, the following development of (5) an EA management plan to manage the enterprise's transition from current states to future architectures, as well as EA documentation which should cover (6) "threads" of common activities presented in all levels of the framework, such as IT-related security, standards, and skill considerations [11]. Artifacts are large organizational entities of value creation. Segments are cross-cutting components of the enterprise, i.e., a human resource database. Levels are a hierarchical construct with the enterprise's strategic initiatives at the top (level 1) and the technology and infrastructure as the base layer (level 5). Level 4 is systems and applications, level 3 is data and information, and level 2 is products and services. Basis to the EA philosophy is the transition from a documented present state to an intended future state. The level-based model briefs and supports interrelations in the enterprise of the distinct technological levels. Each level plays an exclusive role to ensure that the enterprise's operating model, such as products and services, can represent the artifacts required for a business service and a related business model [14]. Business models are defined from the top-level but rely on peculiar hierarchical dependencies [15]. EA supports the creation of business models; for example, in switching from delivering physical products to delivering services for these products.

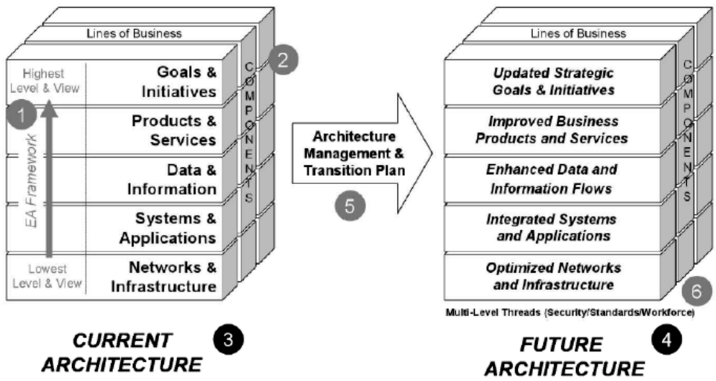

Figure 1. The basic elements of enterprise architecture (EA) analysis and design in EA3 cube framework [11].

Ongoing discussions seek to capture the enterprise's maturity of EA and EA governance [16]. In the case of EA representing the systems and applications of an enterprise, it is closely related to strategic systems' portfolio management and, thus, also definite in selecting the technological elements of the operating model in the enterprise.

Moreover, EA is debated in initiatives on inter-organizational relationships [17,18] and technological interoperability [19]. As an EA is derived from an organization's strategy, there are restrictions on the ability to execute the technological design in other enterprises. However, most levels of the EA rely on external relationships such as parts from suppliers, products for the market, and data sent to and from related parties. Drews and Schirmer [17] suggest that EA can become a positive driver for the creation of business ecosystems. Moreover, EA is often treated as the architecture implementation and maintenance framework known as the Open Group Architecture Framework (TOGAF) [20]. Specifically, TOGAF outlines a methodology for implementation starting with the setting of business objectives and describing the outcome [21], and structures an enterprise from the business, data, application, and technology architectures, whereby engaging with the business surroundings is addressed with an 'enterprise continuum' [22]. TOGAF addresses enterprises' ability to adapt and adopt the technology by showing readiness, organization, management, and structuration level. Thus, implementation proceeds as the core process, known as the architecture development method (ADM) [23]. ISO/IEC/IEEE42010:2011 defines the architecture framework as "principles, and practices for the architecture descriptions established within a specific domain of application or community."

2.1.2. Literature Review for Enterprise Architecture (EA) and Digital IT

Enterprise architecture offers many benefits to companies, such as coordination, communication, and planning between business and IT, and reduced IT complexity [24]. The coherent relationships between EA and business strategy, processes [25,26], and project portfolio management [27] are also discussed and defined. For the delivery of the above benefits, EA frameworks need to cope with the emerging new paradigms, such as cloud computing or enterprise mobility [2]. However, according to the latest studies of systematic literature review on EA [6–9], the relationship between digital platforms and EA was not discussed. The existence of references models (e.g., solutions models) like platform-specific components was only suggested [10].

Mobile IT computing is an emerging concept using cloud services provided for mobile devices [28]. Also, mobile IT applications consist of web services. Many studies discuss the integration of EA with service oriented architecture (SOA), except for mobile IT. The SOA architecture pattern defines the four primary forms of business service, enterprise service, application service, and infrastructure service [29]. The OASIS, which is a public standards group [30], introduces an SOA reference model. Many organizations have invested in SOA as an approach to manage rapid change [31].

At the same time, we focus on new technologies, such as mobile IT, cloud computing, and platforms [32]. From standpoints of service characteristics, there are significant differences between SOA and microservice [29]. Microservice is an approach for distributed systems consisting of the two necessary forms of functional services through an API layer and infrastructure services. The implementation of a mobile IT application is enabled by multiple microservices cooperating to work together [33].

In terms of cloud computing, the National Institute of Standards and Technology (NIST) defined three cloud service models such as software as a service (SaaS), platform as a service (PaaS), and infrastructure as a service (IaaS) [34]. SaaS is a software application developed, implemented, and operated on a platform foundation of PaaS, that is an IaaS platform covering both system software and an integrated development environment. IaaS accommodates PaaS and SaaS, with providing infrastructure resources like computing network storage memory through specific cloud centers [34]. A number of mobile IT applications operate with SaaS cloud-based software [28]. In the literature, the relationship and integration between EA and cloud computing is rarely discussed. Considering the dynamic trends in cloud computing recently, enterprises and organizations need to link EA and cloud computing [35]. The traditional EA approach takes more than several months to develop and start up an EA for a cloud adoption strategy, and organizations will demand adaptive EA to iteratively develop and operate an enterprise architecture adaptive to cloud service technology [36].

Furthermore, according to previous research [37], with strategies covering cloud platforms and mobile IT, it is proposed as a good option that an enterprise or an organization that applies TOGAF or federal enterprise architecture framework (FEAF) can adopt the integrated framework with the adaptive EA framework supporting elements of cloud computing. The author proposed and verified an enterprise architecture framework integrating an adaptive EA cycle with TOGAF or a simple EA framework for different business units in the upper part of the diagram in [4,38] with the case study of a global enterprise. The author of the previous paper described above named this enterprise architecture framework as the "AIDAF" [5,38].

Besides our previous work from [39], the current paper essentially defines the original and now extended base of the digital enterprise architecture reference cube (DEA), in Figure 2. DEA—Digital enterprise architecture reference cube exposes 11 integral architecture domains to support a holistic digital architecture classification model. DEA provides our comprehensive architectural reference model to integrate in a bottom-up manner dynamically composed micro-granular architectural services and their models for supporting intelligent digital services and products.

We have extended our service-oriented enterprise architecture reference model for the evolving context of digital transformation with micro-granular structures, like the Internet of Things and microservices. Furthermore, we associated multi-perspective architecture decision models supported by views and functions of an architecture management cockpit. DEA abstracts from a particular business scenario or technology because it can be applied to a large set of concrete architecture instantiations in digital transformations [40,41] independently of different domains.

The DEA reference cube covers the perspectives of a platform and ecosystem architecture. In our understanding, a digital platform is a repository of business, data, and infrastructure services used to rapidly configure digital offerings from digital services. Digital services and components are slices of code that perform a specific task. We position reusable digital services as parts of an ecosystem of services. A digital platform linearizes the complexity of cooperating services. A digital platform integrates core technology services to provide standardized access points and repositories for an intelligent service ecosystem. A service ecosystem is composed of business services, data services, and infrastructure services. The value of a platform to users is derived from the number of platform and service users. A digital platform [42] and ecosystem should enable shared value creation [43] for all stakeholders and facilitate the exchange of goods, services, and social currency. Platforms do not own or control their resources and are therefore well suited to support scalability within the ecosystem.

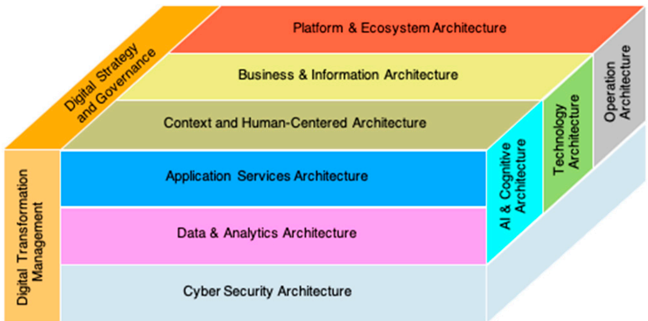

Figure 2. Digital enterprise architecture reference cube.

Table 1 shows the overview of the above literature review for EA and digital IT as below.

Table 1. Overview of literature review for EA and digital IT.

Research Categories	Highlights	References
EA general	Definitions of an architecture framework	[2] A. Alwadain, E. Fielt, A. Korthaus, and M. Rosemann, 2014; Van der Raadt et al., 2008, 2010; Hjort-Madsen, 2006; Martin, 2012
	Benefits of EA	[24] T. Tamm, P. B. Seddon, G. Shanks, and P. Reynolds, 2011; Roeleven, 2008; Gregor et al., 2007
	Business Strategy, Process and Portfolio Management on EA	[25] F. Kitsios, M Kamariotou; 2019 [26] F. Gonzalez-Lopez, & G. Bustos: 2019 [27] C. Gellweiler; 2020
	Systematic Literature Reviews on EA	[6] BD. Rouhani, MN. Mahrin, F. Nikpay, RB. Ahmad, 2015; [7] M. Zhang, H. Chen, A. Luo, 2018; [8] N. Silva, P. Sousa, MM. da Silva, 2020; [9] Z Zhou, Q. Zhi, S. Morisaki, S. Yamamoto; 2020 [10] P. Hadaya, A. Leshob, P. Marchildon; 2020
Mobile IT	Concepts of Mobile IT	[28] K. Muhammad, M. N. A. Khan, 2015
	Analysis of EA and Mobile IT	[37] Y. Masuda, S. Shirasaka, and S. Yamamoto, 2016
Cloud computing	Definitions of Cloud computing	[34] A. Q. Gill, 2015
	Relationships between EA and Cloud computing	[35] K. M. Khan and N. M. Gangavarapu, 2009 [36] A. Q. Gill, S. Smith, G. Beydoun, and V. Sugumaran, 2014
	Analysis of EA and Cloud	[37] Y. Masuda, S. Shirasaka, and S. Yamamoto, 2016

Table 1. *Cont.*

Research Categories	Highlights	References
SOA and Microservices	Definitions of SOA	[29] M. Richards, 2015;
	Reference model of SOA	[30] C. M. MacKenzie, K. Laskey, F. McCabe, P. F. Brown, and R. Metz, 2006
	Benefits of SOA	[31] H. Chen, R. Kazman, and O. Perry, 2014
	Characteristics of Microservices	[32] S. Newman, 2015 [29] M. Richards, 2015 [33] B. Familiar, 2015
AIDAF framework	Case Study in Global Enterprise	[4] Y. Masuda, S. Shirasaka, and S. Yamamoto, 2017
	Architecture Board with Digital Platform	[5] Y. Masuda, S. Shirasaka, and S. Yamamoto, 2018
	Overall AIDAF framework	[38] Y. Masuda, M. Viswanathan, 2019
DEA reference cube	Supporting Digital Transformation	[40] D. L. Rogers, 2016 [41] E. R. Hamilton, J. M. Rosenberg, M. Akcaoglu, 2016
	Digital platform	[42] A. McAfee, Brynjolfsson, E. Machine, 2017
	Ecosystem with value co-creation	[43] S. L. Vargo, M. A. Akaka, C. M. Vaughan, 2017

2.2. Enterprise Architecture for Digital Transformation in Healthcare Industry

2.2.1. Digital Transformation

In particular, recent developments in artificial intelligence, digitization, cloud computing, and mobile IT (e.g., advances in big data technology) have resulted in significant changes in cutting-edge IT technology within a decade as new trends in IT and, at the same time, important strategic drivers for new digital business models. Cloud-based services and accelerated digitized platforms represent a growing percentage of the total IT budget of most enterprises worldwide and are being shifted from existing on-premise application systems to the next era of digital IT [44].

In recent years, digital transformation has evolved in many enterprises, such as cloud, mobile IT applications, big data solutions, and systems related to the Internet of Things as the strategic core of digital IT [38]. Digital transformation is the dominant type of business transformation [40,45] having IT both as a technology enabler and as a strategic driver. Digital technologies are the main strategic drivers [45] for digitalization because digital technologies are changing perspectives on how business is conducted and can potentially disrupt existing businesses.

From today's view, we have to enlarge the above technological core by advances in artificial intelligence and cognition, biometrics, robotics, blockchain, 3D printing, and edge computing. Digital technologies deliver three core capabilities for a fundamentally changing business [45]: ubiquitous data availability, unlimited connectivity, and massive processing power. New technologies, such as deep learning, are strategic enablers and strongly related to advances in digitalization. They allow computers to apply to activities that are in a classical view exclusive to human beings. Therefore, the present emphasis on intelligent digitalization becomes an essential area of research. Digital services and associated products are software-intensive [45] and, therefore, malleable and usually service-oriented. We are at a turning point in the development and application of intelligent digital systems. We see excellent prospects for digital systems with artificial intelligence (AI) [46,47], which has the potential to contribute to improvements in many areas of work and society through digital technologies. We understand digitalization based on new methods and technologies of artificial intelligence and other digital technologies as a complex integration of digital services, products, and related systems.

The origin of the term "digitalization" is the term "digitization". According to [3], we distinguish in Figure 3, four levels of digitalization. When we use the term digitalization, we mean more than just digital technologies. Digitalization [40,41] bundles the more mature stage of a digital transformation from analog to digital to fully digital. In digital substitution (digitization), initially only analog media are replaced by digital media, taking into account the same existing business values, while augmentation functionally enriches the related transformed analog media. In a further step of digital transformation, new processing patterns or processes are made possible by digitally supported modification of the basic terms (concepts). Finally, the digital redefinition (digitalization) of processes, services, products, and systems enables entirely new forms of value propositions for disruptive companies, services, products, and systems. Digitalization is about shifting processes to attractive highly automated digital business processes, not just communication via the Internet. Digital redefinition usually has a disruptive impact on business. Beyond the value-driven perspective of digitalization, digital business requires careful consideration of human, ethical, and social principles.

Considering close related concepts of digitization, digitalization, and digital transformation [40,41], we conclude: Digitization and digitalization are about digital technology, while digital transformation is about the changing role of digital customers and the digital change process based on new value propositions. We digitize information, digitalize processes and roles for extended platform-based business operations, and digitally transform the business by promoting a digital strategy, customer-centric and value-oriented digital business models, and an architecture-driven digital change.

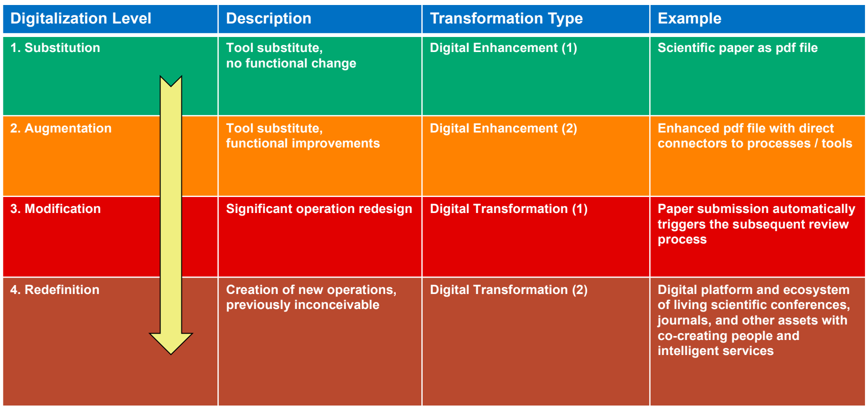

Figure 3. From digital enhancement to digital transformation. Adapted from [41].

Digital transformation [40,41] is broader than digitalization and usually begins with a digital strategy [48,49]. For constructing smart digital services, authors first model the digital strategy (as shown in Figure 4), which sets the digital modeling direction and determines the basis and value-based framework for the digital business models using the business model canvas [50] and the value proposition canvas [51]. Using the basic models for a value-based digital business, authors map these basic services and product models to a digital operating model [45], which defines the basis for the scalability and integration of services. The value perspective of the business model canvas [50] results in a suitable mapping [52] to the value models of the enterprise architecture, such as the AIDAF as mentioned earlier, and the DEA reference cube, sometimes supported by ArchiMate [53]. Finally, the authors set the framework for the systematic definition of digital services and associated products frequently by modeling digital services and product compositions according to semantically related composite patterns [54].

Value is usually associated with worth [43] and aggregates potentially basic categories like importance, desirability, and usefulness. The concept of value is essential for designing appropriate digital services with their associated digital products and aligning their digital business models with value-based enterprise architectures such as the AIDAF and the DEA reference cube. From a financial perspective, the value and price of the integrated resources define the main components of monetary worth. Today's digital business discipline has shifted to a nominal use of the value perspective, where customer experience and customer satisfaction represent essential value-based concepts.

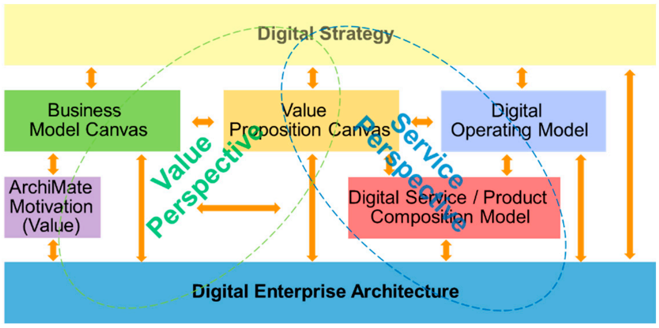

Figure 4. Integral value and service perspective of smart digital services.

2.2.2. Adaptive Integrated Digital Architecture Framework (AIDAF) Framework

It was suggested that when strategically promoting cloud/mobile IT, enterprises having applied TOGAF or FEAF can adopt the integrated framework using the adaptive EA framework supporting cloud computing [37]. In the approach mentioned above, the primary author of this paper proposed an adaptive integrated EA framework depicted in Figure 1 of [4], which should meet with IT strategy promoting cloud computing, mobile IT, big data, and digital IT, and verified this framework in the case study [4]. The proposed model is an enterprise architecture framework integrating an adaptive EA cycle with TOGAF or a simple EA framework for different business units in the upper part of the diagram in [4,38]. The primary author of this paper described above named this enterprise architecture framework as "Adaptive Integrated Digital Architecture Framework (AIDAF)" [5,38].

The AIDAF proposed model with the Architecture Board (AB) [5] is shown in Figure 5 as below. In the adaptive EA cycle, IS/IT project plan documents with architecture of new digital IT projects can be developed on a short-term basis, in the context phase by referring to materials of the defining phase (e.g., architectural guidelines for cloud, security, and digital IT, aligned with IT strategy) per business needs and demands. During the assessment/architecture review phase, the AB should review the architecture in the initiation documents for the IS/IT project. In the rationalization phase, the stakeholders and AB decide upon replaced or decommissioned systems by the proposed new information systems. In the realization phase, the equivalent project team can begin implementing the new digital IT project after deliberating issues and action items [4,5,38]. In the adaptive EA cycle, corporations can adopt an EA framework like TOGAF and simple EA framework, based on an operational division unit in the upper part of the following Figure 5, equivalent to Figure 1 of [4,5,38] in alignment between EA guiding principles and each division's principles, corresponding to differing strategies in business divisions in the mid-long-term [4,5,38].

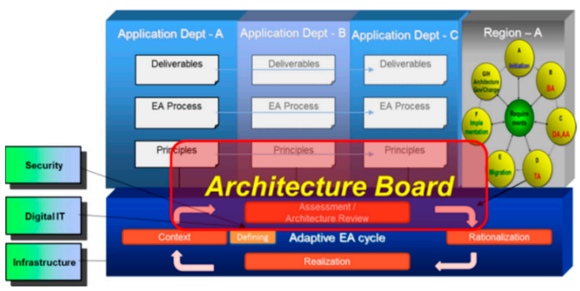

Figure 5. Adaptive Integrated Digital Architecture Framework (AIDAF) proposed model with Architecture Board (ex: TOGAF and adaptive EA framework) [5,38].

2.2.3. Architecture Board and Global Healthcare Company

The AIDAF proposed model with the Architecture Board is illustrated in Figure 5 as below [5,38]. This AIDAF begins with the context phase while referencing the defining phase (i.e., architecture design guidelines related to cloud, security, digital IT aligned with IT strategy). During the assessment and architecture review phase, the Architecture Board reviews the initiation documents and related architectures for the IT project.

In particular, the Architecture Board, the example of the EA framework structure in a specific global healthcare company examined in the previous paper, is explained in this section [4,55]. This global pharmaceutical company is the largest Japan-headquartered global company in the industry in Asia based on a sales basis. In a global EA rollout, we are handling cloud, mobile IT, and big data strategic projects and systems that took priority in Europe and US Group companies well by structuring and implementing EA with the above AIDAF to be consistent with global IT strategy focusing on cloud, mobile IT, big data, and digital IT [4,55,56].

One of the authors worked in this global healthcare company and conducted all phases of structuring and implementing in this EA framework and was the facilitator and managed the coordination of the global Architecture Board. In this global pharmaceutical company, one of the authors had the above responsibilities in the assessment/architecture review phase on the global AB, as shown in Table 2 of [5], which we focused on and performed the above tasks [5,38,55,56].

2.2.4. Social Collaboration Model (SCM) in Architecture Board in AIDAF Framework

We had stated in the above Architecture Board case study while implementing the enterprise portal for this AB, and that each new project planning document was made/submitted and reviewed/evaluated in the AB. The review results were published, and the project gets endorsed after dealing with the necessary action items [5,38]. The above global communication process of AB review on the enterprise portal between the leader, AB members, and new project manager, for review in the AB, can be equivalent to business architecture (BA) for architecture review in AB, that can enhance the business structure and process efficiency. The author proposes the "Social Collaboration Model for Architecture Review in Architecture Board" in Figure 6, while the above global communication process is part of the BA of this social collaboration model (SCM) in the upper part of Figure 6 [5,38].

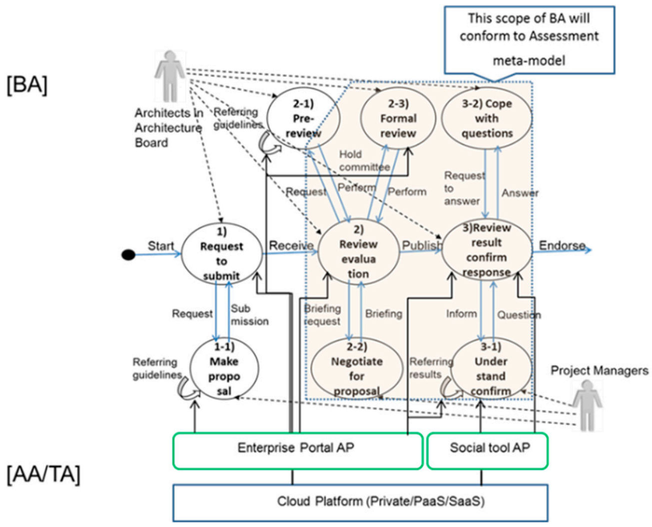

Figure 6. Social collaboration model (SCM) for architecture review in Architecture Board [5,38].

The back-colored scope in Figure 6 suggests that this BA should conform to the assessment model shown in Figure 2 of [5] for architecture reviews in the AB.

Furthermore, the above global communication process as BA of architecture review in AB can be activated on the enterprise portal application and social tool application, as application architecture (AA), built on cloud-based technology platforms like private cloud, PaaS, and SaaS as technology architecture (TA) as depicted in the Figure 6 [5].

2.3. Direction of Drug Discovery

In general, the existing drug discovery process has consisted of the following three parts: Drug discovery, drug design review, and drug development.

- Part 1: "Drug discovery" is processed to target the drug and synthesize drugs from natural sources and chemicals. It covers some assays to test the effectiveness.
- Part 2: The review of "drug design" can focus on how better to select the candidate drugs' selectiveness and effectiveness.
- Part 3: "Drug development" includes preclinical development, clinical development, drug approval, and recall. It emphasizes better understanding about the drug, including potential benefits, safety concerns, best dose, best dosage form, and choice for the route of administration. It also involves experiments on human beings for effectiveness, safety, and other essential elements.

The drug discovery process gradually shifts to the seven-step process, which has been verified by scientists already [57]. These seven steps are as follows.

- Step 1: "Disease Pathology." It answers high-level strategic questions regarding drug discovery, such as the specific therapeutic area and the disease domain.
- Step 2: "Target identification." This step covers figuring out the exact processes in a specific disease area.
- Step 3: "Assay development and screen." It will investigate what kind of assay to run. The primary classification is identifying whether it is target-based or phenotypic.
- Step 4: "Hit to lead." In this step, you will have the hits and triage. Results are categorized into most interesting, possibly interesting, and non-factor.
- Step 5: "Lead optimization." It involves traditional medicinal chemistry, and one will start to improve properties in potency, selectivity, toxic side effects, and pharmacokinetics. The candidates are narrowed down to up to three clinical candidates.
- Step 6: "Preclinical development." The classic scale-up questions for each new medicine should be solved in this step.
- Step 7: "Clinical trial. Drug development" This is the step where the real money is invested. It is the leverage point for the whole process. One has to get everything correct before this step to prevent a waste of money and time.

The first three steps correspond to the traditional drug discovery part, the next three steps correspond to the existing drug design review part, and the last step corresponds to the drug development part.

On the other hand, according to Food and Drug Administration (FDA) in the US, after Step 7 of drug development, the steps of preclinical research and clinical research, which the FDA has defined formally, are following before the step of FDA drug review in the US [58].

The new trends of the drug discovery process shift from existing ones based on a compound to the concepts based on proteins like DNA/RNA.

2.4. Electronic Health Record (EHR) and Clinical Decision Support (CDS)

Over the 50 years that followed the first implementation of computerized patient medical records in the 1960s, technology advances in computer innovations opened the way for advancements in electronic health records (EHRs) and health care [59]. The utilization of software applications and stand-alone computer systems migrated from paper documentation of patient data to digital forms of record-keeping [60]. The ISO standard defined an electronic health/healthcare record (EHR) as a repository of information regarding health status in computer processable form [61]. EHR can include past medical history and medications, immunizations, laboratory data, radiology reports, vital signs, and patient demographics [62]. It brings the potential to reduce the probability of errors during medical exigencies, improve the decision-making process, and create an information-centric source for patients and professionals to interact. As an example of EHR, the system rolled-out by South Australian Health to implement the health records is known as EPAS (enterprise patient administration systems). The EHRs implementation and deployment are widespread in the United States, Europe, and Asia region recently. We emphasize the importance of organizational strategy alignment with IT strategy. Functional structuring of business operations in alignment with information systems strategies can contribute to successful EHR implementation [63]. Developing the strategy for integrating IT systems/platforms with the hospital organization is essential to successful EHR implementation [64].

We describe clinical decision support (CDS) systems as "any computer program designed to help healthcare professionals to make clinical decisions" [65]. They are often referred to as essential elements to enhance patients' safety and quality of care [64,66]. Moreover, one problem is that it is difficult to find out appropriate directions for new drugs and to proceed with drug designs and developments efficiently in pharmaceutical companies, healthcare industry. We consider CDS systems as a by-product of this. Recently, knowledge-based CDS systems are mainly used to support diagnosis, medication tasks, or monitoring processes in intensive care settings [60].

Furthermore, CDS systems are expected to be one of the solutions to lead to the correct direction of new drugs in pharmaceutical companies. In this paper, the authors focus on CDS systems based on biomedical knowledge and inference data in terms of diagnosis and remedy specific to their patients, primarily. As expected, combination with EHRs reveals insights on how to choose the pathology of a newly designed drug to suit individual patient needs.

2.4.1. Case of a Healthcare Organization in Australian Government with Electronic Health Record (EHR)

In Healthcare Agency in the Australian government, the personal controlled electronic health record (PCEHR) system was implemented by 2012. The PCEHR enabled the secure sharing of health information among healthcare providers and can provide a set of Medicare and healthcare records for patients, sets of PCEHR clinical documents in hospitals, and a consolidated view created from these data [67]. However, we have detected issues in terms of security, privacy for EHR related data, clinical systems in each hospital, and provider system in firms in Australia. As potential risks, all Australians could automatically be enrolled into online digital health files unless they intended. As a result, EHR's privacy chief in Australia quit taking responsibility for the above security and privacy issues [68]. These issues can be coped with by architecture reviews aligned with security/privacy architecture guidelines for digital health strategy, involving the risk management model named "STrategic Risk Mitigation Model—STRMM model" in the AIDAF. The digital healthcare organization in the Australian government considers and proceeds to application and implementation of the AIDAF, data governance with EHR while designing and examining the SCM as mentioned earlier model-based digital platforms there [67].

2.4.2. The AIDAF Application with CDS System, a Platform in Healthcare and Medical Organizations

The author proposed the AIDAF framework with CDS system and platform with EHR, an EA framework integrating an adaptive EA cycle in the bottom portion with a FEAF by government or simple EA framework by hospitals and healthcare providers involving the pharmaceutical company in the upper portion [69]. This scheme involves CDS systems and platforms accessed by doctors in hospitals and healthcare professionals in pharma and healthcare providers, and EHR connected to Clinical Decision Support System (CDSS), that can be managed in the alignment with the national digital health strategy and each digital IT architecture strategy in hospitals and healthcare providers involving a pharmaceutical company, as shown in Figure 2 of [69]. Furthermore, the author verified pediatric intensive care in a hospital in Germany that the above AIDAF framework can cope with the system architecting for CDSS with EHR and issues of interface standardization and interoperability there [69].

2.5. Big Data and Cloud Computing, Digital Healthcare with Enterprise Architecture

Cloud computing is an economical option of acquiring substantial computing resources to deal with large-scale data. The vast adoption of cloud technologies in the healthcare industry has been surveyed in several works [70]. The primary cloud-based healthcare and biomedicine applications have been reviewed [71], for instance, "Veeva systems" is a cloud-computing system based SaaS company focused on pharmaceutical industry applications, whose systems are prevailing.

The implementation of big data analytics in the healthcare areas makes progress, which can examine these large data sets involving EHR to uncover hidden patterns, unknown correlations, and other useful information [72,73]. The advances in big data analytics can naturally transform research situations from being descriptive to predictive and prescriptive [74]. Big data analytics in healthcare can contribute to evidence-based medicine and patient profile analyses. Furthermore, big data analytics can effectively reduce healthcare concerns, such as the improvement of healthcare-related systems [70]. From the standpoints of digital healthcare, big data, and enterprise architecture, the author proposed the reference architecture for knowledge-based CDS systems with EHR and related AIDAF framework in the healthcare community and verified them with the case of intensive care in a hospital in the previous research paper [69].

2.6. Artificial Intelligence, Intermediary Knowledge Model, and Global Digital Transformation Communication (GDTC) Model in Enterprise Architecture

Artificial intelligence (AI) is the simulation of human intelligence processes with computer systems. These processes include learning, (i.e., obtaining information and rules for using the information), reasoning (i.e., applying the rules to reach approximate or obvious conclusions), and self-correction. From standpoints of the AI techniques rapidly advancing in healthcare, scenarios are natural-language processing, pattern recognition, and machine learning, which we apply to several specific fields, such as biomedicine and life sciences [70,75]. IBM Watson for the "Drug Discovery" is a platform that uses text and data mining of medical literature to identify, assess, and formalize the relationships among diseases, drugs, and genes to help researchers uncover potential new treatments and find new utilizations for existing medicines. This platform can promote big data to shorten the time to identify new drugs and reuse current drugs for better healthcare.

Besides, we visualized that experiential knowledge and shared through text generalized as explicit knowledge, in organizational computer-mediated communication (CMC) like portals and social networks [76–78]. Fragmented knowledge, which can be disseminated horizontally across the organization by its employees, through corporate digital media, is referred to as intermediary knowledge shown in Figure 7 [76–78]. The knowledge-sharing process based on intermediary knowledge is visualized through publication, resonant formation, collaboration, sophistication, and fragmentation. We had started the aforementioned Architecture Board case study while implementing the enterprise portal for this AB, and that each new project planning document was made/submitted and reviewed/evaluated in the AB. The review results were published, and the project gets endorsed after dealing with the necessary action items [5,38]. The above global communication process of AB review on the enterprise portal between the leader, AB members, and new project manager, for review in the AB, can be equivalent to business architecture (BA) for architecture review in Architecture Board, that can enhance the business structure and process efficiency. The author proposes the "Social Collaboration Model (SCM) for Architecture Review in Architecture Board" in Figure 6, while the above global communication process is part of the BA of this SCM model in the upper part of Figure 3 [5,38].

The back-colored scope in Figure 6 suggests that this BA should conform to the assessment model shown in Figure 2 of [5] for architecture reviews in the Architecture Board.

Furthermore, the above global communication process as BA of architecture review in Architecture Board should be activated on the enterprise portal application and social tool application, as application architecture (AA), built on cloud-based technology platforms like private cloud, PaaS, and SaaS as technology architecture (TA) as depicted in the Figure 6 [5].

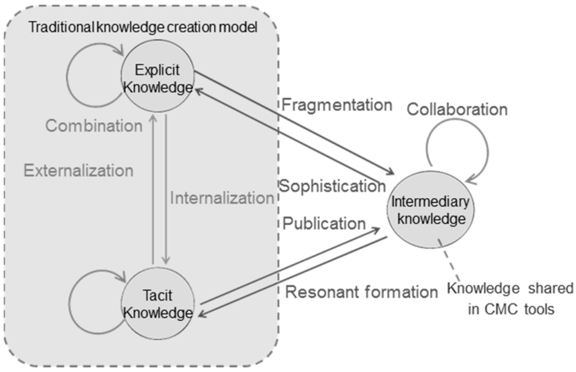

Figure 7. Intermediary knowledge model [38,76–78].

Furthermore, in terms of AI and knowledge sharing, Dr. Yoshimasa Masuda et al. proposed the "Global Digital Transformation Communication (GDTC) model," and verified this model [79]. This GDTC model will be able to promote the digital transformation in the global community as well as the healthcare community. The GDTC model consists of the following three layers: The tacit knowledge group (TKG), intermediary knowledge group (IKG), and explicit knowledge group (EKG) [79].

Figure 8 shows the GDTC model below, which adds IKG to the traditional knowledge process in global communications. CMC tools, like the portal and SNS, are used to support IKG. The square balloons illustrate the representative knowledge process of the GDTC model, while the dotted square balloons show the knowledge processes of traditional global communication styles [79].

The GDTC model can enable the decision-making integrated with multiple AI machine learning. From standpoints of processes for drug design and development, utilization of the GDTC model is assumed in Steps 6 and 7, that is equivalent to the "new drug development" and are easy to define the apparent evaluation criteria for the reviews of the "new drug development plan" comparatively, in the entire process of drug discovery and development.

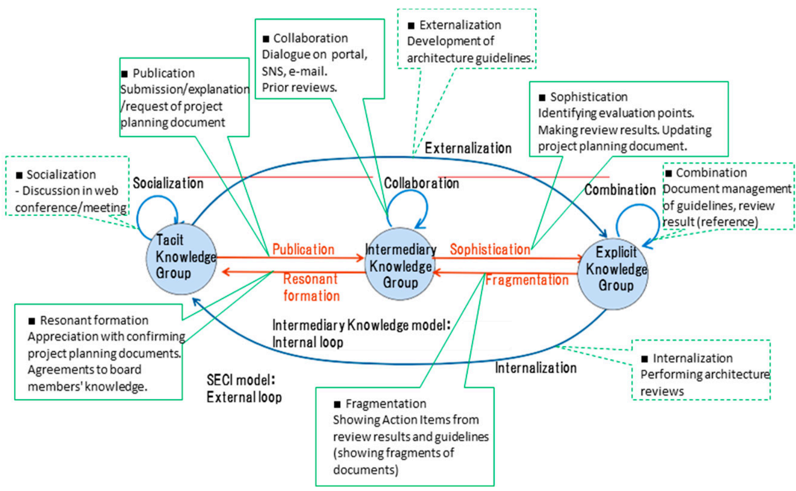

Figure 8. Global digital transformation communication (GDTC) model with knowledge sharing [38,79].

2.7. Hybrid Database

During the drug discovery process, various kinds of data should be collected and need to be stored. There are relational databases (RDB) for structured data like electronic health records (EHR) and the NoSQL database for unstructured data such as images and literature. Furthermore, structured data in the preclinical and clinical trial data can also be stored in a relational database like MySQL. Besides, unstructured data such as text and images can be stored in the NoSQL database like MongoDB. Thus, in this case, a hybrid database combining the above RDB and NoSQL databases should be necessary.

3. Research Methodology

In this paper, the authors first state research questions to understand the relationships between enterprise architecture and digital platforms as well as the digital transformation for the efficiency and progress of the drug discovery and development processes in the healthcare industry. Accordingly, a systematic literature review was conducted to identify, evaluate, and interpret available research relevant to find existing EA frameworks in addition to the AIDAF framework, DEA reference cube. As little research exists regarding EA and digital platforms correlated with the artificial intelligence and intermediary knowledge model, the search extended to EA with digital platforms in relation to healthcare ecosystems. Then, the authors evaluate these research questions using theoretical development and cases in healthcare industries.

The following research questions are evaluated using several cases in healthcare industries and the previous research there.

RQ1: How can enterprise architecture with establishing digital platforms contribute to the digital transformation in the healthcare industry?
RQ2: How can a use case of a digital platform (and services' ecosystem) for drug development contribute to the application and benefits of a digital enterprise architecture for efficiency and effectiveness of reviews?

Then, the following section describes the new process for drug discovery and development which can contribute to efficiency and progress on digital platforms in pharmaceutical companies.

As the next step, the authors propose and describe the "reference architecture for the digital platforms related to the drug discovery and development process," and the authors propose digital platforms for new drug development using GDTC model and SCM in the above AIDAF, that is an EA suitable for digital IT.

Furthermore, structure of the drug development platform involving AI machine learning with RDB and NoSQL database is analyzed with the empirical data of reviewers' activities in Architecture Board in the global healthcare enterprise and discussed from standpoints of concept of database access flow for machine learning programs and activities of the equivalent database (DB) access flow in new drug development review system in case of the AIDAF framework with drug platform board in the pharmaceutical division of the enterprise.

Based on the above research, the authors clarify research findings as this study contribution to research and practice in healthcare industries for EA and digital IT practitioners.

4. Digital Platform with Drug Discovery and Development in Enterprise Architecture

4.1. Drug Discovery Process on a Digital Platform

In this paper, the authors propose the process for drug discovery and development using digital platforms, based on the contents of the aforementioned related works.

4.1.1. Proposed Process in the Part of "Drug Discovery"

There are requirements to overcome the difficulties above to find appropriate directions for new drugs in pharmaceutical companies and healthcare industries. Therefore, especially in Step 1, "disease pathology," of the "drug discovery" part, authors propose that the process for drug discovery using CDS systems should be connected to EHR through a support platform, which can aim at "target identification for new drugs (Step 2)."

In the following steps, data regarding patients' responses to each new drug is collected using sensors, based on the digital platform supporting the functions concerning big data, cloud computing, and artificial intelligence (AI). Moreover, the process for drug discovery can be supported by accumulating large-scaled data into the cloud platform. Then, when a tendency of clinical data is identified using AI, the discovery can be narrowed down to effective new medicine.

4.1.2. Proposed Process in the Part of "New Drug Development"

There are requirements to proceed with drug developments more efficiently in pharmaceutical companies and the healthcare industry. Therefore, to enhance the efficiency in the new drug development in Step 7, "clinical trial, drug development," authors propose the process for drug development utilizing the digital platform, which can support the artificial intelligence (machine learning) and GDTC model for the reviews of new drug development plans with comparatively distinct evaluation criteria before a new drug is developed.

4.1.3. Database for Digital Platform Related to Drug Design and Development

In each step of the above-proposed process for drug design and development, co-operation management between the digital platform and the hybrid database should be necessary. Besides, both the structured data in EHRs and unstructured data like images and doctors' notes will be used.

4.2. Process for Drug Discovery Worldwide, and the Status of Digital Platform

Novartis and Pfizer, which are the largest pharmaceutical companies worldwide, adopt innovative methods with machine learning (image recognition) and molecular library mapping. Novartis has gradually adopted machine learning, thus intensifying its "drug discovery" operations in the drug discovery and development process [80,81]. The automated machine learning algorithms can look at pictures and identify the "new drug target compounds" that are fit to proceed to the experimental stage, thus shortening the timelines of drug discovery and reducing the cost.

Furthermore, they compared the photo images between the cell states, which can lead to the formulation of a new hypothesis to work on the above matters, as depicted in the following Figure 9. The scientists in Novartis can look at screening solutions for compounds and new drug targets efficiently and intelligently [80].

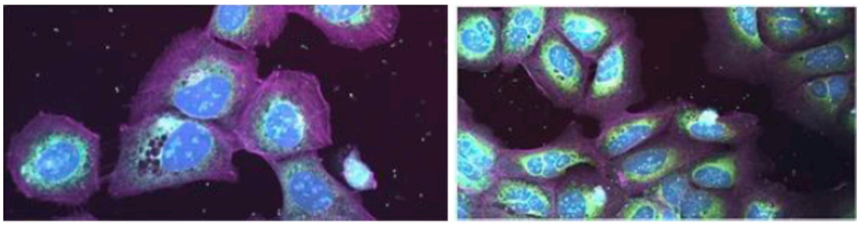

Figure 9. Comparison of situation photo images for each cell of new drug candidates [80].

Pfizer deployed Watson AI for drug discovery and used customized cloud-oriented cognitive functions with machine-learning, natural language processing, and other reasoning simulations of Watson AI for many years [82,83]. Those AI-related technologies help to identify new drug targets. Besides, applying cognitive computing to the central part of their DNA-centric new medicines can help Pfizer to discover immuno-oncology therapies more efficiently.

With these innovative methods using AI and the digital platform supporting these functions, it should be possible for them to contribute to the drug discovery process from Step 2, "target identification of new drugs," to Step 5, "lead optimization," directly.

4.3. Application of GDTC Model for Digital Platform Related to Drug Development

Authors consider that the application of the GDTC model for the drug development process on digital platforms will streamline new drug developments in the healthcare community. The GDTC model consists of three layers: The tacit knowledge group (TKG), the intermediary knowledge group (IKG), and the explicit knowledge group (EKG) [79], as shown in Table 2 in consideration with an environment surrounding new drug developments.

The TKG group contains roles for exchanging tacit knowledge; its group node is human. TKG is related to organizational structures, member roles, and decision-making, among others; hence, TKG can be conducted on telephone or via web conference communications. It is evident that TKG does not generate any documentation for global communication among stakeholders in new drug developments, and authors assume that this will not create any formal documents. The product of TKG is discussions and meetings for new drug developments' planning and reviews; however, it does not always produce tangible deliverables for new drug developments that can be observed.

Table 2. Elements of layers in GDTC model for drug development.

Knowledge Group	Group Node	Media	Documentation	Examples of Deliverables
Tacit knowledge group	Human	Telephone, web conference	No documentation	Discussions, web meetings
Intermediary knowledge group	Portal contents	Portal, SNS, e-mail	Just in time documentation	Drug platform board logs, SNS logs, e-mail logs
Explicit knowledge group	Document	Document management services	Full documentation	Drug platform board results, drug development guidelines

The IKG group performs the role of exchanging intermediary knowledge; its group node is portal contents related to the portal, SNS, digital platform, and e-mail within the healthcare community. IKG provides just-in-time documentation related to new drug developments to the healthcare community members, and CMC tools and digital platforms can be used if one member needs to coordinate with others in communications and meetings for such drug platform (development) boards. The deliverables of IKG are drug platform (development) board related logs, web conferences, SNS, and e-mail logs.

The role of EKG is the exchange of explicit knowledge, and its group node is the document. This document group results from document management services related to new drug developments, whose functions are historical management, enterprise document searching, and document file sharing covering the areas of new drug developments. EKG can provide full documentation to healthcare community members, and its deliverables are documents such as drug platform (development) board results, conference results, and guidelines.

In general, the TKG group will reflect human communication during discussions and meetings for new drug developments. Communication between TKG and IKG covers the processes of intermediary knowledge provisions and acquisitions for new drug developments in digital platforms like the portal, SNS, and e-mail. Communication between IKG and EKG consists of the processes of quotations and documentation of explicit knowledge in digital platforms for drug development, such as the portal, SNS, and e-mail. Especially, SNS related data and technologies can change the practice of new drug developments and are expected to shape the direction of new drug development in the healthcare industry [84] because stakeholders can share their opinions on SNS easily.

4.4. Overview of Digital Platform for Drug Discovery, Drug Development Process Using AIDAF

The whole structure of digital platforms for drug discovery and development needs to be considered toward the realization of the digital platforms. Therefore, the authors propose and show the "reference architecture (RA) for digital platforms related to the drug discovery and development process" in Figure 10, based on previous research in these fields and the above verifications in this study.

By applying the GDTC model in Figure 8, it should become possible to proceed with the reviews for new drug development plans in the "new drug development" of the drug discovery and development process by shortening the timelines of decision-making for reviews' results by AI machine learning used for reviewing each category. Therefore, the authors visualized the functional aspect of this platform based on the GDTC model, and proposed and showed the RA for the drug development platform based on the GDTC model, related to the part of the "drug development" process, in Figure 10.

Moreover, each action on the CDS system consists of patients and doctors using EHRs, medical experts in hospitals and healthcare professionals in pharmaceutical companies using CDS systems, and public groups like governments managing EHRs; therefore, the above actors are necessary for the structure of the CDS platform.

The essential components of this CDS system cover a medical knowledge base and an inference mechanism (rules derived from experts and evidence data from EHR) based on a language for artificial intelligence and big data analytics [85]. Razzaque et al. showed that the EHR and knowledge management architecture facilitates the CDS system by guideline development [86]. The CDS system provides recommendations based on the available patient-specific data (EHR) and medical facts (knowledge base) [85]. Therefore, the authors proposed and showed the RA for a CDS platform with EHR, related to the part of the "drug discovery" process, in Figure 10.

In terms of the part of the "drug design" process, authors are under consideration for working closely with other platforms such as the Watson AI briefed in Section 4.2, as described in Figure 10.

As results of the above studies, comprehensively, authors can propose and show the "reference architecture for digital platforms related to the drug discovery and development process," as shown in the following Figure 10, which will lead to the realization of digital platforms related to the drug discovery and development process in the future.

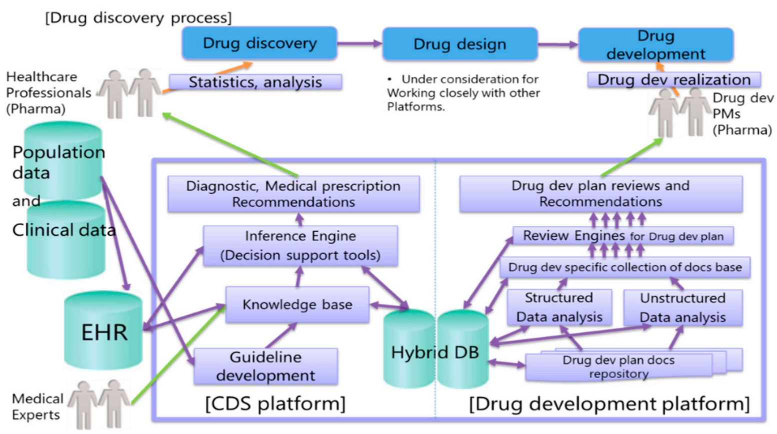

Figure 10. Reference architecture for digital platforms related to the drug discovery and development process.

(The upper part shows the drug discovery process while lower parts show digital platforms for CDS, new drug developments)

As described in Sections 2.1.2 and 2.2, one of our preliminary studies proposed the Adaptive Integrated Digital Architecture Framework (AIDAF) to promote cloud, mobile, big data, and digital IT strategy and was verified by our case study [4,5]. Figure 11 displays the proposed AIDAF framework with a drug platform board for use in the healthcare community.

The AIDAF proposed model with drug platform board (DPB) is an EA framework integrating an adaptive EA cycle in the bottom portion with a TOGAF by a core drug platform team of a global healthcare company's headquarter or simple EA (framework) by each region of global healthcare enterprise in the upper portion. The model covers the core drug digital platforms, such as drug development and CDS platforms, that are accessed and used by new drug development planners and managers, digital IT practitioners, stakeholders, and business users in each region and are reviewed by the drug platform architecture board. The architecture guidelines can thus be issued and should be managed and improved in alignment with the digital platform strategy of the enterprise and the digital IT architecture strategy in each region and department in the pharmaceutical division of the enterprise, as shown in Figure 11. The above platforms involve CDS systems and platforms that are also used by doctors in hospitals and healthcare professionals in pharmaceuticals, healthcare providers, and EHRs connected to CDS. These systems should be managed and improved in the alignment with the national digital health strategy and in consideration of each digital IT architecture strategy in hospitals.

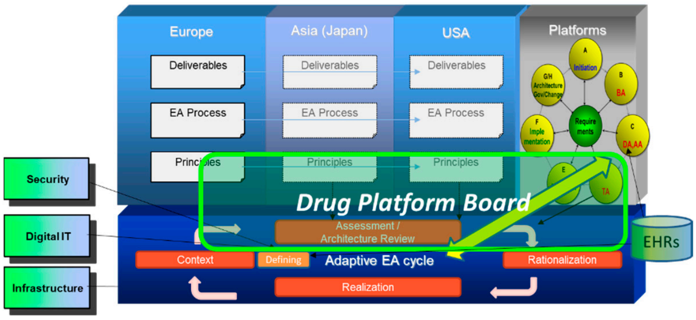

Figure 11. AIDAF proposed framework with drug platform board.

Furthermore, the authors propose the reference architecture for a new drug development review system of the drug development platform based on the GDTC model and SCM in the AIDAF, that will lead to automation of review tasks and extend to ecosystem platform, as shown in Figure 12.

This review system can be constructed in terms of business architecture (BA), application architecture (AA), and technology architecture (TA) based on the SCM and from the standpoints of data architecture (DA) based on GDTC model. All of this can be realized while implementing components for the step of the (2) review evaluation in BA with machine learning for each expertise area (standard conformance, development plan viability, cost). The drug development review system will review new drug development plan documents efficiently and may be able to bring the effectiveness of planning the production and business for new drugs.

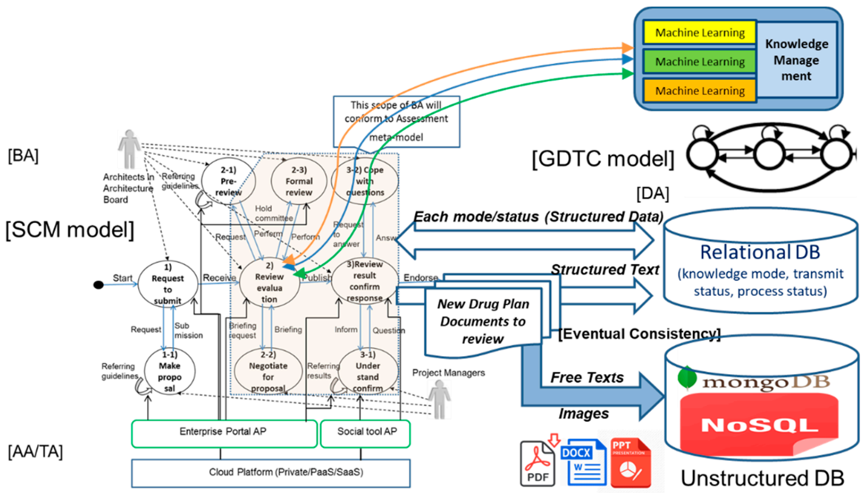

Figure 12. Reference architecture for new drug development review system of drug development platform based on GDTC model and SCM in the AIDAF.

5. Discussion

5.1. Structure for Implementation of the New Drug Development Review System

The proposed drug development review system can offer functions for reviewing development plan documents of new drugs uncovered in the drug discovery process and optimized in the drug design process. This system can be constructed and implemented based on the SCM model in the AIDAF from the standpoints of BA, AA, and TA and implemented based on the GDTC model from standpoints of DA, as shown in Figure 12. Each new drug development planning document should be submitted and reviewed in the drug platform board (DPB), as shown in Figure 11. Additionally, the above new drug development plan's review results can be published on the drug development platform portal, and the new development plan and project will be endorsed after addressing the necessary action items. Specifically, the business architecture covers the communication process of the DPB reviews for the new planning document on the enterprise portal among the leader, DPB members, and project manager of the new drug development, as shown in Figure 12. The colored background of the SCM in Figure 12 suggests that the BA scope should conform to the assessment model shown in Figure 2 of [5] for reviewing new drug development plan documents. The application architecture activates the above BA communication process for new drug development plan reviews in the DPB on the enterprise portal and social tool applications, as shown in Figure 12. The technology architecture should be designed and built for the above AA on cloud-based technology platforms, such as private clouds, PaaS, and SaaS. The data architecture must encompass the structured data of each mode and status regarding "Knowledge mode," and "Transmit status" in the GDTC model and "Process status" in the SCM model of the RDB. The DA must cover the unstructured data of new drug plan documents, drug platform review results, drug development guidelines in free pdf, doc, and ppt formats in unstructured databases like NoSQL, as shown in Figure 12. Also, while implementing "(2) Review evaluation" in the BA with machine learning for each expertise area by analyzing with the data of reviewers' activities in Architecture Board in the global healthcare enterprise, the new drug development review system should review new drug development plan documents efficiently and automatically using machine learning algorithms. Next, while executing each machine learning program for the above, the data consistency among the databases and the necessary elements of reviewed documents must be established in the DA with the business logic level of each process step in the BA. Finally, eventual consistency for the above data should also be ensured within each process step in the BA.

The concept of database access flows from machine learning programs are denoted as (a) topic modeling, (b) clustering, and (c) program performing reviews in Figure 13.

The purpose of the topic modeling, i.e., the latent Dirichlet allocation (LDA), is to automatically discover the topics from a collection of documents [87]. In this new drug development system, the new drug planning documents themselves should be observed, while the topic structure—the topics, per-document topic distributions, and the per-document per-word topic assignments—should be hidden structures.

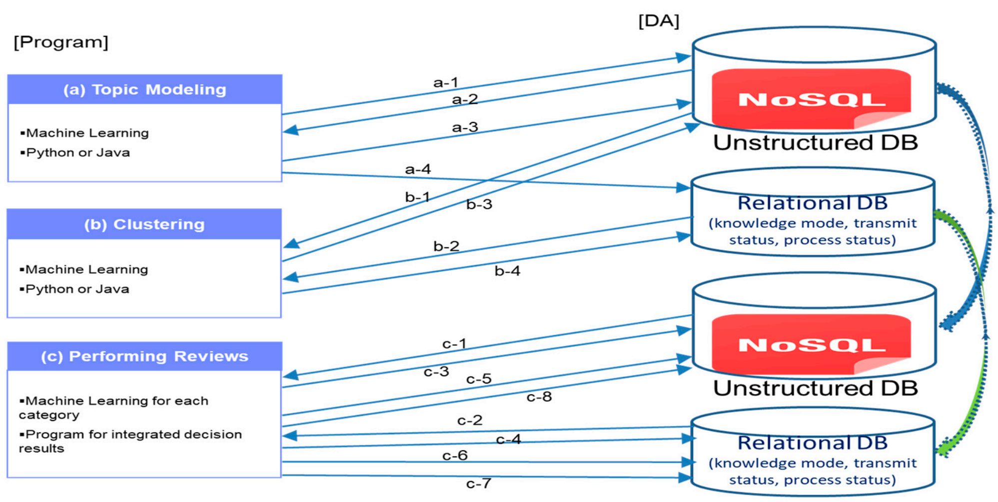

Figure 13. Concept of database access flow for machine learning programs in new drug development review system.

Thus, the topics in the new drug planning documents will be selected and refined in the topic modeling machine learning algorithm with the DB access flows from a-1 to a-4, as shown in Table 3.

The k-means clustering method can group the objects based on the definition of similarity provided, which can only come from subject matter considerations [88]. In the new drug development review system, most of the popular clustering algorithms take a dissimilarity (agglomerative) matrix as the input from new drug planning documents. Thus, authors must first construct pairwise dissimilarities (agglomerations) between the observations from the documents. The most popular clustering algorithms can assign each observation to a group or cluster without regard to a probability model describing the data from the documents [88]. Therefore, each proportionated group of a topic and a document will be formulated by the clustering's machine learning algorithm with the DB access flows from b-1 to b-4, as described in Table 3.

The machine learning algorithms for performing reviews need to be coded for each topic of new drug development planning documents while deriving the inputs of the topic-related documents from the NoSQL (unstructured) database and related attributes from the RDB. After the algorithm in each topic is executed, a document file of the review results will be input into the NoSQL database, and related attributes will be updated into the RDB with the DB access flows from c-1 to c-8, as described in Table 3.

Table 3. Each activity of the equivalent DB access flow in new drug development review system.

Category	DB Access Flow No.	Each Activity of the Equivalent DB Access Flow
(a) Topic Modeling	a-1	PDFs, MS Word files, ppt files of new drug plan documents are requested from machine learning programs to NoSQL DB.
	a-2	Get PDFs, MS Word files, ppt files of new drug plan documents.
	a-3	Selected topics are input into NoSQL DB (unstructured data).
	a-4	Selected topics are input into Relational DB.
(b) Clustering	b-1	Topics' group is read from NoSQL DB (unstructured).
	b-2	Topics' group is read from Relational DB.
	b-3	Proportionated topics and documents are input into NoSQL DB.
	b-4	Proportionated topics and attributes of documents are input into Relational DB.
(c) Performing Reviews	c-1	Each topic related documents are read from NoSQL DB (unstructured data).
	c-2	Each topic related documents' attributes are read from Relational DB.
	c-3	A file of review's result in a category is input into NoSQL DB.
	c-4	A file's attributes of review's result are input into Relational DB.
	c-5	Integrated result of reviews in all categories is input into NoSQL DB (unstructured data).
	c-6	Three elements (knowledge mode, transmit status, process status) are updated into Relational DB.
	c-7	While the integrated review result's report is uploaded and published on web portal, necessary attributes of the above report are input into Relational DB.
	c-8	While the integrated review result's report is uploaded and published on web portal, a file of the above review result's report is input into NoSQL DB (unstructured data).

5.2. Study Contribution to Research and Practice

5.2.1. Research Findings 1: Streamlined Processes through Digital Platforms in Organizations in the Healthcare Industry

Applying the GDTC model in the AIDAF in Figure 8 should be possible to proceed with the DPB's reviews for new drug development plans in the "new drug development" of the drug discovery and development process on drug development platform gradually. Shortening the timelines of decision-making for reviews' results by automating with AI machine learning in each topic there, as illustrated in Sections 4.4 and 5.1. Furthermore, in two of the largest pharmaceutical companies worldwide, screenings for new drug targets are performed efficiently with the AI machine learning algorithms to shorten the timelines of drug discovery and design, thus reducing the cost. Therefore, the processes for drug discovery and development should be streamlined through the digital platforms efficiently in healthcare enterprise and industry as illustrated in Figure 10, that cover the drug development platform based on GDTC model, SCM model in the AIDAF and the above AI machine learning as illustrated in Sections 4.4 and 5.1.

5.2.2. Research Findings 2: Informal Knowledge Supply and Sharing among Organizational Members on Digital Platforms in Healthcare Communities

Each action on the CDS system consists of patients and doctors inputting their information and referring to EHRs from hospitals, healthcare professionals in pharmaceutical companies using CDS systems, and public groups like governments managing EHRs; therefore, the process for drug discovery itself can also be conducted and activated in Step 1, "disease pathology" [63]. Moreover, Novartis, one of the largest pharmaceutical companies worldwide, also adopts AI machine learnings for drug discovery, and the "drug discovery" step in the drug discovery and development process is conducted and activated across patients, hospitals, and pharmaceutical companies [80]. Furthermore, the "drug development" step in the drug discovery and development process can also become efficient on drug development platform with the necessary data consistency between Relational database and NoSQL database while sharing informal knowledge such as new drug development planning documents being reviewed in drug platform board in the AIDAF among DPB members and new drug project managers there, as illustrated in Figure 12, Sections 4.4 and 5.1. Therefore, processes for drug discovery and development can be conducted and activated efficiently through digital platforms covering CDS systems in the alignment with EHRs and the drug development platform involving AI machine learning with RDB and NoSQL database in the community of healthcare industries, where organizational members in the enterprise, community in healthcare industries can supply and share informal knowledge among one another on digital platforms.

5.2.3. Research Findings 3: Improvement of Efficiency and Effectiveness in Planning Production and Business on Digital Platforms for Drug Development

In the healthcare industry, big data analytics with AI can effectively reduce the workload of the related tasks and costs while enhancing correctness and comprehensiveness in performing the above tasks. As described in Section 5.1, by implementing AI components for the step of the "(2) Review evaluation" in Figure 6 of SCM model as the BA with machine learning for each expertise area (standard conformance, development plan viability, cost) in the drug development review system of the new drug development platform, the above unstructured data analytics with machine learning programs can effectively enhance the accuracy, comprehensiveness (i.e., standard conformance, costs' aspects) for the above tasks of reviewing new drug development documents in the step of the "(2) Review evaluation" of SCM model. Furthermore, in the case of the Architecture Board in global healthcare company described in Section 2.2.3, during the 15-day period in which the Architecture Board was held in the applicable month there, six actions (40% of all actions per month) from the fifth action to the 10th action in Table 2 of [5], that are equivalent to the scope of the "Step (2) Review evaluation" in the SCM model and can be automated by the above AI components of machine learning programs in the new drug development platform, had occurred for four days within five days when the global organization had been particularly active for architecture reviews (from the fifth action to 12th action in Table 2 of [5]) in Architecture Board. Thus, the above data analytics with machine learning programs in the new drug development platform will be able to improve the efficiency of workload for reviewing new drug development documents by shortening the above four days (26.7% of all the 15 days period of the above Architecture board in the applicable month [5]), and the improvements of efficiency and effectiveness in production planning and business structure on digital platforms for drug development were confirmed as a research finding in this paper.

5.3. Verifying Research Question 1

In this paper, with the scope of processes related to drug discovery and development on digital platforms in the healthcare industry, the authors attested Research Findings-1 and Research Findings-2 as the above, namely "processes and activities for drug discovery and development can be streamlined, conducted, and activated across the organizations through digital platforms within the healthcare industry in the AIDAF" and "informal knowledge supply and sharing among organizational members on digital platforms in healthcare communities," based on case studies and previous researches in a demonstrative manner. Furthermore, the case of the Australian government's digital healthcare organization in Section 2.4.1 and the case with CDS systems/platforms in hospital in Section 2.4.2 can also support the contributions of enterprise architecture with establishing digital platforms to digital transformation in the healthcare industry. Therefore, authors have also verified RQ1, as the processes for drug discovery and development can be streamlined and activated on digital platforms in the healthcare industry through the AIDAF and organizational members in the enterprise and community in healthcare industries can supply and share informal knowledge among one another on digital platforms. And there, enterprise architecture with establishing digital platforms using the AIDAF can enhance the business structure, process efficiency, and digital transformation in the healthcare industry.

5.4. Verifying Research Question 2

As described in Section 5.2.3 while briefed in Section 5.1, with unstructured data analytics by machine learning programs in the drug development review system, the improvements of efficiency and effectiveness in planning production and business on digital platforms for drug development were shown, and the authors attested Research Findings-3. Specifically, the above data analytics functions for reviews with AI components in the new drug development plan review system on the drug development platform can show effectiveness of correctness and comprehensiveness in terms of each expertise area as described in Section 5.2.3, and the above new drug development plan review system of that platform can enhance the efficiency in planning new drug developments and business with the assumed 40% improvement as the number of necessary actions and the expected 26.7% improvement as required time periods as briefed in Section 5.2.3. Moreover, the AI components, that need to be implemented as the inference engines for CDS platform in Figure 10, will be able to contribute to enhancement of efficiency and effectiveness in terms of ecosystem services covering hospitals and pharmaceutical firms. Thus, authors verified RQ2 in the above ways, as the new drug development platform can enhance the efficiency and effectiveness in planning the production and business structure for new drugs while aligned with digital IT strategies using the AIDAF, where a use case of a digital platform and services' ecosystem for drug development can contribute to the application and benefits of digital enterprise architecture for efficiency and effectiveness.

6. Conclusions

In this paper, the authors proposed and described the "reference architecture for the digital platforms related to the drug discovery and development process." The authors propose the "new drug development review system of drug development platform" using GDTC model and SCM in the AIDAF. The structure of the drug development platform involving AI machine learning with RDB and NoSQL database was analyzed and discussed with the empirical data of reviewers' activities in Architecture Board in the global healthcare enterprise in terms of concept and activities of database access flow for machine learning programs in new drug development review system in case of the AIDAF framework with drug platform board in the pharmaceutical division of the enterprise. In contrast, processes for drug discovery conducted and activated through digital platforms covering CDS systems were investigated, confirmed, and screenings for new drug targets with AI machine learning algorithms were investigated in cases of the largest pharmaceutical companies worldwide. The authors then clarified the Research Findings-1 of "Streamlined processes through digital Platforms in organizations in the healthcare industry” and the Research Findings-2 of “Informal knowledge supply and sharing among organizational members on digital platforms in healthcare communities.” Therefore, the authors verified RQ1 that EA with establishing digital platforms using the AIDAF could contribute to digital transformation in the healthcare industry.

Furthermore, the authors investigated the effectiveness and efficiency of AI in new drug development review system as well as the CDS platform aligned with the AIDAF and analyzed the above efficiency in consideration with the case of the Architecture Board in global healthcare company, showed the effectiveness qualitatively and efficiency quantitively there. Then the authors clarified the Research Findings-3 of “Improvement of efficiency and effectiveness in planning production and business on digital platforms for drug development,” and verified RQ2 as the new drug development platform can enhance efficiency and effectiveness in planning the production and business structure for new drugs in the alignment with digital IT strategies using the AIDAF, where a use case of a digital platform (and services’ ecosystem) for drug development can contribute to the application and benefits of a digital enterprise architecture for efficiency and effectiveness of reviews.

The main limitation of this study is the scope of research. The research was based on the data obtained from several case studies and previous research in the healthcare industry, such as global pharmaceutical companies, healthcare organizations in the government, and the hospital.

On the other hand, as based on the latest trends, new technologies can emerge, such as molecular modeling applications coping with the shift to targeting new medicines based on DNA and proteins of RNA. Therefore, it will be necessary to pursue new digital platforms that will be able to contribute to the drug discovery for these new medicines effectively.

In future research, a quantitative analysis must be performed to verify the streamlining of the drug discovery and development process through our proposed digital platforms while developing and using a prototype of the new drug development review system on the drug development platform. Practical methods for a hybrid database must also be verified that encompass both structured and unstructured databases. Regarding AI, deep learning can be utilized in the new drug design phase. Moreover, natural language processing (NLP), ontology, and symbolic AI may be incorporated into the aforementioned new drug development review system to enhance its functions and benefits. These AI concepts are a crucial consideration for future work. Moreover, it will be valuable to analyze how doctors, healthcare professionals in pharmaceutical companies, and patients can get benefits on digital platforms for the drug discovery and development processes covering preventive drugs for pandemics like COVID-19 while contributing to the healthcare ecosystem. Finally, regarding platform and ecosystem architecture in the DEA reference cube, architecture frameworks related to the Industry 4.0 (RAMI4.0) and Society 5.0 should be further analyzed for the application to case studies.

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