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Investigating The Role Of Digitalization In Operational Excellence Programs – A Case Study From The Pharmaceutical Industry

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Abstract

For years, manufacturing companies have been implementing Operational Excellence (OPEX) programs with the goal of effectively and sustainably improving their performance. Now, companies are also gradually recognizing the possibilities of Digitalization for advancing their operational processes. Even though both OPEX and Digitalization are directed towards the same goal of improved operational performance, there is neither an answer in research nor in practice on how they are or can be interlinked. That is, how processes and the organization to align and reconcile should look like?

To address this question, we conducted 25 interviews with pharmaceutical companies. Thereby we interviewed corporate OPEX functions and Digitalization experts over a timespan of three years. That way we also examine whether companies have adapted and investigate patterns in their development.

Our findings acknowledge that pharmaceutical companies aim to exploit synergies between OPEX and Digitalization for achieving higher operational performance. We further applied a dynamic capabilities perspective to identify how companies align OPEX and Digitalization. Our limitation is that we conducted interviews only within the Pharmaceutical Industry and that each company is unevenly reflected over the duration of the investigation. However, we mitigate that limitation by considering a rather large number of cases reflected in a sample size (16 companies) with a good balance of different company sizes (2.000 – 110.000 employees) and business areas (generics, labelled, and contract manufacturing).

Keywords

Digitalization; OPEX; Dynamic Capabilities; Continuous Improvement; Lean; Pharma Industry

1. Introduction

Operational Excellence (OPEX) can be understood as constant activities to enhance the level of organization-wide performance through targeted, incremental change [1]. Companies have tried to formalize their OPEX activities in programs that consist of organized systems allowing for discovery and implementation of process changes. Despite the need of an infrastructure to support both the execution and coordination of OPEX projects, most organizations perform respective initiatives by running ad-hoc projects and thereby ignore the more difficult part of project coordination [2]. This is particularly undesirable, since it has been shown by several researchers that OPEX deployments with inadequate coordination will become ineffective after generating initial success [3]. On the contrary, there is the potential that Digitalization can enhance OPEX activities as Digitalization efforts facilitate sharing of easily available and distributable information. As a result more informed decisions and greater autonomy for project groups at lower hierarchy levels can

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be taken [4]. Similarly, Alavi et al. [5] argue that Digitalization allows for flatter hierarchies, decentralized information flows, and greater organizational flexibility. However, identifying the right organizational structure is a complex task managers must deal with [6]. It is only possible to achieve higher performance when an organization's structure is tailored to the particular needs of the organization [7]. Based on this understanding, we investigate the organizational alignment process between OPEX and Digitalization. We ground our theoretical background on OPEX and Digitalization literature, and thereby apply the lens of dynamic capabilities [8] as well as the framework of Yeow et al.[9] describing how to align digital and other business departments through sensing, seizing and transforming. We add to literature by identifying specific alignment activities, incorporating the practical perspective and numerous Case Studies from the Pharmaceutical Industry.

2. State of Research

Organizational structures can be defined as patterns of coordination and interaction, by which technology, tasks and humans are synchronized to achieve an organization's purpose. By identifying the right organizational structure, effective coordination-integration and decision making can be facilitated [6]. Organizational structures are dynamic constructs, in fact, they change over the time [10] by adapting to major changes in the organization such as mergers, reallocations, decentralizations, or centralizations [11]. The creation of the right organizational structure around OPEX programs is not an easy task, but it is strategically important to establish a structure to coordinate multiple simultaneously ongoing OPEX initiatives [3]. For example, Anand et al. [12] in their extensive research on CI infrastructures state: "*Infrastructure practices can fulfill the important role of coordination and support of projects and create a culture for continuous improvement to help sustain a CI initiative beyond its immediate gains*" (p.446). However, this structure should not be a static concept as it is rather based on dynamic capabilities that generate the correct environment for integrating lower managerial tiers in strategy deployment and organizational learning [13].

In recent years, digital tools and initiatives have become increasingly prevalent in the manufacturing landscape. However, there is a general lack on how to align new digital strategies with OPEX infrastructures. Literature [14,15] recognizes a positive impact on performance from the alignment of digital and business strategies. Nevertheless, the alignment of digital to other organizational structures presents numerous challenges. For example, organizations have to deal with tensions between formal top-down approaches to exploit existing resources and simultaneously need to take advantage of emergent opportunities applying informal approaches [16]. Moreover, companies often see themselves confronted with organizational inertia [17]. To overcome these challenges, and align digital to other internal organizations, companies must be able to create, extend, and modify their resource base [18]. Yeow et al. [9] use the dynamic capabilities to analyze the alignment of digital and business departments. This approach argues that companies do not only change their resources, as supported by the Resource Based View [19], rather their product, services and organizational structures to survive new challenges [20]. Our unit of analysis, the Pharmaceutical Industry, is considered as process industry facing several challenges, such as, drug products market instability, fixed batch sizes, low modularity, complex product changeovers, and output limitations defined by the equipment [21]. Strategic management literature highlights the contribution of dynamic capabilities in improving firm's productivity [22], and supporting the implementation of new strategic initiatives even in Pharmaceutical Industry [23].

3. Methodology

In order to investigate how dynamic capabilities help pharmaceutical companies to align OPEX and Digitalization, we conducted 25 semi-structured interviews between 2020 and 2022. Semi-structured interviews have been selected as a method of research as they are accompanied by a number of advantages.

These advantages are expressed by e.g., the possibility of spontaneous and guideline-oriented interaction, the clarification of arising questions and the avoidance of incomprehensibilities, which eventually improves the reliability of research. In total we gathered data from 16 different pharmaceutical companies [A-P] with company sizes ranging from 2.000 – 110.000 employees. We rely on the selected sample approach [24] with three evaluation criteria to determinate companies for the interviews. Those criteria were, prior engagement with the authors, diversity of business areas and expertise in OPEX or Digitalization. This in turn assures that the same and transparent understanding of the topic was communicated before conducting the interviews and further allowed to picture a holistic view on Pharmaceutical Industry. Interviewees hold corporate OPEX functions and Digital roles. Transcriptions of interviews were conducted using the commercial transcription program *trint* and coding was done in *Atlas.ti*. The data coding was performed in two steps. First, the companies were clustered according to their alignment level of OPEX and Digital functions. Thereby, three different stages of alignment between OPEX and Digital functions have been identified: no alignment, partial alignment, and full alignment. This guaranteed that the analysis can capture capabilities necessary at different alignment maturity stages and the development of an alignment model can be generalized to all cases [24]. Second, we used a two-step abductive approach to code the interviews. Initially we applied attribute coding technique to consider literature findings of dynamic capabilities (Sensing, Seizing, Transforming) followed by sub-coding technique to account for the explorative, open nature of research [25].

4. Results and Discussion

4.1 Sensing

To gain insight into new opportunities, organizations need to use sensing as described in literature [26]. Especially in digital strategy contexts, where strategy is ongoing and evolving, organizations must develop strategic approaches to identify and understand what changes are needed and how they can be implemented [9]. Sensing is enhanced by the following actions. First, *scanning* action refers to organizations exploring opportunities and markets, gathering information from internal and external sources such as clients or vendors, and filtering relevant information to understand potential opportunities [8]. Second, *learning* action considers efforts to create further knowledge to learn and assess potential opportunities. By monitoring performance this activity helps to gain more insights to eventually identify specific areas for further actions [27,28] . Third, with *calibrating* action, organizations refine their prior actions and determine implications for future actions after probing specific opportunities and identifying implications [29].

Scanning

Numerous interviewees explained that they conduct assessments to identify opportunities from an internal and external perspective. *Internal assessments* were mainly driven by OPEX in order to revise processes and perform analysis on overall performance. In this regard [A] stated “we have observed that the productivity of the company started to decrease […] and we needed to understand why […] [So,] we have decided to perform this digital transformation”. Other companies, such as [F; L] indicate that they identify opportunities of digitalized processes by observing the processes at the site. That is why “global transformational leaders […] are spending 80% of their time on the shop floor, […] and start to have a clear view on what could be digital opportunities”. Further methods to internally assess and explore opportunities are interviews of internal customers [E], use of digital plant frameworks, playbooks and maturity assessment [B; G; H; I; J]. *External assessments* in contrast are related to adopt an outside-in perspective. Methods mentioned in that case are external Benchmarking [B; F], Ideation workshops, Technology Screening [B; F; G; H; J; L], Hackathons [D] and digital transformation days [H], where digital technology can be showcased and tested. Lastly [E] pointed out that the informal exchange with peer companies is also considered very useful in understanding learnings and experiences with technology implementation. [H] stated in that context: “We

have guys that actually just go out there and look at technology and see what might be useful". Company [L] for example mentioned: "We started by looking at what are other companies doing. We had several initiatives, e.g., a workshop […] to see how different teams are improving Digitalization. It was a good opportunity to observe what Digitalization can bring to the strategy and to help us understand what OPEX, IT […] teams could bring in."

The interviews further revealed that pharmaceutical companies approach opportunities regarding their digital transformation and OPEX in a fourfold way. The first approach can be considered as a *Top-Down Approach*. This approach is mainly characterized by a push from digital teams or leadership [B; I]. Company [I] sees the following reasoning: "we're getting pushed [towards] training and awareness training […] to start thinking about where there's opportunities long term to be utilizing". Especially in the case where performance pain points were identified from senior leadership, a top-down approach was followed [F]. Company [E] describes it the following: "So there are some people at management level [who] say here is a clear potential. I cannot live with the lack of transparency in this area. So, I would like to propose a solution, and can we then engage and create a small project?" The second approach, the *Bottom-Up Approach*, was explicitly mentioned by company [F; J]. A *combination of Top-Down and Bottom-Up* Approach was identified for [A; B; F; H; K]. The argumentation at this point was most suitable summarized by Company [J] "It is all so dependent […] on the size of the technology. […] I've seen that […] a particular group will see a gap and they'll say, hey, I want to have some kind of system here to fill this gap […] they'll say, I know about this tool. I want to implement this tool. [K] complementary explanation here was: "We first introduce the processes in paper, and later on we digitalize them. [..] The [OPEX] and the digital team are developing the tools. To bring them to the sites we have a site digital roadmap that has been top-down defined. The roadmap is created from both teams." Lastly, we observed the *Scattered Approach*. Especially in the cases where no formal Digitalization strategy was established, the Scattered Approach based on local initiatives was noticeable [E]. The Scattered Approach can also be explained by directions which are highlighted by [O] when they say: "We digitalize every process, but we don't evaluate if the process is ready for being digitalized or mature enough".

The last activity relating to the Scanning action refers to Decision Making. Decision Making in our understanding is supported by evaluation criteria, which are used to steer through uncertainty. The first evaluation criteria is strongly correlated to what we call *Guiding Principles*. To name a few of them, the interviews revealed performance, decision making support, energy consumption [H], cost reduction [G; H], speed, network distribution, quality improvement, complexity reduction [B], waste elimination [A], supply flexibility [G] or savings [D]. Company [C] indicated, that "[one has to] understand and demonstrate the added value of Digitalization in order to get the financial resources". In that context, Company [J] emphasized to first "focus on the business process […] and then holistically think about a technology solution". As a second evaluation criteria, we identified *Strategic Control.* Company [E] stated that it is important to have a drill-down system of KPIs related to operational goals in order to evaluate process changes due to Digitalization. Company [G] points out that the digital value creation needs to be evaluated from functional areas in combination with cascaded strategies. When we raised the question, Company [A; O] referenced to their vision, which sets a focus on Digitalization and orientation through uncertainty.

Learning

To create knowledge about opportunities, we wanted to understand what pharmaceutical companies have learned and how they learn. We have identified *Organizational Feedback* as a first construct. In that context [N] stressed that digital solutions need to be incorporated, however they shouldn't undermine the OPEX culture. [C] adds: "Start small is the best way […] We started with the most motivated site to proof to other sites the benefits of Digitalization. We also took in consideration the OPEX maturity of each site before starting pilot projects. We cannot start with digital processes with people that are not used to OPEX tools". [P] argues in a similar way, when the interviewee said, "you need people owning the standards, updating

them, and so on […]. You need the same element even when implementing digital solutions." Company [F] confirmed that the people aspect is very important, because people tend to react very emotional towards Digitalization. Furthermore, we see that pharmaceutical companies pursue a culture of driven towards more *Agility*. [J] stated that sometimes it happens that parts of processes are not well understood, which can lead to a temporary stop of a digital project. [M] saw it similarly saying that "continuous improvement is constantly changing. We're constantly finding different problems; we're constantly finding better ways of doing things. And technology is continuously improving in the digital side as well".

Calibrating

With respect to the Calibrating action, we have identified the activities of *Challenging* and *Refining*. *Challenging* activity constitutes a basic attitude which can be adopted by both OPEX and Digital teams to question possible changes. [A] asserts the following: "We challenged the digital team last year not to revise the road map, because when they have developed the road map, it was quite centric on the digital. And we said, try to forget that and see what the needs of the company are." [I] generalized at this point: "From our perspective, you know, with the things related to operational excellence, we always kind of go back [and ask] what problem are you trying to solve? Equally Company [A] said "digital also makes the same thing. So, they always challenge the client [and ask] why do you want this?" [G] interprets the role of OPEX as an important part to critical reflection, when saying: "Some people in the organization sometimes just jump into quick [digital] solutions […], but without really looking at the big picture, which is the language of strategy […] I'd say [that is] more so in OPEX side". This is also seen by [L] and exemplified in the context of project organization: "We bring in ourselves, by saying, we suggest here analysis projects, which are conducted before, so that we then can co-determine the direction of those projects". A similar observation can be made for [O]: "We can make projects visible and evaluate the benefits of a certain approach. We then develop visibility studies to the leadership, and they decide if we want to continue with them or not. […] The teams that can present the study can be from OPEX or IT department." *Refining* as a second activity centers around questions like "is this something that is going to be scalable? Is it going to stand in any way implementable in the future?" [B]. Another observation was made by interviewing [J], when the interviewee said, "as far as the project goes, it might not be identified in the beginning, but as the project goes on, there might be elements where it's recognized […] that we need some assessment of the business process processes within the technology implementation that needs more attention". [E] perceives the role of experimentation in the digital environment as particularly important here. [F] specified that they are doing a "return of experience" of everything that was done before including investigations of pitfalls and good practices. [A] adds: "we are becoming more realistic, and we have evolved where to look after one year of implementation of the roadmap". Overall, [M] sums it up well: "[…] sensing is a big part of us understanding what our competitors are doing, understanding what our current problems are, and making sure that the strategy is […] reflective of what challenges we currently have from a digital climate data perspective, from an intelligence perspective and understanding what is the current state? […] And making sure that we're partnering with the right companies […]."

4.2 Seizing

Seizing is the second critical capacity for organizationally aligning to digital strategies. It allows to take advantage of the earlier identified opportunities. Seizing involves going beyond understanding new business opportunities to actually making specific changes across the organization and taking action in order to capture possibilities [28,8]. Seizing comprises *designing*, *selecting* and *committing. Designing* action describes the process of planning and designing new structures and processes within an organization [9]. *Selecting* action refers to organizational activities around selecting between various options available in order to capture opportunities. Different opportunities can e.g., involve the choice of business models, suppliers, platforms, products or services. Decisions for capturing opportunities revolve around their design and further

potential solutions. Lastly, *committing* action consists of decisions made by the organization on how to implement the designs and on specific options for partners, services, processes, or business models [26].

Designing

Within the aligning action of Designing, we observed the activity of *Roll-Out Preparation*. Companies like [F] are designing huge transformation programs, which allow cross-functional work and avoid silo-thinking. They argue: **"**If we don't do […] a transformation around the product in terms of new governance and new roles, new trainings to be delivered, […] either people don't use it, or they do use it but extracting a very low value out of the full potential. So, […] the idea is to combine the digital products that are coming from it with the top programs so that we deploy the tool and then we do the transformation around it in a synchronized way". In addition to conducting basic OPEX training, [B] and [J] also see a great importance in training employees to interface and leverage digital tools. [L] argues that more and more waiting times are associated with appointing IT experts. "That is why short-, medium- and long-term cycles are taken into account in various aspects of personnel development, personnel recruitment, plant planning […]". Regarding the design procedures for roll-out across the network, companies usually describe that they target pilot sites in the first place [H; C]. The roll-out preparation strategy of [H] for example foresees the development of a minimum viable product, the creation of lessons learned in small units, e.g., small labs at the site, the roll-out at the same site and then the pilot for two sites at the same time. Overall [H] achieves at least four to five increments and improvements of digital product before rolling out across the whole network.

Selecting

When analyzing the interview data, we ascertained, that the aligning action of Selecting between different options refers to *Use Cases* and *Sites*. *Use Case Selection* describes how companies choose possible applications. [I] holding a OPEX position explained that "we have opportunity to define needs and pass them on to digital and central IT. But we also have of course global [standards] so that we need to align on first of all the use case [and then] also decide on timelines of priorities with respect to processes and products in the site". Moreover, we observe that Use Cases were also selected based on external push. For example, companies like [B] had to change their tier meetings to virtual due to Covid. *Site Selection* explains how companies choose in which sites they deploy their strategy. [C] referenced to a project management office (PMO) which evaluates each project that should be done on the site. [B] described their approach to selecting sites as "socializing" across the network to determine where to start first. The interviewee of [I] specified that OPEX and Digital have ongoing touch points any way. Especially in the case of OPEX strategy deployment projects digital functions are pulled and integrated into project core teams, whenever the need to digitalize at the site was identified before.

Committing

Within the Committing action we identified the *Roadmap Re-Vision* activity. Overall, the interviewed pharmaceutical companies state that they have recently revised their digital strategies and roadmaps. Overall, answers ranged from the year 2015 to 2020. [B] formulated: "It started really from the top with our CEO […] at the time kind of putting it as one of the company's goals and objectives to drive Digitalization". [B] complemented, that shortly after a global team took over to start a digitization strategy discussion the focus on the digital strategy was determined.

4.3 Transforming

Transforming as the third dynamic capacity is critical to aligning resources for a new strategy and adding new resources to fill existing gaps. In addition to the relative novelty of digital strategies and the resources associated with them, many companies don't have the internal expertise, so accessing external resources or

creating new resources may be significant in aligning to digital strategies [30]. The first action of *leveraging* is used to reassign resources to new tasks [31]. In that phase especially fungible resources are reassigned [32]. By applying those resources to other products and processes, organizations build new capabilities which are aligned to new digital strategies. The second action of *creating* is thereby used to develop and combine new resources and processes to eventually build new competencies. This expertise can be expressed in e.g., new technological or market competence [31]. The third phase of *accessing* foresees the use of external resources, e.g., from vendors or partners [20], that are complementary to existing resources. Examples in the context of Digitalization refer to web hosting services or business community platforms [33]. The fourth activity of *releasing* includes the reduction of existing resources in circumstances which are found to be not optimal. This may be the case, for example, if it has been analyzed that the existing configuration does not support the digital strategy [20].

Leveraging

Resource Reconfiguration is what we have identified within the Leveraging action. [J] pointed out that, "You can't have the same sort of lean IT group if you've implemented five new systems […]. So operationally we have to support the systems that we've rolled out […], but also by adding more programmers to help when things break and adding more infrastructure people". [J] continued to highlight that skillset and capabilities of people needs to change when digital infrastructures are built differently from classical IT systems. [F] introduced an example of their transformation program, which represents a step-by-step guide to prepare the infrastructure and to build up the team from existing resources at the sites".

Creating

We see that pharmaceutical companies accompany the development of new competencies by building new organizational structures. The most distinct activities we have observed are *Tier Management*, *Communities of Practice* and *Positions*. Fully digitalized *Tier Management* as described by [B; H] will be soon used to connect- and manage the lowest level of operations to the senior level. In that context [F] stated that "all our boards are going to digital format today". Besides digitalized Tier Management structures, pharmaceutical companies create governance and steering structures like Digital Advisory Boards [I], IT Architecture Boards [L], Forums [B; J], Operations Groups [C] or Market Places [G]. What these structures have in common is that they are highly cross functionally staffed. All of them include experts from OPEX and Digitalization. Typical working tasks comprise the identification and harmonization of the IT and tool landscape [L], facilitate exchange for decision making [G] or provide a platform for digital initiatives [G; I; J]. [B] mentioned that their platform facilitates the preparation of digital initiatives which required funding outside the business as long as they drive alignment on the roadmap. Besides those formal structures, the interviewed companies stated that they also leverage *Communities of Practice*. In the case of [I] they are "driven by digital data science" including regional as well as global groups where best practices coming from the sites are shared". In addition [G] explains that they offer webinars, such as one week and one year data science courses as well as one-week trainings for selected people which are installed as digital champions to build digital capabilities across their entire entity. Lastly, the creation of new *Positions* is considered as a further activity to develop new resources. The motivation behind that can be e.g., the idea to centralize Digitalization with a "digital head" [C], merge digital programs with a new "Chief Digital Officer" [F] or to strengthen the company wide perception that activities related to OPEX and Digitalization are aligned, and collaboration will be further enhanced. That is why [P] said: "So far we changed the name of the leader, and in the strategy deployment we use the term lean digital".

Accessing

The use of external resources, especially in the case of *Collaborations* with software providers was also mentioned by some companies [O; E]. Especially when maintaining complex IT-systems, pharmaceutical companies heavily rely on their vendors. However, the interviews revealed that a lot of effort is put into internal digital capability building as they have acknowledged the strategic relevance of Digitalization for their business [A; G; L].

Releasing

Finally, the interviews have also shown that to some degree the release of resources in order to better support the digital strategy has taken place. The first activity was interpreted as *OPEX Support*, which means that OPEX takes over some tasks, which were originally performed by a digital function. [A] for example showed a very pragmatic perspective saying: "I have two persons that work very well in programing […]. So, I have said, I don't need to have digital to create reports or to create basic before they allow us to develop". [O] commented similarly: "first we make some tests in Excel with some macros and some programing. And then we use that kind of mockup". [C] has put the before mentioned statements into a broader context: "OPEX took over some goals from IT […] OPEX is informing the IT-roadmap with its values but also integrating Digitalization [within] OPEX roadmap tools. For example, the introduction of digital visual boards." The second construct of *Digital Support* describes the reverse distribution of roles. Thereby, digital functions are more perceived as service provider. [N] described the situation as following; "OPEX is doing what they need to do, and they're usually in the production area. If they need Digitalization aspects, they call for it".

Figure 1 summarizes the described alignment process between OPEX and Digitalization.

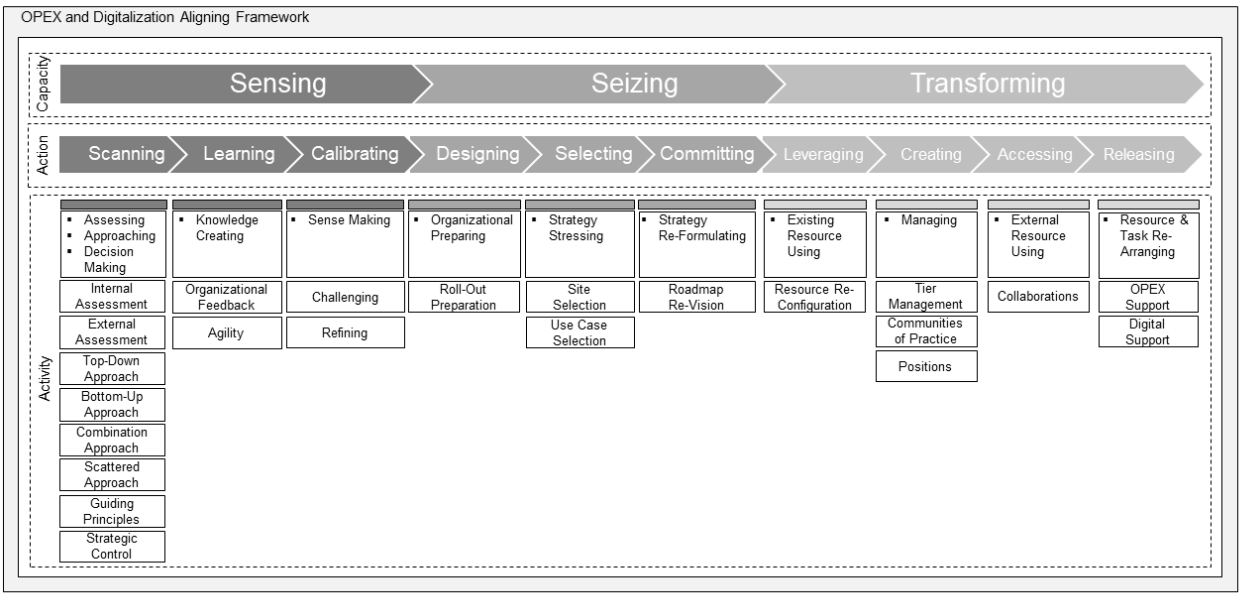

Figure 1: OPEX and Digitalization Aligning Framework

5. Conclusion and Future Research

Companies have acknowledged that they have to combine their Digitalization efforts with OPEX when they want to stay competitive. The question that emerged is how companies align those two and how does the process of alignment look like. We contribute to answering this question by using the dynamic capabilities approach. Our insight driven approach within the Pharmaceutical Industry revealed various aligning activities. We thereby add to literature by presenting a holistic set of activities. Thus, practitioners can reflect upon their current configurations and their status quo of Alignment.

The research at hand offers several future research opportunities. First, an in-depth literature review can reveal further aligning activities, which have not come to light from practice. Second, an in-depth examination of each case's aligning activities including emerging challenges could support the formulation of implications to successfully drive the digital transformation of OPEX programs. Third, a quantitative approach to investigate to what extent Digitalization facilitates the establishment of a Continuous Improvement infrastructure, culture and behaviour could also be investigated. And fourth, a longitudinal study as described by Yeow et al [9] can also be one possible direction for future research.

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