Ecosystem Disruption and Regulatory Positioning:

Entry Strategies of Digital Health Startup Orchestrators and Complementors

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Abstract

Through a multiple case study of six digital startups in the healthcare ecosystem, we develop a framework of entry through innovation in a regulated ecosystem. The framework reveals the interplay of two dimensions that have not been examined in conjunction so far: 1) the degree of ecosystem disruption brought by the entrant's innovation; 2) the impact of regulation/policy on the entrant's innovation. Based on these two dimensions, our data reveal four scenarios for entrants: dual constraint; regulatory-enabled orchestration; regulatory-constrained complementation; and dual enablement. The paper provides several contributions to ecosystem research, including a new definition of ecosystem disruption, the joint consideration of two key dimensions of ecosystem entry, and an emergent framework illustrating specific strategies, governance mechanisms, and the likelihood of success for each entry scenario. We show that start-up entrants can be successful orchestrators if they are enabled by regulation, that they can shift their positioning to seize enabling regulations, and that being an orchestrator or a complementor is a strategic choice related to an entrant's ecosystem disruption strategy.

Keywords

Ecosystem disruption, orchestrators, complementors, regulation, digital health, startups.

1. INTRODUCTION

Recent years have seen an exponential growth of ecosystem studies (Adner, 2006; Adner and Kapoor, 2010, 2016; Baldwin, 2012; Iansiti and Levien, 2004; Jacobides, Cennamo, and Gawer, 2018; Bogers et al., 2019). This is not surprising because the ecosystem concept encompasses important contemporary transformations including platform orchestrators, systemic changes beyond industry boundaries, and coopetition with mutually interdependent actors. An ecosystem is defined as a network of actors with different roles exploiting complementarities and interdependencies to jointly create value (Adner, 2006; Bogers et al., 2019). Scholars have examined the structure of interdependencies among ecosystem components (e.g., Ganco, Kapoor and Lee., 2020), ecosystem governance mechanisms (Baldwin, 2018; Gawer, 2014; Kapoor and Lee, 2013; O'Mahony and Karp, 2022), ecosystem actor roles (Baldwin, 2012; West and Wood, 2014), and formation strategies in emerging ecosystems (Hannah and Eisenhardt, 2018).

Despite these significant advances, we continue to lack a clear understanding of one crucial ecosystem dynamic: ecosystem disruption. The concept of ecosystem disruption is related in part to the concept of disruptive innovation typically pioneered by entrants (Christensen, 1997), but it is also distinctive because the latter historically referred to product-based innovations. Ecosystem research has started to examine how entrants can disrupt ecosystem incumbents (Ansari, Garud, and Kumaraswami, 2016) and how innovative incumbents can disrupt their own complementors (Ozalp, Cennamo, and Gawer, 2018). It has also studied some of the ecosystem-level processes behind entrants' business model disruption (Cozzolino, Verona, and Rothaermel, 2018; Cozzolino and Verona, 2022; Snihur, Thomas, and Burgelman, 2018). However, given the importance of value-creation interdependencies in ecosystems (Adner, 2017), research would benefit from a definition of ecosystem disruption that is firmly anchored in these interdependencies. Research would also

benefit from deeper insights into the mechanisms used by entrants to manage the disruption of existing actors and relationships in ecosystems.

A second important gap in the literature lies in the understanding of how ecosystems and regulatory/policy concerns relate to each other (Adner and Kapoor, 2016). This is surprising because many business ecosystems are highly regulated, including telecommunication, transportation, and healthcare. Regulators and policymakers are important ecosystem actors who can affect ecosystem governance and innovation success (Aversa, Huyghe, and Bonadio, 2021), and failing to account for regulation can cause misinterpretations of innovation success (Finch, Harkness, and Geiger, 2017). Yet, the challenges, strategies, and consequences of innovating in a regulated ecosystem remain understudied (Gurses and Ozcan, 2015). Moreover, the interactions between regulation and ecosystem disruption are still unexplored.

To address these important gaps, we investigate the following research questions: *What are the strategies of entrants in relation to ecosystem disruption and regulatory positioning when innovating in an existing ecosystem, and how can these entrants increase their likelihood of success?* We examine these questions in a healthcare ecosystem, a context known for its high level of regulation and for its multiple interdependencies and complementarities (Kapoor and Lee, 2013; Barlow, 2016; Dattée and Barlow, 2017). Innovation in healthcare is challenging due to the complexity of the ecosystem and its many cultural and institutional barriers (Edmondson, Bohmer and Pisano, 2001; Sander et al., 2012), a major one of which is regulation. Moreover, disruption is a significant concern in healthcare (Barlow, 2016).

Through an in-depth qualitative study, we investigated the entry of six startups within the U.S. healthcare ecosystem between 2004 and 2020. To delimit the ecosystem boundaries (Autio and Thomas, 2014) and ensure comparability, we selected startups that were active in

the broad area of digital health, excluding wellness-related applications. Our six startups operated in the areas of digital therapeutics, e-health platforms, and smart health devices. They varied in their level of disruption of the healthcare ecosystem and in their positioning with respect to regulation. They attempted to govern specific ecosystem bottlenecks and regulatory hurdles by engaging with multiple ecosystem actors, including hospitals and physicians, pharmaceutical companies, government healthcare agencies, regulators, technology companies, business customers, and insurance companies.

Our findings significantly add to ecosystem research in several ways. We offer definitional clarity to ecosystem studies by centering our definition of ecosystem disruption on the fact that ecosystem disruption can impact not only focal incumbents but any ecosystem actor that creates value as well as actors' value-creating relationships. Our study brings together the notions of disruption and ecosystem orchestration by arguing that attempting a high level of ecosystem disruption is more likely to involve a subsequent orchestrator positioning, whereas lower degrees of ecosystem disruption are more likely to imply a complementor positioning. We further demonstrate that startup entrants can become orchestrators (see Lingens, Böger, and Gassmann, 2021a) and disrupt an ecosystem particularly when the startup can position itself in a regulatory-enabling context, contrary to common evidence that sees incumbents more suited to leading an ecosystem (Iansiti and Levien, 2004; Jacobides et al., 2018).

These insights emerged from our joint consideration of two important but separate dimensions, ecosystem disruption *and* regulatory positioning. By combining these two dimensions or elements of an entry strategy, we developed a framework of four scenarios in which entrants can operate: *dual constraint*, *regulatory-enabled orchestration*, *regulatory-constrained complementation*, and *dual enablement.* Each scenario is characterized by specific strategies, governance mechanisms, and likelihoods of success. The combination of

the two dimensions also allowed us to respond to a call for a more integrative perspective of ecosystems that accounts for regulation (Adner and Kapoor, 2016) and to add to the few studies considering regulation as beneficial to disruptors rather than as a constraint (McDuffie, 2018; Rugman and Verbeke, 1998).

Our evidence concerning structural positionings in the ecosystem and our methodological approach of mapping value networks as sub-ecosystems are apt to progress studies on ecosystem-as-structure (Ganco et al., 2020; Jacobides et al., 2018; Shipilov and Gawer, 2020). We also observed that a structural positioning is not static given that one of our entrants shifted its positionings from one scenario to another to benefit from new regulations. Finally, the study provides insights into value creation in ecosystems (e.g., Bogers et al., 2019) and the management of healthcare innovations (Edmondson et al., 2001; Sander et al., 2012).

2. THEORETICAL BACKGROUND

2.1 Disruption in ecosystems

Scholars have recently started to examine ecosystems in relation to disruption (Adner and Kapoor, 2016; Adner and Lieberman, 2022; Ansari et al., 2016; Gans and Stern, 2003; Ozalp et al. 2018; Snihur et al., 2018). The classic view of disruption defines disruption at the product level as a process where an entrant's innovation at the lower end of the market relentlessly gains a foothold in the incumbents' higher-end mainstream market, eventually causing their demise (Christensen, 1997; Markides, 2006). However, Christensen et al. (2018) recently called for considerations of disruption at the system level (see also Kumaraswamy, Garud and Ansari, 2018; Teece, 2018). Accordingly, ecosystem scholars have now begun to extend the disruption concept to ecosystem actors, relationships, and interdependencies.

One of the first studies referring to disruption in this new systemic fashion is Gans and Stern (2003). While the authors do not use the terms ecosystem and disruption, they consider whether innovative entrants can tap into or reproduce existing value chains, and they distinguish four commercialization environments for entrants. Adner and Kapoor (2016) examined several disruptive cases causing technological substitution. They theorized that the time of adoption of a new technology depends on the resolution of challenges in an emerging ecosystem caused by bottlenecks and on the opportunities for extension of existing technology in the old ecosystem. Ansari et al.'s (2016) study is one of the first to explicitly refer to disruption and ecosystems in their examination of how an entrant like TiVo disrupted several actors and relationships in the TV ecosystem. In their paper, disruption refers to incumbents, or their assets or strategies ("technologies, products, or business models", "existing relationships"). Ozalp et al. (2018) examined an incumbent introducing next-generation platform technologies, which challenged its own complementors' value-creation activities because the platform's more advanced capabilities steepened complementors' learning curves. Vice versa, Adner and Lieberman (2022) noted a case where value-creating complementors became disruptors for incumbents over time. Cozzolino et al. (2018) distinguished between disruptive technologies and disruptive business models by investigating how disruption affects value creation and capture among ecosystem actors (see also Cozzolino and Verona, 2022). Snihur et al.'s (2018) study of how Salesforce created a new ecosystem shows an entrant with a disruptive business model using initial framing of distinctiveness and leadership and then adapting to the reaction of other ecosystem participants and incumbents over time. Similarly, by focusing on ecosystem interdependencies, Öberg (2023) examined how incumbents rely on other ecosystem participants, particularly customers, to cope with disruption.

These studies broaden the classical view of disruption in a product innovation context (Christensen, 1997) by including a range of actors that are potentially disrupted, the sources of disruption, and the strategies through which ecosystems are disrupted. While they do not explicitly provide a definition of ecosystem disruption, they share a view of ecosystem disruption that is close to Kumaraswamy et al.'s (2018, p. 1027) explanation that innovations can "disrupt existing relationships among the members of entire industries and ecosystems instead of disrupting just specific incumbents". Thus, based on existing studies, disrupting relationships (e.g., Ansari et al., 2016; Kumaraswamy et al., 2018) and disrupting other actors in the ecosystem beyond the focal actor (e.g., Ozalp et al., 2018; Öberg, 2023) stand out as two defining building blocks of ecosystem disruption. It is useful to note that, for both of these elements, disruption centrally affects the value-creating activities within the ecosystem.

Building on this literature, we derive the following definition. We define *ecosystem disruption* as an innovation challenging value-creation interdependencies in an ecosystem to the extent that the competitive advantage of one or more actors is threatened. The disruption can pertain to ecosystem actors' technologies, products, business models, assets, or relationships among actors and with customers. Disrupted actors are likely to include incumbents, but can also extend to suppliers, complementors, and competitors. Based on this definition and consistent with prior research, an organization is successful in its ecosystem disruption when it gains a foothold by upending one or more elements of value creation in the existing ecosystem. Vice versa, the organization is unsuccessful when its technologies, products, or business models fail to materially change any value-creating element of the ecosystem. In assessing the likelihood of success, scholars might also consider the power and role of the challenged actors. For example, disrupting a leading ecosystem orchestrator such as Google is not equivalent to disrupting an ecosystem complementor.

It is important to note that ecosystem disruption is not a binary outcome. Rather, the degree of ecosystem disruption can vary on a continuum from low to high along two dimensions: number of disrupted actors/relationships and extent of the disruptions. The continuum of ecosystem disruption depends on whether the innovation is challenging a single actor or relationship versus multiple actors/relationships, and it is based on the extent of the threats to value creation for each.

Because our study relates ecosystem disruption strategies to the attempt to become an ecosystem complementor or orchestrator, respectively, we briefly recall these concepts from the literature before examining them in the context of ecosystem disruption. In general, the literature considers complementors as actors producing ecosystem components that complement the focal offer (Kapoor, 2018). Examples are video game producers for console gaming. Orchestrators, also known as hub or focal firms, are actors occupying a central position in the structure of the ecosystem and setting the rules for complementors (Adner and Kapoor, 2010; Jacobides et al., 2018). In platform-based ecosystems, the platform owner often takes the orchestrator role to enable ecosystem transactions and incentivizes some actors to be complementors, constantly balancing cooperation and competition with and among the ecosystem actors (Baldwin, 2018; Gawer, 2014). While orchestrators are typically identified with powerful companies, researchers have started to suggest that startups can sometimes behave like orchestrators (Lingens et al., 2021a) – an aspect further explored in our study. For clarity, we characterize "high disruption as orchestrator" when an organization attempts to occupy a position in the ecosystem that mediates value-creation relationships between ecosystem actors by challenging prior value propositions and/or relationships. We define "low disruption as complementor" when an organization attempts to complement the value proposition of one or more ecosystem actors and tries to keep challenges to the value

proposition of ecosystem actors low. We recall from our definition above that 'high' and 'low' should be understood as points on a continuum rather than binary oppositions.

The literature has recently noted that there can be situations where a complementor over time becomes a disruptor of the actor it initially complemented (see Adner and Lieberman, 2022), but our empirical evidence does not capture this long-term dynamic. Thus, disruption as orchestrator and disruption as complementor correspond, respectively, to higher and lower degrees of ecosystem disruption in our study and findings.

2.2 Ecosystem and Regulation

An ecosystem is broadly constituted by a supply side, a demand side, and an institutional side, the latter often including regulators (Adner and Zemsky, 2006; Ansari, et al., 2016). Although some studies have recognized regulators as important components of ecosystems and called for research considering institutional and regulatory aspects (see Adner and Kapoor, 2016), ecosystem scholars have often neglected to examine the impact of regulation and policies on the functioning of ecosystems, and especially on ecosystem disruption. Our study responds to this call by demonstrating that regulators and governments can act either as enablers or constrainers of focal innovations. Moreover, we show for the first time the interplay between regulatory impacts and ecosystem disruption brought about by entrants.

While some valuable studies have examined the effect of regulation on innovation (Aversa and Guillotin, 2018; Gurses and Ozcan, 2015; McDuffie, 2018; Ozcan and Gurses, 2018; Rugman and Verbeke, 1998), these have not engaged with the key tenets of ecosystem research. For instance, Rugman and Verbeke (1998) theorized that environmental regulation can be complementary or conflicting with respect to industrial performance, but they also noted that it is difficult to predict the effect ex-ante. Aversa and Guillotin (2018) examined incumbents' technological responses to two types of regulatory changes - permissive versus

restrictive - but did not study the interactions between firms or the ecosystem's reactions to the firms' technological innovations. Gurses and Ozcan's (2015) study showed how entrepreneurs fight against incumbents that are protected by regulation by using strategic framing and collective action, while Ozcan and Gurses (2018) demonstrated that incumbents also use framing contests against regulators when entering new product categories. However, neither study took account of structural ecosystem features such as complementarities, interdependencies, or bottlenecks. Aversa et al.'s (2021) study of the car-sharing market in Spain traced regulators' and incumbents' differentiated reactions to two entrants but did not engage with interdependencies between firms. To integrate these studies, our research examines regulation in conjunction with the key structural features of an ecosystem an entrant potentially disrupts: interdependencies, bottlenecks, and ecosystem actors' roles.

Because one of our findings relates to bottlenecks, we briefly recall this concept from the ecosystem literature. Bottlenecks are components or actors whose presence can constrain the focal offer's value proposition, for instance, batteries' limited performance or scarce charging stations for the adoption of electric vehicles (Hannah and Eisenhardt, 2018; Kapoor and Furr, 2015; Kapoor, 2018). Preliminary evidence indicates that firms can strategically position themselves where bottlenecks are less present (Baldwin, 2018) or they can develop architectural knowledge to recognize bottlenecks (Hargadon and Douglas, 2001). Our study further clarifies these two important considerations about how entrants use structural positioning and related governance mechanisms to reduce the negative effects of ecosystem bottlenecks on innovation adoption.

3. METHODOLOGY

Seeking to gain insights into entry strategies in regulated ecosystems necessitates a research approach situated simultaneously at the entrant and the ecosystem levels. We thus adopted an

embedded multiple case study design. According to Eisenhardt (2021, p. 149), the multiple case approach allows solving "a significant puzzle like… technology adoption in an ecosystem". Multiple case studies facilitate theory building or theory elaboration (Eisenhardt and Graebner, 2007; Maitlis, 2005). In our case, we situated our study within the realm of theory elaboration because existing ecosystem research provides a solid foundation for our study, "obviating the need for a purely inductive approach" (Maitlis, 2005). The multiple case design facilitates a replication logic, where each case is considered as an experiment to confirm or disconfirm an inference (Graebner, 2004; Yin, 1994). This logic is further enhanced when an empirical setting offers a quasi-natural experimental design. This was the case in our setting, in which we found that two pairs of companies were positioned differently toward an external force (regulation) and a third pair was unaffected, thus allowing us to keep certain features constant while varying others through our case selection.

3.1 Research setting

As mentioned briefly in our introduction, we sought out an ecosystem where regulation was an important shaping force and where we could observe potentially disruptive entrants. We chose the U.S healthcare ecosystem and the entry of digital health startups as our research setting. This is an ideal setting for our theoretical concerns as it exemplifies the encounter between potentially disruptive technology startups and an existing ecosystem where regulation typically dictates a slower pace of innovation (Barlow, 2016). Digital health technologies range from consumer-facing technologies such as step counters or smartphone apps through sensor-enabled devices such as asthma inhalers to administrative tools (Mesko, 2015). All digital health technologies are subject to data security protocols, but they vary in the extent to which they fall under FDA (U.S. Food and Drugs Administration) regulations (Duggal et al., 2018; Geiger and Kjellberg, 2021).

While strongly shaped by regulatory and policy decisions, the healthcare ecosystem displays further barriers to innovation for digital health entrants, including cultural (Sanders et al., 2012) and professional ones (Edmondson et al., 2001). Among these multiple barriers, the strength of existing complementarities and fears of disrupting existing relationships are some of the most significant (Dattée and Barlow, 2017). Any healthcare service relies on a number of complementarities and interdependencies between several ecosystem actors: healthcare providers (physicians, nurses, general practitioners), proprietary Electronic Health Record platform vendors (henceforth EHR vendors), payers (government payers, insurance companies, or self-insured employers), medical technology companies, pharmaceutical firms, and other product providers (see Figure 1). In ecosystem terms, many of these relationships are 'non-generic', that is they require specific alignments for value creation (Jacobides et al., 2018; Shipilov and Gawer, 2020). The complexity of this ecosystem renders innovation adoption more unpredictable (Barlow, 2016; Edmondson et al., 2003; Ferlie et al., 2005). Again, all these features make entry into the healthcare ecosystem an ideal setting for our theoretical concerns (Sounderajah et al., 2021).

For clarity, we specify that two ecosystem actors depicted in Figure 1 display peculiarities in the U.S. healthcare system: Proprietary electronic health record (EHR) vendors, such as Cerner and Epic, sell to healthcare providers or provider networks (the U.S. does not have a national electronic health record system). Self-insured or partly self-insured employers are typically large companies directly funding their employees' healthcare costs rather than outsourcing this risk to insurance companies (Acs et al. 1996; Dalton and Holland, 2019). We refer to partly- or fully self-insured employers henceforth as 'employers', including in Figures 1 and 3.

INSERT FIGURE 1 ABOUT HERE

3.2 Data collection and analysis

In 2014 the second author started following digital health activities in the U.S. through online newsletters and on Twitter. In parallel, she traced the ecosystem's evolution since the early 2000s through an archival search in U.S. newspapers, using the Nexis database and search strings 'digital health', 'eHealth', 'connected health' and 'telehealth', and taking particular note of all regulatory changes and decisions. Between 2015 and 2017, she conducted participant observations at numerous digital health events mainly on the U.S. West Coast and in the Greater Boston area, including conferences, meet-ups, and industry showcases. She then carried out 28 interviews with individuals representing all relevant nodes of the healthcare ecosystem – industry incumbents, consultants, conference organizers, healthcare providers/users, payers, and regulators (see Table 1). Ecosystem interviewees were chosen based on their experience with healthcare innovation dynamics and with the introduction of digital health into this ecosystem.

Starting this study at the systemic level not only permitted us to grasp the ecosystem's broader dynamics but also allowed us to identify a number of entrants from which to sample our embedded cases. Our sampling strategy was theoretically driven, which meant choosing cases where the focal phenomenon was likely to occur and where similarities and differences across cases could support theory elaboration (Eisenhardt and Graebner, 2007). Through our expert interviews and documentary research, we identified digital health entrants whose business model positioned them differently toward regulation. Companies had to be fully focused on digital health, which eliminated firms that offered more general-purpose technologies.

From an initial pool of cases, we selected six firms: two sets of two 'treatment' case firms that had entered (or, in one case, moved) into favorable versus unfavorable regulatory contexts, respectively, plus two 'control' cases, consisting of firms that were judged to be relatively unaffected by regulatory decisions. The inclusion of the control group enabled us to

establish whether the mechanisms that we would identify for the four regulatory impacted entrants were in fact related to regulation, thus improving the robustness and generalizability of our findings. Table 2 provides a short profile of each case firm and lists our data collection efforts. Table 3 illustrates the qualitative operationalization of our two empirical dimensions: regulatory impact and level of disruption. To note, while the regulatory dimension (enabled/constrained/neutral) served as a theoretical sampling criterion, the disruption dimension emerged during the early fieldwork.

From 2015 to 2020, we collected all available secondary data on our six case firms through Nexis and through extensive internet searches, which amounted to more than 1550 pages; we also transcribed more than 30 hours of video interviews with founders or senior managers of the firms in question. The second author attended numerous presentations and showcases by our six entrants, visited each firm in their headquarters, and interviewed the CEO or Chief Technology Officer (CTO) and one advisor or venture capital partner per company at least once. Above and beyond our large corpus of secondary data and video footage, this yielded 15 case-specific interviews in addition to the 28 ecosystem-specific interviews for a total of 43 interviews and 124 hours of observation over 20 separate occasions, as Table 2 illustrates.

INSERT TABLES 1, 2, and 3 ABOUT HERE

All interviews were semi-structured and most were carried out face-to-face (with two completed on Skype). Questions revolved around how interviewees and their organizations first became involved in digital health; how the healthcare ecosystem has evolved since their involvement started; who the main actors were and what challenges or opportunities they represented for our entrants; what relationships they entertained with other actors; what strategies entrants followed to introduce their innovations; and how they saw their venture developing. Most interviews were tape-recorded; where permission was not given ample

notes were taken by the researcher. Subsequently, interview transcripts and field notes were de-identified, verified for accuracy, and uploaded into QSR NVivo10. Secondary data were also uploaded into NVivo for data management.

Data analysis evolved in three different stages: a chronological mapping of digital health innovations in the U.S. healthcare ecosystem; individual case analysis; and cross-case analysis. In stage 1 we drew up a timeline of digital healthcare innovations and regulatory/policy developments based on our ecosystem-level documentary data and interviews. Stage 2 comprised an analysis of case-specific field notes, interviews, and secondary data in order to draft a case history for each company. We endeavored to understand the starting point and evolution of each entrant's business model, external events and internal decisions that may have influenced this evolution, and the ecosystem's reactions to the entrants. We sought additional information where gaps in our understanding of the individual case chronologies became apparent. In stage 3, we began the cross-case analysis through comparing the firms' entry strategies, their ecosystem bottlenecks, and the respective regulatory dynamics. During this stage, our analytical focus zoomed between case comparisons and specificities of each case. This process of constant and recursive comparison of our data was facilitated by the development of tables and graphs for each case and across cases, which included the main challenges, response strategies, expected consequences, and corresponding quotes. These tables also served to reduce our data in a systematic process (Miles and Huberman, 1994). Cross-case comparisons occurred among the six entrants but also at the sub-group and within-group levels, considering the three pairs of regulatory-enabled, constrained, and unaffected cases.

In the latter stages of data analysis, we took recourse to pertinent academic literature, moving in an abductive manner between data and theory consistent with our theory elaboration objective, which further served to sharpen our emerging analytical framework

(Eisenhardt, 2021). Early findings were presented to several industry and academic panels for feedback and refinement.

4 . FINDINGS

Our data suggest that successful entrants take a strategic approach to positioning themselves in an existing ecosystem. A first element of the entrant's strategy pertains to its intent to generate a high (or low) degree of *ecosystem disruption*, which is implemented at a structural level through the adoption of an orchestrator (or complementor) role. Three of our cases attempted to disrupt ecosystem actors and relationships by positioning themselves as orchestrators, while the other three cases endeavored to keep the disruption relatively low by positioning themselves as complementors. A second element of an entrant's strategy refers to its regulatory positioning, whereby the *regulatory / policy impacts* on the innovation can be enabling or constraining. Two of our cases entered regulatory-constrained contexts. One case entered a regulatory-enabled context directly, while another entrant strategically shifted its positioning over time from a regulatory unaffected to a regulatory-enabled context. Importantly, the two elements of the strategy represent dimensions whose interplay generates four main scenarios (see Figure 2): *dual constraint; regulatory-enabled orchestration; regulatory-constrained complementation;* and *dual enablement.* Figure 2 also shows two control group scenarios because two cases remained largely unaffected by regulation while embarking on a high/low ecosystem disruption strategy, respectively. We describe each scenario with reference to one of our cases. A simplified structure of the value networks our startups tried to build is depicted in Figure 3 (a to f).

INSERT FIGURES 2 AND 3 ABOUT HERE

4.1 Dual constraint (*DigitalMedicine)*

This scenario is characterized by a high degree of disruption of the ecosystem's actors and/or their interdependencies, coupled with the need to resolve considerable regulatory or policy constraints. The entry strategy in this scenario is the most difficult because it presents a dual constraint: the need to convince incumbents to cooperate with a potentially disruptive entrant that aims to orchestrate parts of the ecosystem, and the need to solve regulatory hurdles. *DigitalMedicine* was the revelatory case for this scenario. Founded in 2001, the startup's innovation is an ingestible sensor, encapsulated in a pill that, once swallowed, sends a signal onto patients' smartphones to record their adherence to their medication schedule and other health data. Ecosystem value creation, in this case, was seen in an improvement in medication adherence, which is a major issue in healthcare provision.

Regulation was a major constraint for *DigitalMedicine*. The Chief Medical Officer (CMO) and Co-founder articulated the steep hurdles posed by regulation:

> In health care… we can never take a chance of injuring the patients. That is why we are regulated and all of that is the right stuff. That orientation though can sometimes become so embedded that it effectively becomes an excuse for just saying no, without trying something.

The innovation was subject to stringent FDA regulations and required additional regulatory efforts because it challenged existing regulation in new ways - as noted later in this section, the regulator lacked cross-cutting expertise in areas as diverse as wearable technologies and ingestible sensors.

With its innovation, *DigitalMedicine* intended to disrupt incumbent pharmaceutical companies, the value-creation relationships between healthcare providers and pharmaceutical companies, and the relationships between healthcare providers and patients – thus embarking on a strategy of high ecosystem disruption. *DigitalMedicine's* CMO and Co-founder formulated this disruptive ambition in a 2015 talk:

> A business model …whose days I think are largely numbered, is the current pharma practice, which amounts to selling chemicals by weight for extremely high prices,

> whether or not they work… digital techniques enable a new kind of payment structure, and that is what we sign up to!

By collecting real-time data on drug efficacy and adherence, the startup could undermine the existing revenue models of pharmaceutical companies, thus disrupting them. By challenging the way pharmaceuticals are evaluated, the startup also threatened to disrupt the relationship between pharmaceutical firms and healthcare providers. Further, the continuous data generated by the ingestible sensor threatened to disrupt healthcare providers' workflows, diagnostic and evidentiary practices, and customer relationships. The CEO of a partner pharmaceutical company explained at the 2017 CNS Summit:

> (*DigitalMedicine*'s ingestible sensor) has provided more data points than all the clinical data trials that the pharmaceutical company has ever done… and part of the challenge is how you look at the data and how often… Doctors are very concerned with data overload.

This intent of high ecosystem disruption corresponded to an attempt to become an ecosystem orchestrator. The startup endeavored to forge new interdependencies as a hub connecting pharmaceutical companies, healthcare providers, and patients, controlling previously unavailable real-life data in a 'medicine-as-a-service' value network. The CMO and Co-founder told us: "We're a bit like Apple … coming up with better ways to delight the patient... we're worth the price that payers are paying for the whole thing". Figure 3a depicts *DigitalMedicine's* value network as it emerged from our analysis, illustrating the potential disruption of actors/relationships, its structural positioning as an orchestrator creating new relationships and technological interfaces, and the constraining regulation.

We found that in the dual constraint scenario an entrant needs specific governance mechanisms to mitigate both the regulatory hurdles and ecosystem bottlenecks, as summarized in Figure 4 below. "Proving the innovation to regulators" emerged as a first important mechanism, and it refers to proving compliance extensively and often repeatedly to regulators or policymakers. The CMO and Co-Founder told us:

> What's required is a step by step, careful, time-consuming, painstaking approach to build the science and build the evidence base that not only is this safe and performs well, but it is actually clinically valuable, and it's economically valuable, and build that case and make it hermetic and continue to educate people.

The startup demonstrated the safety of the innovation through multiple clinical studies. The effort to provide evidence is also illustrated by the significant number of innovations that the startup needed to patent, owning over 500 patents by 2012.

A second mechanism was "cooperation to overcome ecosystem bottlenecks and regulatory hurdles". This is a strategy to establish collaborations with bottleneck components in the ecosystem, in our case the regulator and pharmaceutical companies. In 2008, *DigitalMedicine* started an active collaboration with the FDA to develop a new regulatory pathway, finally pioneering an entirely new regulatory category, as this report indicates:

> The device itself was approved by the FDA in June after dozens of clinical studies … But regulatory hurdles have been a brake on innovation as the FDA and its counterparts elsewhere scramble to develop the expertise needed to assess the safety and efficacy of a new category of medical products. (Financial Times, 2015)

Besides collaborating with the regulator directly, *DigitalMedicine* also started collaborating with an incumbent pharmaceutical company. But even with these collaborations, the regulatory hurdles were not easily removed, as the President of the U.S. branch of their pharmaceutical partner acknowledged:

> We have done double duty with *DigitalMedicine* on almost all of the discussions and interviews [with the FDA] I think that they [the FDA] recognized that it was going to be precedent setting. (at the CNS Summit 2017).

A third governance mechanism was "educating the ecosystem actors about the innovation" to help adoption. Given the high level of disruption in the ecosystem, *DigitalMedicine* needed to convince a range of ecosystem actors about the uses and benefits of its innovation. Hence, education was aimed in part to explain an innovation that was new to the world, and in part to persuade ecosystem actors to accept something that potentially

disrupted them. An expert described how difficult it was for *DigitalMedicine* to translate the value to healthcare providers:

> You have to be out there with the on-ground sales force, and most of that is selling to payers and physicians and educating the market to ensure that you're changing the prescribing behavior that needs to be changed (in Medical Marketing & Media, 2022).

Similarly, the former CEO of a large healthcare provider noted the startup's extensive educational effort with government buyers, healthcare providers, and pharmaceutical incumbents in an interview:

> Now *DigitalMedicine* ... got good conversations with [a large US health system], they've got a couple of conversations going on with a couple of drug companies, but it's like: this is so new and you think you put a digital pill in somebody's mouth and they swallow it? Will they like having that, and isn't that Big Brother? And you know, they have to get over all that stuff every time they have the conversation.

The dual constraint of tackling ecosystem bottlenecks and regulatory hurdles simultaneously forced this startup to spend a great deal of time and energy on proving, educating, and seeking collaborations. In addition, the high price of the ingestible sensor limited the immediate use case to medicines where adherence was a central issue. In 2020, after a long uphill journey and despite what one expert called the 'incredible value to what the company achieved', *DigitalMedicine* filed for bankruptcy and sold off its technical assets to its former pharmaceutical partner. Our evidence suggests that the likelihood of success in the dual constraint scenario is low (Figure 4): the cooperations the entrant can form might be unstable not only because incumbents are unwilling to sustain a relationship with their disruptor (see Ansari et al., 2016) but also because regulatory constraints place significant additional hurdles on the collaboration.

4.2 Regulatory-enabled orchestration *(CollaborativeHealth)*

Our second scenario is one in which the entrant attempts to disrupt the ecosystem while positioning itself in a favorable regulatory context. The startup exemplifying this scenario, *CollaborativeHealth*, intentionally shifted its positioning over time from a neutral to a

regulatory-enabling context, a strategic move that greatly facilitated its ecosystem disruption strategy. The startup was founded in 2006 to develop a digital platform where hospitals share information about patients' frequency of access to their emergency rooms (ERs). It aimed to create value for hospitals by reducing unnecessary visits to ERs and prescription misuse by flagging individuals who overused hospitals' emergency services.

The startup was potentially disruptive to hospitals' relationships with other hospitals and with their EHR vendors. Indeed, it intended to disrupt the ecosystem's relationships by becoming an orchestrator between unconnected healthcare providers and drawing together data from hospitals' standalone IT systems (see Figure 3b and Figure 4). Hospitals would be required to embrace an ecosystem model of sharing their patients' data with other hospitals on a third-party platform, which was quite disruptive to their way of operating and potentially threatening to their own power base, as *CollaborativeHealth's* CMO explained to us in 2016:

> Even more troublesome is the belief that data is power, and when you think about value-based care… then they (hospitals) do not want to share data about the patient with other hospitals for concerns that you may poach them.

Hospitals were also afraid of a potential fallout in their relationship with the EHR vendors on which they depended to provide and manage their IT infrastructures. The California Health Care Foundation explains what exactly *CollaborativeHealth's* strategy required:

> *CollaborativeHealth* addresses those challenges by mining data universally available in all EHRs and filtering those data.

Yet, EHR vendors had a reputation for being reluctant to interface with other IT providers. One EHR vendor's CEO reportedly even urged their hospital customers to oppose a government proposal making it easier to share data between hospitals (Farr, 2020). The CMO of *CollaborativeHealth* explained in a Digital Health Podcast:

> Why is the technology integration cumbersome? There are structural reasons, there are different technology vendors, EHR vendors, out there, Cerner, Epic, Meditech, …and there is a technology limitation about the standard for which they are supposed to share data.

Figure 3b shows that the startup positioned itself as an orchestrator linking up multiple previously unconnected healthcare providers and managing part of their data in a new way, through a platform that could interface with all major EHR systems.

Importantly, while starting off in 2006 through a strategy that was relatively unaffected by regulation and only very slowly gaining traction as an ecosystem disruptor, at a crucial point in its evolution *CollaborativeHealth* seized a significant regulatory opportunity (Figure 3a): a policy change in the State of Washington in 2011. Washington limited by law the State's public reimbursements to hospitals to three emergency room visits per patient per year "in an effort to reduce a US$32 million Medicaid [public healthcare] deficit" (www.vacep.org). The startup intentionally focused its efforts there to benefit from this policy opportunity. The new regulation created an incentive for hospitals to cut ER costs, and the startup responded swiftly by focusing its efforts on Washington State to fit in with all the policy rules. Thus, within this scenario, a first governance mechanism is to "fit in with the regulatory and policy context" (see Figure 4). The mechanism refers to an effort to leverage existing or new regulatory or policy rules to gain ecosystem benefits. The company's VP of Policy said:

> Policy for its own sake is not valuable. It's all about listening to the specific needs of both the private and public sector and then finding common ground to develop personalized solutions. (in Business Wire, 2019).

The fitting-in mechanism does not liberate a company from the burden of proof but it provides a clear path toward benefitting from policy or regulation. This is different from the proving mechanism in the regulatory-constrained context (e.g., *DigitalMedicine*) where companies may need to prove their innovations without gaining direct ecosystem benefits.

A second governance mechanism in this scenario is "educating ecosystem actors about the innovation". As already observed for the other case with a high degree of ecosystem disruption *(DigitalMedicine)*, the educating mechanism aims to counteract

ecosystem bottlenecks by teaching key actors about the benefits of the innovation to foster their adoption and engagement. *CollaborativeHealth* pursued a concerted educational effort to turn the perception of disruption by hospitals toward a focus on the benefits of collaborating, but as the CEO and Co-Founder told us, this proved highly laborious before the company shifted to a regulatory-enabled strategy:

> The first several years didn't go well for us. Nobody would collaborate. … The hospitals themselves do not want to because they do not want to lose members… We made progress by asking for the least amount of info possible, really innocuous data, not full clinical records.

A third related mechanism is "cooperation to overcome ecosystem bottlenecks". The startup needed to cooperate with other ecosystem actors to reduce the perception of disruption and to jointly create the value proposition. Integrating with existing EHR software by asking for a 'thin' slice of available data rather than threatening them through potential substitution was one such strategy. The startup also tried to align the incentives of health plans, payers, and physicians to induce them to share data. An analyst commented:

> The program was a collaborative effort between many sets of stakeholders, including some groups that are not often included in the conversations, like emergency physicians themselves. (in Brookings Report 2015)

Once hospitals understood the benefit of cooperating to improve their insights into ER patients and reduce their costs, they started to show willingness to collaborate – a willingness that was vastly boosted by the regulatory changes, as this ER Doctor explained:

> We had a guillotine over our head… [We said] instead of blocking access, let us coordinate the care of high utilizers. (in Forbes, 2017)

Thus, this scenario shows a higher likelihood of success for entrants attempting to orchestrate than our last scenario (of *DigitalMedicine)* because they can exploit enabling regulations (Figure 4) to solve ecosystem bottlenecks and gain ecosystem actors' cooperation. The CEO and Co-founder clarified:

> The result was that the notion of doing case management together all of a sudden did not seem outlandish anymore. We had roughly 35% of all hospitals considering us,

> now all of a sudden it went to 95%, and they all adopted us quickly. … It is harder to rely on regulation to make a business case, but it also allowed us to measure impact and outcomes. …Absent that original regulatory catalyst – I'm not sure if we had succeeded.

By positioning itself to benefit from enabling regulatory changes from 2011 onward, *CollaborativeHealth* managed to swiftly gain a foothold as an orchestrator, leveraging its first-mover position to move into additional states as these successively adopted similar regulations to the Washington one. Following the platform's widespread adoption in Washington State, 13 States had legally mandated the implementation of *CollaborativeHealth* 's platform by 2017, and the American College of Emergency Physicians had endorsed it as a best practice. Moreover, in 2018, the company was the first to be technologically integrated with a major State prescription drug database, which further enhanced their ED customers' holistic data access (www.biospace.com). While such enabling regulation could attract competitors, *CollaborativeHealth's* early positioning as an orchestrator buffered it from competition until it became the de facto ecosystem standard. By the time the company was sold for over US$650 million in 2020, at a price that yielded substantial returns for investors and founders, it had penetrated 39 states and had expanded into other facets of care collaboration, further building out its orchestrator position.

4.3 Regulatory-constrained complementation *(SmartAsthma)*

An opposite scenario to the one described above is when the entrant attempts to limit ecosystem disruption, but it enters a context that is regulatory-constrained. *SmartAsthma* was the case informing this scenario. Their innovation was a smart handheld device for children with asthma and their parents to measure breathing and detect asthma attacks early without going to hospitals for tests. The startup was regulatory constrained because it aimed to introduce a pediatric medical device, which requires additional tests, and because it wanted to make this device directly available to consumers, which adds further regulatory hurdles. A

venture capitalist explained to us that regulation becomes particularly stringent in this context:

> When you talk to physicians, when you are selling to physicians, there are certainly lots of laws involved and regulation. But they pale in comparison to the [FDA] review required to market directly to consumers.

A low level of ecosystem disruption characterized the startup's strategy. The founders' aim was to create value for patients and healthcare providers by complementing rather than disrupting providers' workflows. The CEO and Co-founder of *SmartAsthma* explained:

> We have a device that people just blow into, and our app alerts users saying whether they're fine, need to take medication, or go to the ER. What we are doing is translating something that is found in the hospital to the home setting (National Science Foundation, 2018).

None of the key ecosystem actors were significantly threatened by the innovation. Hospitals remained necessary to manage chronic pulmonary diseases, and their relationships with patients were not disrupted. Medical device manufacturers were not disrupted because spirometers would remain necessary in the hospital setting where they were used, and as the system consisted of a standalone patient-facing app and a web portal for providers, data interoperability issues with EHR vendors did not arise. Thus, *SmartAsthma* positioned itself as an ecosystem complementor, as Figure 3c shows.

In this situation, with FDA regulations representing the major hurdle, the first mechanism was to "prove to regulators and governments" through a high level of research effort, similar to *DigitalMedicine*. After finishing a validation study with children and following a grant from the National Science Foundation, in early 2016 a Co-founder commented:

> Now we have our sights set on getting to market as soon as possible and will soon be seeking FDA clearance in hopes of bringing our potentially life-saving device to homes in early 2017. (*Huffington Post*, 2016)

However, it took the company another three years after this statement to complete the regulatory approval. In this context, a second mechanism was vital to the resolution of the regulatory bottleneck, namely "cooperation to overcome regulatory bottlenecks". Strong collaborations in the ecosystem were not difficult to establish because the startup was complementing its actors with an innovative, value-creating solution. The cooperation mechanism was particularly visible in a collaboration with a Californian university to validate the asthma device. After several small-scale clinical tests, *SmartAsthma* received funding and development support from the university's medical school in 2017 to benchmark the device with hospital spirometers in a clinical trial (*New York Times*, 2017). Their chief of pediatric pulmonology explained in the university magazine: "A true spirometer that is both portable and affordable could have a huge impact in our field." With additional federal funding in 2019 and the university's continued collaboration, the startup refined and retested the device on a larger scale to support their FDA application.

A third mechanism associated with a low degree of disruption was the ease of "learning about ecosystem actors and interdependencies". With felicitous conditions in the ecosystem – actors willing to make the innovation happen rather than feeling threatened by it – *SmartAsthma* was able to focus on a learning approach rather than spending time and effort educating the ecosystem, as *CollaborativeHealth* and *DigitalMedicine* had to do. The absence of a disruptive impact on the ecosystem allowed the startup to access vital resources from ecosystem actors, as this pediatric pulmonologist admitted:

> They had identified a real problem with the availability of critical diagnostic equipment, so we decided to help them with development and testing. (University Magazine, 2016)

Compared to the "dual constraint" scenario in which *DigitalMedicine* operated, the current scenario offers greater chances of success to the entrant's innovation in virtue of the low ecosystem disruption. As shown, this creates favorable conditions for the entrant to solve

the regulatory hurdles via eased cooperation and learning. While *SmartAsthma* is still young, it has closed a US$2.3 million Series A funding round in 2020 and continues to grow.

4.4 Dual enablement *(PreventiveCare)*

This last scenario depicts the easiest strategy to enter a regulated ecosystem; it is the opposite of the "dual constraint" scenario. In the "dual enablement" scenario, the entrant avoids major disruption to the ecosystem *and* positions itself in a regulatory-enabling context, meaning that it can greatly simplify and potentially accelerate the adoption of its innovation in the ecosystem. The entrant informing this scenario was *PreventiveCare*, a startup founded in 2011 to create a digital diabetes prevention program (DPP). From its founding, the company positioned itself in a space where it would very likely be regulatory-enabled, as the CEO and Co-founder explained to us in 2016:

> We went to the CDC (Center for Disease Control) conference and heard that it is written into the Affordable Care Act (ACA) to try to make the diabetes prevention program happen, but in a brick-and-mortar fashion, like, face-to-face programs across the country. … We thought we might be able to do this digitally. …And they [the CDC] were excited by our ambitions, saying: look if you publish the data that shows that there can be equivalency, we will consider changing the standards to allow for online programs.

Three years later, the company received full CDC recognition as the first virtual DPP provider[1]. One of its investors explained to us how they carefully positioned themselves in a space where they would be enabled by governmental policies rather than constrained:

> We're not regulated by the FDA, we looked at all that, and we think there is a bigger play because we look at what CMS is doing in preventative medicine and Obamacare and the ACA and it looks like they want to spend more money on preventive medicine, which makes sense from a systems perspective, so we think there's a longer play if they decide that preventative medicine is good that we would fit right in.

The startup was also strategic about keeping ecosystem disruption low. Despite the innovation being potentially disruptive (by lowering costs and using a performance-based

[1] Different from the FDA, the CDC is not a regulatory authority in the narrow sense of the word. However, as a federal agency it has a public health mandate and significant influence on healthcare expenditure and reimbursement.

revenue model), neither hospitals nor pharmaceutical companies were significantly challenged by the innovation as it addressed a pre-disease condition rather than a diagnosed disease. The public health system even gained value through the cost savings of online prevention. Healthcare providers were still needed and their productivity could be increased through the digital offering. As illustrated in Figure 3d, the startup positioned itself as a complementor in the healthcare ecosystem by occupying a space on the prevention side of the healthcare continuum, thus supporting hospitals, governments, employers, and patients. Similar to *SmartAsthma*, *PreventiveCare*'s app-based system did not require data interoperability with EHR systems. The CEO and Co-Founder confirmed that this low level of disruption was a strategic choice:

> Healthcare is one of those spaces where it is not helpful to try to reinvent the wheel. We could have taken a different approach: this has not been done before, this is a new way, but this approach can slow you down as healthcare can be risk-averse, there are a lot of legacies (interviewed by Rock Health, 2015)

PreventiveCare's CMO expressed even more clearly the low disruption intent:

> One of the first things we did was to have a sense of humility, it is very tempting in Silicon Valley to say we are disrupting, we are ignoring the old rules, circumventing them. But that is not always the right thing to do. (in High Resolution, 2017)

Similar to *CollaborativeHealth's* strategy, a first mechanism to operate in a regulatory-enabled ecosystem was to "fit in with the regulatory and policy context"; in *PreventiveCare*'s case to take advantage of government bodies' new interest in disease prevention triggered by the 2010 introduction of the Affordable Care Act. Unlike other digital health firms such as *DigitalMedicine* or *SmartAsthma*, *PreventiveCare*'s strategy of fitting into existing policy was evident in the way the startup spent time and effort to carefully fit in with opportunities created by government interventions. The CEO and Co-Founder explained at the Digital Health Summit 2016:

> There are now clinical entities like the U.S. Preventive Services Task Force that looked at the entire landscape of literature and said yes, "lifestyle" should come

> first… We map under this clinical landscape to make PreventiveCare a program standard of care.

As with *CollaborativeHealth,* fitting in required showing evidence of tight alignment with government or policy criteria:

> In order to achieve full CDC recognition, DPP providers must meet rigorous standards. These include… a minimum percentage of participants entering the program with a qualifying blood test, a minimum level of participant engagement, and the achievement of average participant weight loss in accordance with CDC standards (Press Release, 2018)

A second mechanism for the scenario was "learning about ecosystem actors and interdependencies". The CEO and Co-founder told us how understanding joint value creation is essential for an entrant seeking adoption by an existing ecosystem:

> I don't think there is a shortcut for selling in healthcare without considering the mindset of all the stakeholders. What is the value to the employer, what is the value for the clinician? What is the value for the patient? We are constantly learning.

As in *SmartAsthma's* case, a learning strategy was consistent with and facilitated by the intent to keep ecosystem disruption low. The CMO described the process that they followed to learn from the ecosystem's key actors:

> So as a founding team, one of the initial things we did was to know what we are talking about, know what we are disrupting, know why it was that way. Get to talk to people in leading health plans, lead benefits at employers, and chief medical officers. (in High Resolution, 2017)

As a third mechanism for this scenario, the company sought out a strategy of "cooperation to realize the value proposition". By playing within the ecosystem's rules, collaborations were forged with various actors of the ecosystem. The CEO and Co-Founder explained:

> The CDC is right by this, you can't embrace a digital offering until there is clinical data to support it. …We were like friends from afar in the earlier days and then, once this effort started to materialize more properly, we became like proper colleagues. Not just with the CDC but with the American Medical Association, the American Diabetes Association, the Diabetes Advocacy Alliance, you know, all the stakeholders that help influence diabetes policy. They have been super supportive of what we are doing!

According to funding databases and media reports, the company continues to build on its impressive early successes: in 2022 it closed a large Series E funding round, is now considered a 'Unicorn' with a valuation of over US$1bn, and it has successfully branched out into other pre-disease categories. While the regulatory enabling condition in which *PreventiveCare* operated attracted a number of competitors, the startup was the first to prompt the CDC to support a broad rollout of its digital preventive program, thus gaining significant network effects.

4.5 Control scenarios (*HealthMarketplace* and *CleverHeart)*

Our last two cases worked as a sort of control group. While the prior four entrants were positively or negatively impacted by regulation and policy, the last two entrants were not significantly affected. They only varied in their level of disruption for the ecosystem, thus providing additional corroboration of our findings regarding ecosystem disruption and its related mechanisms and likely outcomes. We discuss these two startups briefly as a means to corroborate our findings.

HealthMarketplace was a startup that was potentially highly disruptive to the ecosystem but without being significantly affected by regulation. The startup was founded in 2011 to create value for patients by building a platform for patients to compare treatment costs and schedule appointments for multiple healthcare providers. By enabling price comparisons across multiple hospitals and thus potentially encouraging patients to switch providers, *HealthMarketplace* threatened to disrupt hospitals' business models and their relationship with patients. Consistently, the startup tried to become an orchestrator connecting patients to multiple healthcare providers, thus replacing their existing interdependencies. Figure 3e shows the high level of ecosystem disruption and the structural positioning of *HealthMarketplace*. The startup's orchestration attempt was similar to what we had seen in the other two startups that were highly disruptive to the ecosystem

(*DigitalMedicine* and *CollaborativeHealth*), thus further corroborating the evidence that planning a high degree of ecosystem disruption likely implies pursuing an orchestrator role. This orchestrator intent was further underlined when the startup pivoted into providing a blockchain-based platform for pulling payer data together, which was seen as a direct threat to existing EHR vendors. The Chief Technical Officer of *HealthMarketplace* equated the startup's model to that of leading digital orchestrators such as Amazon:

> *HealthMarketplace* is an expansive healthcare marketplace for the consumer …We're changing the complete paradigm of how healthcare and health services and health enterprises deliver. So we want to deliver in the same fashion as Amazon or eBay or Priceline deliver, straight to the consumer (Company video).

This comparison is of course an inexact one, as healthcare services have unknown service quality and relatively high switching costs even if prices are transparent. However, it expresses the firm's orchestrator ambition.

While *HealthMarketplace* announced the successful construction of a consortium of 40 collaborating companies at the TechCrunch Conference in 2017, it was not effective at implementing this orchestration strategy. The specific bottlenecks that the startup faced were the hospitals, and inability to remove this bottleneck translated into a failure to obtain adoption. We could not find evidence of the use of the governance mechanisms necessary to implement an ecosystem disruption strategy, and this further contributed to the failure. Crucially, unlike in the case of *CollaborativeHealth,* the absence of regulatory enabling support in this case helps to explain the failure to gain traction. In 2018 the company was acquired at far less than total investment value and dissolved into its acquirer's platform. The case shows how difficult it is for an entrant to effect a strategy of high ecosystem disruption and to become a successful orchestrator, and it underlines the importance of effectively implementing appropriate governance mechanisms, whose absence can undermine success.

CleverHeart, the second control case, was a startup that avoided to significantly disrupt the ecosystem and strategically eschewed overly-stringent regulation. Founded in

2013, the startup helped people trace their blood pressure and heart rate through a digital reader. While the innovation per se had some disruptive features (low cost and ease of access to personal health data), the disruption of the ecosystem was low. Hospitals, healthcare professionals, and EHR vendors were not disrupted because the app was positioned mainly to self-insured employers as an offering that would not interfere with hospital-owned data. Employers and employees gained value by reducing the chances of employees' heart attacks, reportedly saving employers an average of just under US$2,000 per affected employee (MedCityNews 2022).

The entrant positioned itself as a complementor of ecosystem actors including Apple. As it seamlessly integrated with the Apple technological ecosystem, Apple soon used the startup as a demonstration project for its own orchestration ambitions in healthcare. In general, the startup operated by complementing the value creation of several ecosystem actors. Finally, by carefully avoiding falling under the medical device category, this entrant escaped heavy regulatory constraints. Figure 3f shows the startup's positioning in the ecosystem.

We found that learning and cooperation to realize the value proposition were two of the most important mechanisms used by *CleverHeart* to push its innovation. This is a further validation of the mechanisms for low ecosystem disruption similar to what we observed at *PreventiveCare*. For instance, the executives at *CleverHeart* learned rapidly from their customers, as the CMO told us:

> What are the most pressing employers' needs or problems in relation to healthcare at the moment? Decrease costs! They're very open at the moment to seeing solutions that can help them contain or lower the costs of their health plans. … [A Fortune 500 company] explained to us what they wanted from us. We then started to co-develop side by side with them the presentations that would allow them to sell the app internally! (in 2017)

Like our other two low-disruption cases (*PreventiveCare* and *SmartAsthma*), the learning mechanism allowed the startup to develop clinically validated data, which in turn earned them the collaboration with Apple to complement its Healthcare Suite:

> *CleverHeart* is the first and currently only smartphone solution that has a peer-reviewed study for hypertension and heart health management. … A lot of wellness solutions are trying to get patients to improve their [health], but there's a very big gap between intention … and actual clinical outcomes that are proven and validated. (MobiHealthNews, 2018)

The result of this strategy and governance mechanisms was a relatively smooth adoption by employers and other ecosystem actors including a leading U.S. pharmacy chain, which further established the company as a valuable complementor in the healthcare ecosystem. As of the time of writing, the startup had continued to attract multi-million dollar funding in a Series C round and gained multiple prizes for best digital health startup / best employer health solution.

4.6 Explaining the mechanisms behind ecosystem disruption and regulatory positioning

Our findings allow to draw up a framework of four main scenarios characterized by different ecosystem and regulatory strategies, specific governance mechanisms, and different likelihoods of success, illustrated in Figure 4 (with further empirical evidence in Table 4). Here, we briefly recall the governance mechanisms impacting an entrant's likelihood of success in different scenarios. We found that "educating the ecosystem actors about the innovation" is particularly useful in the high ecosystem disruption scenarios (QI and QII) to limit negative perceptions by potentially disrupted actors and thus solve ecosystem bottlenecks. In ecosystems with important digital components, this may include convincing ecosystem actors of the value of new technological or data platforms. "Learning about the ecosystem actors and interdependencies" is particularly suitable for scenarios when ecosystem disruption is comparatively low (QIII and QIV). Here, entrants act as complementors and learn from ecosystem actors willing to share their knowledge with them;

this includes learning how to best interface with existing actors technologically, in our case for instance through making their systems interoperable with major ecosystem players or avoiding any threat to those players' systems.

The cooperation mechanism was common among the four scenarios but its scope varied. "Cooperation to overcome ecosystem bottlenecks" was used to manage disrupted ecosystem actors in the high ecosystem disruption scenarios (QI and QII), while "Cooperation to overcome regulatory hurdles" was used in the regulatory-constrained scenarios (QI and QIII). In the scenario where there were no particular ecosystem bottlenecks and regulatory hurdles (QIV), "Cooperation to realize the value proposition" allowed our case firm to quickly seize on network effects and solidify its ecosystem position. Finally, the mechanism of "fitting in with regulatory and policy contexts" was used to govern the regulatory-enabled scenarios (QII and QIV), while the mechanism of "proving to regulators and government" needed to be deployed in the regulatory-constrained scenarios (QI and QIII). Importantly, we do not claim that these mechanisms are exclusive to each scenario. For instance, the mechanisms "learning about ecosystem actors and interdependences" and "educating the ecosystem actors about the innovation" may be applicable to all scenarios but their relevance varies significantly depending on each scenario.

INSERT FIGURE 4 and TABLE 4 ABOUT HERE

5. DISCUSSION

Our inductive study of six digital startups innovating in the healthcare ecosystem offers several contributions to the ecosystem disruption literature and to ecosystem literature more generally. First, we clarify the definition of ecosystem disruption around value-creation interdependencies. Second, we highlight that startups can become successful ecosystem orchestrators by relating two relevant dimensions of entrants' strategies that were previously

unconnected: the level of ecosystem disruption and regulatory/policy effects. Third, we suggest an emerging framework of four entry scenarios characterizing strategies, governance mechanisms, and likelihoods of success for disruptive entrants in regulated ecosystems (Figure 4). Fourth, we refine the relationship between ecosystem disruption and the structural roles as orchestrator or complementor. Fifth, we forefront the consideration of regulatory effects in the study of ecosystem disruption, and we contribute novel insights into the dynamics of strategic changes between scenarios. Beyond ecosystem disruption insights, our findings contain several important contributions to ecosystem researchers more generally, including reflections on when ecosystem orchestration is possible for startups and how value creation varies in the ecosystem.

5.1 Contributions to ecosystem disruption

Our first contribution to ecosystem disruption studies is a definition that adds conceptual clarity to this literature, which will help to gain cumulative research advancement. Building on the few ecosystem disruption studies to date (e.g., Adner and Lieberman, 2022; Ansari et al., 2016; Öberg, 2023; Ozalp et al., 2018; Snihur et al., 2018) and on our empirical evidence, we posit that ecosystem disruption refers not only to focal incumbents (Christensen, 1997) but to any organization that creates value within the ecosystem, including complementors and suppliers, and moreover it includes disruption not only of ecosystem actors but also of their value-creation relationships.

Our definition of ecosystem disruption — as an innovation challenging value-creation interdependencies in an ecosystem to the extent that the competitive advantage of one or more actors is potentially threatened — centrally incorporates a relational focus (Kumaraswamy et al., 2018). It also highlights value creation in ecosystems (Adner, 2017; Adner and Kapoor, 2010) as a vital element of succeeding in ecosystem disruption. We

encourage future research on ecosystems and disruptions to build on this definition and test its applicability to a variety of ecosystems.

Our second contribution lies in illustrating two central dimensions of entrants' strategy in an ecosystem and examining their interplay: the first dimension, which directly follows from our definition of ecosystem disruption, pertains to the degree of ecosystem disruption (from high to low) that the entrant intends to generate. The second dimension relates to the entrant's strategic positioning vis-à-vis enabling/constraining regulations or policies. Prior studies have examined these dimensions separately, focusing either on disruption strategies (Ozalp et al., 2018; Cozzolino et al., 2018; Snihur et al., 2018) or on the regulatory dimension (Aversa et al., 2021; Gurses and Ozcan, 2015). We observe that the interplay of these dimensions offers new insights into entrants' ecosystem strategies.

The resulting framework of ecosystem disruption and regulatory positioning is our third and main contribution (see Figure 4). The framework reveals four distinct scenarios: *dual constraint* (Quadrant I - QI), *regulatory-enabled orchestration* (QII), *regulatory-constrained complementation* (QIII), *and dual enablement* (QIV). In each scenario we detail an entrant's strategy, specific governance mechanisms, and its likelihood of success. The framework contributes a fine-grained understanding of the strategies to enter an ecosystem (Adner and Kapoor, 2010, 2016; Dattée and Barlow, 2017). It also contributes a contingent perspective of some of the governance mechanisms identified by the ecosystem literature (Adner, 2017; Kapoor and Lee, 2013; O'Mahony and Karp, 2022). Finally, the framework offers suggestions on how to overcome some of the barriers identified by the innovation adoption literature (Edmondson et al., 2003; Ferlie et al., 2005) as it shows strategies and scenario-specific mechanisms to favor adoption (likelihood of success in our study).

The generalizability of the framework to other contexts seems broad. The *dual constraint* (QI) scenario for instance explains how Thomas Edison entered and governed

bottlenecks and regulatory hurdles in the energy ecosystem. As Hargadon and Douglas (2001) showed, Edison "educated ecosystem actors" through a specific framing of electric lightning, "cooperated with ecosystem actors", and "proved to governments" that electric lightning was more secure and efficient than gas lightening. The *regulatory-enabled orchestration* (QII) scenario helps to explain for instance how Tesla disrupted many components and interdependencies in the automotive ecosystem (Kapoor, 2018; MacDuffy, 2018). Similarly to Edison, Tesla also positioned itself as an orchestrator and used the mechanisms of its scenario: "cooperation" with car manufacturers, "education of the ecosystem about the innovation" of sustainable energy, and "fitting in" with regulations and policies favoring electric vehicles. The *regulatory-constrained complementation* (QIII) scenario captures how Waymo is acting as a complementor of car manufacturers "collaborating" with them and "proving to government" the safety of its autonomous vehicle innovation (Reuters, 2020). The *dual enablement* scenario may describe the entry of solar panel companies in the energy ecosystem (Furr and Kapoor, 2018) often as complementors of energy public utilities, positioned in regulatory-enabling environments and using "cooperation with ecosystem actors to realize the value proposition", "learning" from existing institutions, and "fitting in" with enabling policies.

Our fourth contribution is to clarify the relationship and dynamics between ecosystem disruption and orchestration/complementation (Adner and Kapoor, 2016; Baldwin, 2012; Dattée et al., 2018; West and Wood, 2014). Based on our findings, higher degrees of ecosystem disruption are more likely to involve a subsequent orchestrator positioning, whereas lower levels of ecosystem disruption likely imply a complementor positioning. Prior literature tends to imply a similar sequencing between high disruption and orchestration, although not explicitly referring to the two concepts. Snihur et al. (2018) for instance showed that the disruptor Salesforce first used a distinctiveness frame to signal visibility and then a

leadership frame to legitimize its position and achievements as a new central ecosystem architect.

Our study allows us to specify this dynamic relationship by suggesting that a low ecosystem disruption strategy almost necessarily entails a complementor positioning as challenges to actors and relationships are minimized and value creation remains unthreatened. Vice versa, pursuing a high level of ecosystem disruption will almost by necessity require a certain degree of orchestration as ecosystem actors and relationships are challenged. On this basis, we suggest that the intent to disrupt (or not) an ecosystem likely precedes an entrant's positioning as orchestrator/complementor. The structural positioning takes time to roll out as it requires "learning about the interdependences", "cooperation to overcome ecosystem bottlenecks and regulatory hurdles" or "fitting in" and "proving" efforts to receive support or satisfy constraints from regulators and governments. We also note that the sequencing may be co-evolutionary. For instance, if an entrant has been successful with a high level of ecosystem disruption and positioning as orchestrator, this positioning will likely reinforce the original intent of high ecosystem disruption. We encourage future research to investigate these important feedback dynamics.

As a fifth contribution, we bring focal attention to the regulatory/policy dimension in the study of ecosystem disruption, which also involves the use of non-market strategies as part of an ecosystem strategy. Studies on ecosystem disruption (e.g., Ansari et al., 2016; Ozalp et al., 2018; Cozzolino and Verona, 2022; Snihur et al., 2018) have not yet considered regulatory effects on disruption, while studies that focused on the effect regulation on innovation and industry performance have not considered ecosystem disruption (Finch et al., 2017; Gurses and Ozcan, 2015; McDuffie, 2018; Rugman and Verbeke, 1998).

Other scholars explicitly referred to regulation and policies as non-market forces affecting performance and called for deeper understanding of non-market strategies (Baron,

1995; Dorobantu, Kaul, Zelner, 2017; Uzunka, Rigtering, and Ozcan, 2018). We add to this literature by showing how an intentional regulatory positioning can be an effective strategy to become an orchestrator or complementor in an ecosystem. We also show how an innovation can receive legitimacy in an institutional context (Dorobantu et al., 2017) by using mechanisms of "fitting in" and "proving" to obtain support and approval from key non-market actors of an ecosystem. We encourage researchers to further probe into potential interaction effects, where firms may actively influence regulatory or policy decisions to subsequently benefit from regulatory enablement – though our case of *DigitalMedicine* also points to the difficulties in gaining such influence, at least in healthcare ecosystems.

Our final insight into ecosystem disruption concerns the importance of an adaptive strategy across the two dimensions of disruption and regulation. *CollaborativeHealth* is a startup illustrating this strategy of dynamically balancing challenges and opportunities. The company started by focusing on the high ecosystem disruption element of its strategy without giving greater attention to regulation/policy effects and struggled with adoption. Importantly, it later made a strategic shift when it moved to exploit a significant policy opportunity, which enabled the startup to overcome the ecosystem bottlenecks of its high-disruption strategy. Future research should investigate other cases of adaptive strategies in the balancing of regulation and ecosystem disruption.

5.2 Other contributions to ecosystem theory

As a first contribution to general ecosystem theory, we provide evidence that even a startup can succeed as an orchestrator when enabled by regulation. Common perceptions would suggest that orchestrators are typically large and powerful companies (Iansiti and Levien, 2004; Jacobides et al., 2018). Based on our data, we propose that entrants can succeed in an orchestrator role if they position themselves in a regulatory/policy-enabled environment and

implement the governance mechanisms suitable for these environments. Therefore, we add contingencies to the study of the conditions under which entrants can become orchestrators (Lingens, Miehé, and Gassmann, 2021b). Our evidence also extends Lingens et al.'s (2021a) conception of startups as orchestrators. We show how startups can utilize disruption to orchestrate an ecosystem and predict startups' likelihood of success. This importance reflects Gans' (2020) prediction that disruptive startups often turn toward a "Plan B" when facing powerful incumbents, though we observe that powerful incumbents can accept startups' disruptions as orchestration when policy interventions propel them to do so.

We recognize that enabling regulation can attract potential competitors but our evidence suggests that early engagement with the regulator may provide first-mover advantages based on network effects and the satisfaction of regulatory thresholds – in some cases, startups may even be involved in setting these thresholds (Geiger and Stendahl, 2023). We also note that leveraging a regulatory-enabled context is not sufficient in itself to be a successful orchestrator: a well-developed product and the use of appropriate governance mechanisms are necessary. Our insights into the benefits of enabling regulations for startup orchestration can generalize to other ecosystems but especially to those where regulation and policy are important.

A second general insight from our data is that orchestrating versus complementing is a strategic choice. Ecosystem research seems to assume that orchestration is the goal of every firm – perhaps oversampling on this strategy (as is the case of Lingens et al., 2021a). Our data suggest that orchestration is only one option and not always the most attractive in terms of likelihood of success. Instead, a complementor positioning is less challenging even when the regulatory environment is unfavorable (e.g., *SmarthAsthma* in QIII), and it is likely to be successful when combined with regulatory enabling conditions (e.g., *PreventiveCare* in QIV).

A third observation adding to ecosystem theory is that while research often treats value creation as an ecosystem property shared by all the actors (e.g., Borges et al., 2019), we found different value creation perspectives for complementors and orchestrators. Our data suggest a "joint value creation" view for startups attempting complementation, as revealed by their mechanisms of "cooperation to realize the value proposition" (see *PreventiveCare* in QIV) and "learning about ecosystem actors and interdependences" (see *SmarthAsthma* in QIII). Vice versa, we found a "firm-driven/distinctive value creation" view for startups attempting orchestration, as revealed by their mechanisms of "educate the ecosystem actors about the innovation" (see *DigitalMedicine* in QI) and "cooperate to overcome ecosystem bottlenecks" (see both *DigitalMedicine* and *CollaborativeHealth* in QI and QII). This suggests that the study of ecosystem value creation may be contingent on the structural positioning of actors.

A fourth related contribution is to the ecosystem-as-structure perspective (Adner, 2017; Adner and Kapoor, 2010; Ganco et al., 2020; Jacobides et al., 2018; Shipilov and Gawer, 2020). According to Ganco et al. (2020, p. 646), empirical studies have not sufficiently explored ecosystem-level structures; consequently, "how ecosystem-level structure impacts the innovative processes …remains unclear" (though see Adner and Kapoor, 2010, 2016). Our relational view of ecosystem disruption and our graphical representation of entrants' value networks may provide a template for future research to capture changes in the structure of ecosystem interdependencies (Figure 3). In particular, by leveraging the "input-output flow of interdependencies" described by Ganco et al. (2020), we depicted the relevant structures in which the six startups were operating and identified their strategic positioning. Shipilov and Gawer (2020) and Ganco et al. (2020) suggest the use of interdependency or complementarity matrices to assess the multilateral relationships in ecosystems. We approximated the matrices with simpler graphs in Figure 3, depicting only

the most relevant interdependencies and their dynamics, given the complexity of the examined ecosystem and the difficulty of a multiple-case design.

Finally, our research adds actionable insights for studies at the intersection between healthcare and management (e.g., Dattée and Barlow, 2017; Geiger and Stendahl, 2023; Edmondson et al., 2001; Reay, Goodrick, and D'Aunno, 2021; Sanders et al., 2012; Sounderajah et al., 2021). This tradition has examined the significant barriers to innovation in healthcare (Ferlie et al., 2005; Geiger and Stendahl, 2023; Sanders et al., 2012) and recently has started to examine disruptive innovation (Sounderajah et al., 2021). Our detailed assessment of digital startups in the healthcare ecosystem shows when and how innovation is possible in healthcare, and it adds an ecosystem disruption perspective to this conversation.

5.3 Limitations

We acknowledge several limitations to our study. Due to our qualitative approach and the small sample of startups examined, our study cannot establish causality, although we sought to mitigate this limitation by adding control cases in addition to conducting cross-case comparisons. Hence, we do not exclude additional or rival explanations, such as the role of external events or entrepreneurs' prior experience and linkages with the ecosystem.

While we distinguish between regulatory enabling and constraining conditions, we do not consider the strengths of these forces within each condition. Of the two regulatory-enabled cases, *CollaborativeHealth* (Figure 3b) faced a much stronger policy-enabling effect than *PreventiveCare* (Figure 3d). Of the regulatory-constrained cases, *DigitalMedicine* (Figure 3a) faced a stronger effect than *SmarthAsthma* (Figure 3c). Further, as noted, while the governance mechanisms we identified are particularly useful in specific scenarios, they are not limited to one scenario and can overlap; based on our limited sample it is also likely that other mechanisms exist that we did not detect. Another limitation is our time window,

with five of the cases still too young to judge success in definitive terms. Also, we found only one example of an adaptive strategy among our sample (*CollaborativeHealth)*, and we did not explicitly sample cases on the basis of documented changes in regulatory positioning. We finally acknowledge that a given positioning can sometimes be the result of external circumstances beyond company control or intent. All these limitations represent fruitful opportunities for future research.

REFERENCES

Acs, G., Long, S. H., Marquis, M. S., & Short, P. F. (1996). Self-insured employer health plans: Prevalence, profile, provisions, and premiums. *Health Affairs*, *15*(2), 266-278.

Adner, R. (2006). Match your innovation strategy to your innovation ecosystem. *Harvard Business Review*, 84 (4), 98-107.

Adner, R. (2017). Ecosystem as structure: An actionable construct for strategy. *Journal of Management*, 43(1), 39-58.

Adner, R., & Kapoor, R. (2010). Value creation in innovation ecosystems: How the structure of technological interdependence affects firm performance in new technology generations. *Strategic Management Journal*, *31*(3), 306-333.

Adner, R., & Kapoor, R. (2016). Innovation ecosystems and the pace of substitution: Re-examining technology S-curves. *Strategic Management Journal*, *37*(4), 625-648.

Adner, R., & Zemsky, P. (2006). A demand-based perspective on sustainable competitive advantage. *Strategic Management Journal*, *27*(3), 215-239.

Ansari, S., Garud, R., & Kumaraswamy, A. (2016). The disruptor's dilemma: TiVo and the US television ecosystem. *Strategic Management Journal*, *37*(9), 1829-1853.

Autio, E., & Thomas, L. (2014). *Innovation ecosystems* (pp. 204-288). The Oxford handbook of innovation management.

Aversa, P., & Guillotin, O. (2018). Firm technological responses to regulatory changes: A longitudinal study in the Le Mans Prototype racing. *Research Policy*, *47*(9), 1655-1673.

Aversa, P., Huyghe, A., & Bonadio, G. (2021). First impressions stick: Market entry strategies and category priming in the digital domain. *Journal of Management Studies*.

Baldwin, C. Y. (2012). Organization design for business ecosystems. *Journal of Organization Design*, 1(1), 20-23.

Baldwin, C. Y. (2018). Design Rules, Volume 2: How Technology Shapes Organizations: Chapter 14 Introducing Open Platforms and Business Ecosystems. Harvard Business School Research Paper Series, 19-035.

Barlow, J. (2016). *Managing innovation in healthcare*. World scientific publishing company.

Baron, D. P. (1995). Integrated strategy: Market and nonmarket components. *California Management Review*, 37(2), 47-65.

Bogers, M., Sims, J. & West. J. (2019). What *is* an ecosystem? Incorporating 25 years of ecosystem research. Working Paper, Paper presented at the 2019 Meeting of the Academy of Management.

Christensen, C. M. (1997). *The Innovator's Dilemma,* Harvard Business School Press

Christensen, C. M., McDonald, R., Altman, E. J., & Palmer, J. E. (2018). Disruptive innovation: An intellectual history and directions for future research. *Journal of Management Studies*, 55(7), 1043-1078.

Cozzolino, A., Verona, G., & Rothaermel, F. T. (2018). Unpacking the disruption process: New technology, business models, and incumbent adaptation. *Journal of Management Studies*, 55(7), 1166-1202.

Cozzolino, A., Verona, G. (2022). Responding to Complementary-Asset Discontinuities: A Multilevel Adaptation Framework of Resources, Demand, and Ecosystems. *Organization Science*, 33(5), 1990-2017.

Dalton, C. M., & Holland, S. B. (2019). Why do firms use insurance to fund worker health benefits? The role of corporate finance. *Journal of Risk and Insurance*, *86*(1), 183-212.

Dattée, B., & Barlow, J. (2017). Multilevel organizational adaptation: Scale invariance in the Scottish healthcare system. *Organization Science*, *28*(2), 301-319.

Dattée, B., Alexy, O., & Autio, E. (2018). Maneuvering in poor visibility: How firms play the ecosystem game when uncertainty is high. *Academy of Management Journal*, *61*(2), 466-498.
Dorobantu, S., Kaul, A., & Zelner, B. (2017). Nonmarket strategy research through the lens of new institutional economics: An integrative review and future directions. *Strategic Management Journal*, 38(1), 114-140.
Duggal, R., Brindle, I., & Bagenal, J. (2018). Digital healthcare: regulating the revolution. BMJ, 360, k6.
Edmondson, A. C., Bohmer, R. M., & Pisano, G. P. (2001). Disrupted routines: Team learning and new technology implementation in hospitals. *Administrative Science Quarterly*, *46*(4), 685-716.
Eisenhardt, K. M. (1989). Building theories from case study research. *Academy of Management Review*, *14*(4), 532-550.
Eisenhardt, K. M. (2021). What is the Eisenhardt Method, really?. *Strategic Organization*, *19*(1), 147-160.
Eisenhardt, K. M., & Graebner, M. E. (2007). Theory building from cases: Opportunities and challenges. *Academy of Management Journal*, *50*(1), 25-32.
Finch, J., Geiger, S., & Reid, E. (2017). Captured by technology? How material agency sustains interaction between regulators and industry actors. *Research Policy*, *46*(1), 160-170.
Ferlie, E., Fitzgerald, L., Wood, M., & Hawkins, C. (2005). The nonspread of innovations: the mediating role of professionals. *Academy of Management Journal*, *48*(1), 117-134.
Farr, C. (2020). EPIC's CEO is urging hospital customers to oppose rules that would make it easier to share medical info. CNN, Jan 22.
Furr, N., & Kapoor, R. (2018). Capabilities, technologies, and firm exit during industry shakeout: Evidence from the global solar photovoltaic industry. *Strategic Management Journal*, *39*(1), 33-61.
Ganco, M., Kapoor, R., & Lee, G. K. (2020). From rugged landscapes to rugged ecosystems: Structure of interdependencies and firms' innovative search. *Academy of Management Review*, *45*(3), 646-674.
Gans, J. S., & Stern, S. (2003). The product market and the market for "ideas": commercialization strategies for technology entrepreneurs. *Research Policy*, *32*(2), 333-350.
Gawer, A. (2014). Bridging differing perspectives on technological platforms: Toward an integrative framework. *Research Policy*, *43*(7), 1239-1249.
Geiger, S., & Kjellberg, H. (2021). Market mash ups: The process of combinatorial market innovation. *Journal of Business Research*, *124*, 445-457.
Geiger, S. and Stendahl, E. (2023). Breaching, Bridging and Bonding: Interweaving Pathways of Social-symbolic work in a flanked healthcare movement. *Journal of Management Studies* (online first).
Graebner, M. E. (2004). Momentum and serendipity: How acquired leaders create value in the integration of technology firms. *Strategic Management Journal*, 25(8-9), 751-777.
Gurses, K., & Ozcan, P. (2015). Entrepreneurship in regulated markets: Framing contests and collective action to introduce pay TV in the US. *Academy of Management Journal*, *58*(6), 1709-1739.
Hannah, D. P., & Eisenhardt, K. M. (2018). How firms navigate cooperation and competition in nascent ecosystems. *Strategic Management Journal*, *39*(12), 3163-3192.
Hargadon, A. B., & Douglas, Y. (2001). When innovations meet institutions: Edison and the design of the electric light. *Administrative Science Quarterly*, *46*(3), 476-501.Healthcare Innovation, 2018

Iansiti, M., & Levien, R. (2004). Strategy as ecology. *Harvard Business Review*, 82(3), 68-78.
Jacobides, M. G., Cennamo, C., & Gawer, A. (2018). Towards a theory of ecosystems. *Strategic Management Journal*, 39(8), 2255-2276.
Kapoor, R. (2018). Ecosystems: broadening the locus of value creation. *Journal of Organization Design*, 7(1), 1-16.
Kapoor, R., & Furr, N. R. (2015). Complementarities and competition: Unpacking the drivers of entrants' technology choices in the solar photovoltaic industry. *Strategic Management Journal*, *36*(3), 416-436.
Kapoor, R., & Lee, J. M. (2013). Coordinating and competing in ecosystems: How organizational forms shape new technology investments. *Strategic Management Journal*, *34*(3), 274-296.
Kumaraswamy, A., Garud, R., & Ansari, S. (2018). Perspectives on disruptive innovations. *Journal of Management Studies*, *55*(7), 1025-1042.
Lingens, B., Böger, M., & Gassmann, O. (2021a). Even a Small Conductor Can Lead a Large Orchestra: How Startups Orchestrate Ecosystems. *California Management Review*, *63*(3), 118-143.
Lingens, B., Miehé, L., & Gassmann, O. (2021b). The ecosystem blueprint: How firms shape the design of an ecosystem according to the surrounding conditions. *Long Range Planning*, 54(2), 102043.
MacDuffie, J. P. (2018). Response to Perkins and Murmann: Pay attention to what is and isn't unique about Tesla. *Management and Organization Review*, 14(3), 481-489.
Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook*. Sage.
Mesko, B. (2015). *My health: upgraded: revolutionary technologies to bring a healthier future.* Webicina.
O'Mahony, S., & Karp, R. (2022). From proprietary to collective governance: How do platform participation strategies evolve?. *Strategic Management Journal*, *43(3)*, 530-562.
Öberg, C. (2023). Disruption and the ecosystem: The changing roles of ecosystem stakeholders in the course of disruption. *Technological Forecasting and Social Change*, 194, 122679.
Ozcan, P., & Gurses, K. (2018). Playing cat and mouse: Contests over regulatory categorization of dietary supplements in the United States. *Academy of Management Journal*, *61*(5), 1789-1820.
Reuters (2020). U.S. regulators open process to ensure self-driving car safety. Nov. 19 2020.
Reay, T., Goodrick, E., & D'Aunno, T. (2021). *Health care research and organization theory*. Cambridge University Press.
Rugman, A. M., & Verbeke, A. (1998). Corporate strategies and environmental regulations: An organizing framework. *Strategic Management Journal*, 19(4), 363-375.
Sanders, C., et al., (2012). Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. *BMC Health Services Research*, 12(1), 1-12.
Shipilov, A., & Gawer, A. (2020). Integrating research on interorganizational networks and ecosystems. *Academy of Management Annals*, *14*(1), 92-121.
Sounderajah, V., Patel, V., Varatharajan, L., Harling, L., Normahani, P., Symons, J., Barlow, J., Darzi, A. & Ashrafian, H. (2021). Are disruptive innovations recognized in the healthcare literature? A systematic review. *BMJ innovations*, *7*(1), 208–216.

Teece, D. J. (2018). Profiting from innovation in the digital economy: Enabling technologies, standards, and licensing models in the wireless world. *Research Policy*, *47*(8), 1367-1387.

Uzunca, B., Rigtering, J. C., & Ozcan, P. (2018). Sharing and shaping: A cross-country comparison of how sharing economy firms shape their institutional environment to gain legitimacy. *Academy of Management Discoveries*, 4(3), 248-272.

West, J. & Wood, D. (2014). Evolving an Open Ecosystem: The Rise and Fall of the Symbian Platform, *Collaboration and Competition in Business Ecosystems* (*Advances in Strategic Management, Vol. 30*), Emerald Group, Bingley, pp. 27-67.

Yin, R. K. (1994). *Case study research: design and method*. Sage. London.

Table 1: Ecosystem interviews (all conducted in 2015)

Sector	# interviews	Interviewees roles
Academia	1	Professor of Health Management
Industry analyst	1	Partner
Conference organizer	2	CEO, Conference Organizer
Consultants	3	Independent Consultant (1x); Partners (2x)
Government/Policy	2	Government Chief Technology Officer; FDA (retired)
Healthcare provider	4	MD; CTO; CIO; CEO (retired) – four different healthcare systems
Incubator	4	Project Manager, Data Scientist, Design Lead, CEO
Insurance	2	Global Strategy Office; Strategy Group
Medical Device Multinationals	2	Managers
Pharma Multinationals	2	Innovation Lead (x2)
Tech Multinationals	4	Vice-President Global Digital; Digital innovation manager; Direct of Civic Engagement; Director of Digital Integration
Patient Organization	1	Digital Liaison Manager
Think Tank	1	Advisor
Venture Capitalists	2	Partners

Table 2: Case data

Company	Founding	Innovation produced	Funding to 2022	Employees	News and reports	Web articles and blogs	Secondary interviews	Primary interviews	Informal interviews at events and observations
Digital Medicine	2001	Ingestible sensor and analytics	$500m (11 rounds) $15m exit	400 before acquisition	129	71	13	2 (CTO, VC, in 2016)	7
Collaborative Health	2006	Hospital platform for emergency rooms	$47.5m (1 round) $650m exit	130 before acquisition	41	25	8	2 (CEO, advisor, 2015- 16)	4
SmartAsthma	2013	Asthma sensor, app and device	$2.3m (1 round)	8	12	14	5	4 (3 CEO*, 1 investor, in 2015-17)	2
Preventive Care	2011	Digital therapeutics	$450m (9 rounds)	600	140	62	8	3 (CEO, VC, Advisor, in 2015- 16)	12
HealthMarket-place	2011	Platform for price comparison and scheduling	$55m (6 rounds)	80 before acquisition	78	12	11	2 (CEO, CTO, in 2016)	5
CleverHeart	2013	Smartphone app (clinical-grade)	$68m (6 rounds)	8	17	9	4	2 (CTO, in 2015 and 2017)	6

Table 3: Operationalizing the dimensions by cases

	Degree of disruption	**Regulatory impact**
DigitalMedicine	**High** - Pharmaceutical companies - Healthcare providers - Relationship between providers and patients	**Constrained** - FDA requiring multiple tests on all components to approve the innovation because of ingestible aspect; - FDA approvals required for all pharmaceutical drug combinations - Novel regulatory pathways needed beyond Software as a Medical Device regulations.
Collaborative Health	**High** - Relationship of Hospitals with other hospitals - Relationship of Hospitals with EHR vendors	**Enabled** - Washington State Health Care Authority mandate 2011, followed by other States.
SmartAsthma	**Low** - None of the key actors significantly threatened - Minimal disruption to spirometer vendors	**Constrained** - FDA Pediatric Medical Device and Software as a Medical Device pathways
PreventiveCare	**Low** - None of the key actors significantly threatened (pre-disease condition)	**Enabled** - ACA incentivizes prevention programs - CDC recognizes digital forms of diabetes prevention
Control group		
HealthMarketplace	**High** - Hospitals and their relationship with patients significantly affected	**Unaffected** - Only standard HIPAA (health data security) regulations apply

CleverHeart	**Low** - None of the key actors significantly threatened.	**Unaffected** - Only standard HIPAA (health data security) regulations apply

Table 4: Evidence of findings

Scenario	Entry strategy in the ecosystem	Governance mechanisms	Likelihood of success
Dual constraint *(DigitalMedicine)*	**Orchestrator** "We can take every single medicine that has ever been approved and turn it into a digital object. It's an all new pathway for innovation in this industry based on software…" (CEO & co-founder at Wired Health, 2014) **Fight unfavorable regulation** "Unfortunately, that project hit a bit of a setback… when the FDA declined to approve the companies' New Drug Application (NDA). Because both halves of the system are already cleared or approved by the FDA, the companies expected a swift approval. Instead, they were issued a Complete Response Letter (CRL), a non-public document issued by the FDA that lays out the additional steps a non-approved drug must take to secure approval." (MobiHealthNews, 2016)	**Proving** *DigitalMedicine* has been working with the FDA for several years to develop a regulatory framework for its products and others like it that follow. The device itself was approved by the FDA in June after dozens of clinical studies involving 800 patients. (Financial Times, 2015) **Educating** "It is no good telling some scientists for whom this is new, look we already handled that, because appeals to authority are not good with scientists, you must do the work again". (Interview with CMO & co-founder) **Cooperating to overcome ecosystem bottlenecks and regulatory hurdles** "We will assess your data, and we will work together to see if it's actually achieving the results that we've demonstrated in trials, if it isn't, we'll work together to try to improve that" (CMO & Co-Founder at a University in 2005)	**Unlikely unless ecosystem bottlenecks and regulatory hurdles are overcome** "After disappointing sales, *DigitalMedicine* filed for bankruptcy earlier this year and in September, *PharmaCo* ended up buying what was left of *DigitalMedicine* for $20 million. … it was a huge fall from grace for *DigitalMedicine* which was once valued at $1.5 billion." (Pharmaforum, 2022)
Regulatory-enabled orchestration (*Collaborative*	**Orchestrator** "*CollaborativeHealth* is succeeding toward a vision that has eluded the healthcare industry for so long, to connect providers and plans across	**Fitting in** "At Mat-Su Regional Medical Center in Palmer, Alaska, use of the *CollaborativeHealth* combined with state-wide prescribing guidelines has resulted in a 61 percent reduction in opioid	**Likely if ecosystem bottleneck are overcome** *"CollaborativeHealth* is engaged with every national health plan in the country,

Health)	the continuum, in real time, so they can collaborate at scale for the benefit of the patient. Achieving this vision requires a disruptive mindset" (Business Wire, 2018) **Exploit favorable regulation** "The first to implement the company's Emergency Department Information Exchange (EDIE) was Washington, which in 2011 had its hand forced by Washington State Health Care Authority to limit non-emergent visits to the ED to three per year in an effort to reduce a $32 million Medicaid deficit". (Vacep, 2017)	scripts written between 2015 and 2017 and a 47 percent reduction in opioids given in the ED". (Business Wire, 2018) **Educating** "It's harder to rely on regulation to make a business case. But it also allowed us to measure impact and outcomes to show that the world didn't implode, hospitals didn't haemorrhage money because they were sharing this information." (Interview with CEO, 2015) **Collaborating to overcome ecosystem bottlenecks** "To have networks effect you need to have a network first.. and somebody need to jump first. This is the problem we encountered across our markets even when we first went live in Washington State 10 years ago and somebody needed to go first… Hence, part of what we do is to identify who are the most innovative players and talk to them first knowing that, if they go, others will likely go" (Interview with CMO, Digital Health Podcast 2019)	hundreds of hospitals and health systems, and tens of thousands of providers and care managers including those in emergency departments, primary care practices, skilled nursing facilities, home health agencies, emergency medical services, and mental and behavioral health organizations. *CollaborativeHealth's* network has visibility across 13 states, with an additional 10 states expected to go live in 2018*"* *(www.hitconsultant.net)*
Regulatory-constrained complementation (*SmartAsthma)*	**Complementor** "We have a device that people just blow into, and our app alert users saying whether they're fine, need to take medication, or go to the ER. What we're doing right now is translating something that's found in the hospital to the home setting" (Interview with Founder by Funding agency) **Fight unfavorable regulation** The regulatory constraints were so significant that it took until 2020 for	**Proving** *SmartAsthma* just finished a validation study with 66 children at UCSF Benioff Children's Hospital. "Now we have our sights set on getting to market as soon as possible and will soon be seeking FDA clearance in hopes of bringing our potentially life-saving device to homes in early 2017." (Interview with CMO, funding agency website) **Learning** "Every single opportunity I get in meeting people, I always go, like I always follow up, I always show up to things, and I always try, and I always ask questions, and I always ask for help. Like from everyone, almost everyone I meet. And I think it's just being able to utilize their resources that are brought and	**Likely if regulatory hurdles are overcome** "Apple is currently building up its healthcare line. Spirometry is one piece, but they don't have their own spirometer to collect the measurements. They are partnering with large institutes like the Mayo Clinic. Their physicians are asking for it (spirometers). They approached us and wanted to help with the user

	the company to receive FDA clearance, three full years after it submitted a so-called "Pre-sub" to the FDA (a written request for feedback as a first step toward regulatory clearance), which substantially delayed its market launch.	put in front of you" (Interview with founder) **Cooperation to overcome regulatory hurdles** Partnered with UCSF pulmonologists to benchmark the device with hospital spirometers in clinical trials (Synapse, 2015) and done several validation studies with children (Huffington Post, 2016).	interface and design." The CEO said that "Bayer and Genentech have also expressed interest in using the technology as a remote monitoring tool to drive up their own patient enrolments" (University Magazine interview)
Dual enablement (*PreventiveCare)*	**Complementor** "if it doesn't save the system a material amount of costs and fit into workflow, you're not going to be successful." (interview with VC, 2016) **Exploit favorable regulation** "We also heard about the CDC's National Diabetes Prevention Program (DPP) and that was founded by the Affordable Care Act to create a world where there is a standard of care for anyone who is at risk of type-2 diabetes through a program based on their standards. We thought there needs to be a digital complement to that. We asked if they might support that if we gave it a go" (CEO & Co-founder interviewed by Rock Health, 2015)	**Fitting in** "What clinical evidence do we have today that shows that if we give a person this kind of behavioral therapy or give them this kind of drug, and we make sure they take it, that we can improve their disease and therefore lower their cost, meaning lower their frequency of hitting the system or needing interactions with that human labor." (Interview with VC, 2016) **Learning** "Some entrepreneurs think you need that level of arrogance, you need to build from scratch, because you can get tangled in legacy and get pulled down. I disagree. What harm comes from understanding how it really works? …We met a lot of amazing doctors and clinicians spending their life on this and that have a lot to teach us. The moment you think you cannot be taught, it's over for you." (CMO interview by High Resolution, 2017) **Cooperation to realize the value proposition** "Our partnership with Cigna has been about so much more than capital," says *PreventiveCare* co-founder and CE". "The ability to collaborate with, learn from and integrate deeply with a health services company.. has enabled us to accelerate innovation, advance our capabilities, and grow our customer base." (Press release, 2017)	**Likely** "*PreventiveCare* has raised more than $250 million, making it one of the most highly valued digital health companies. When it raised its previous round in 2019, the company was valued at $600 million. …In the past five years, *PreventiveCare* has expanded its scope to offer more services tailored to those with behavioral health challenges, as well as a range of cardiovascular conditions." (cnbc.com 2020)

Figure 1 Key Actors in the Healthcare Ecosystem

(Note: HIPAA and HITECH are U.S. federal regulations for data portability and security; Medicare and Medicaid are government public health programs)

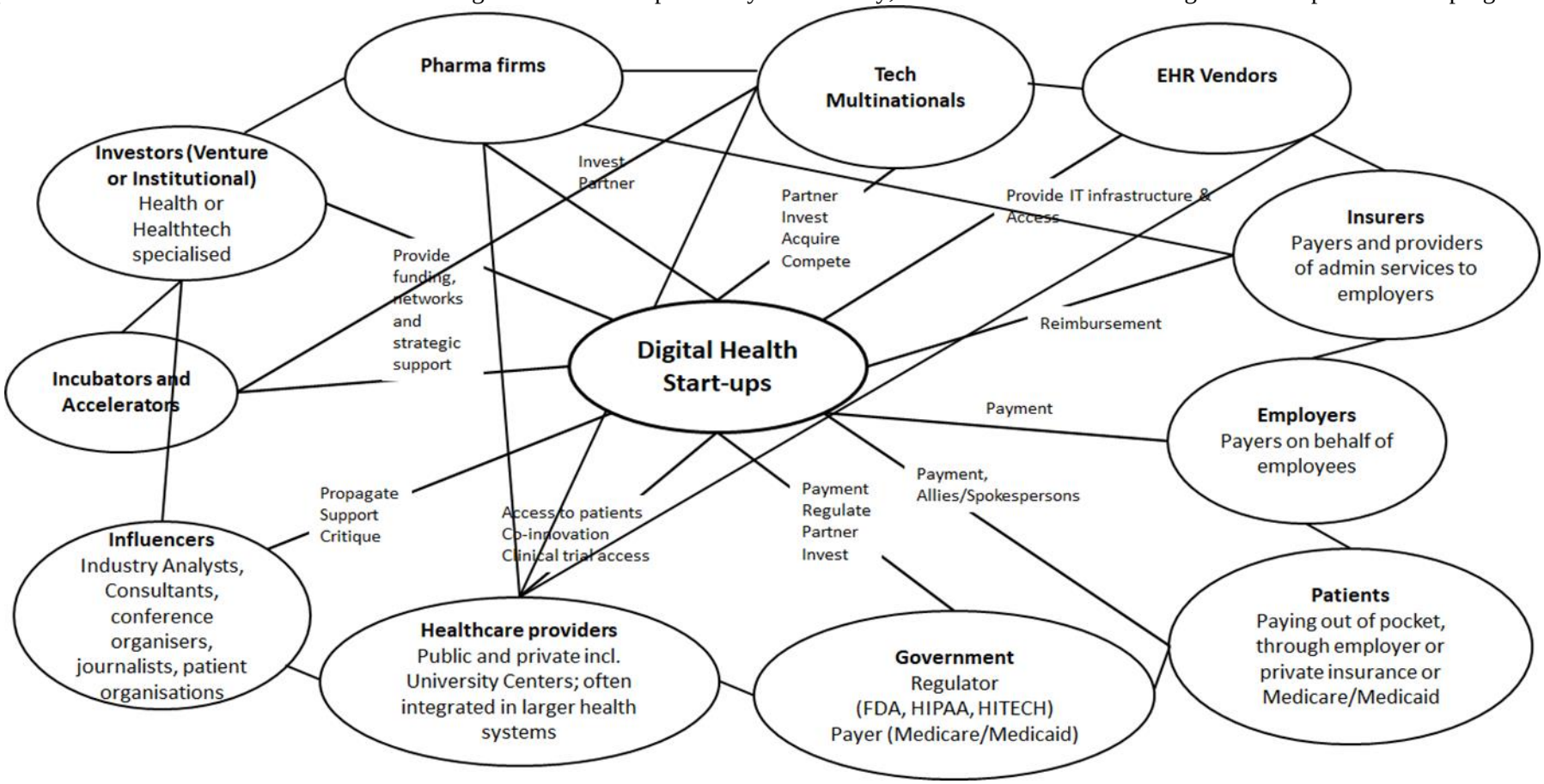


Figure 2: Scenarios for entry into a regulated ecosystem

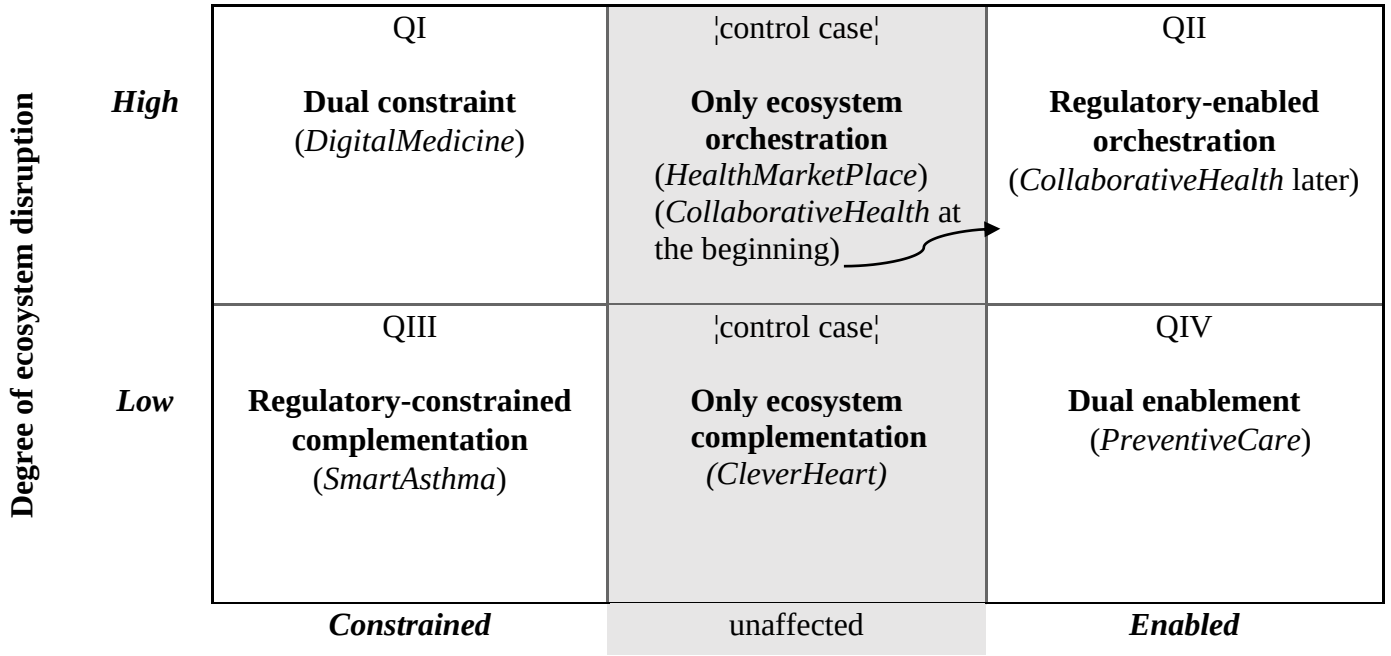


Figure 3 Simplified value networks for the six entrants

Figure 3a: DigitalMedicine

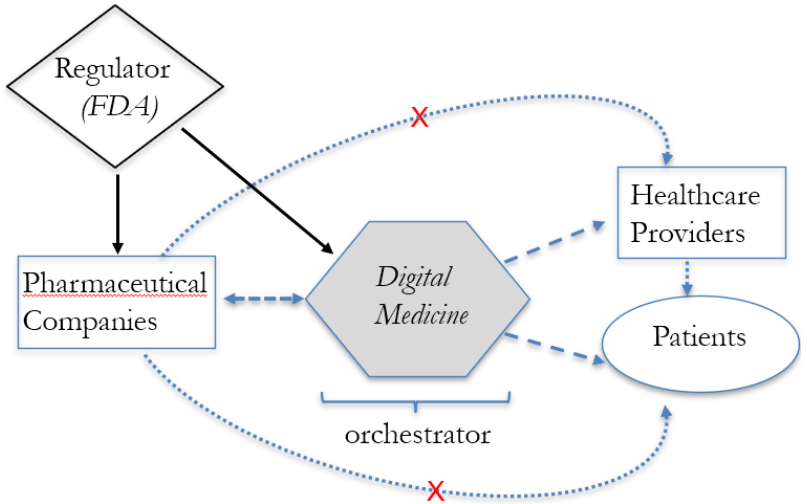


Figure 3b: CollaborativeHealth

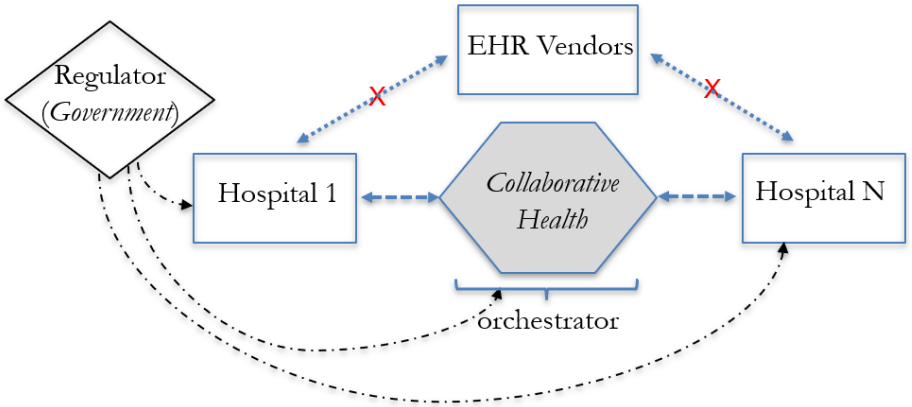


Figure 3c: SmartAsthma

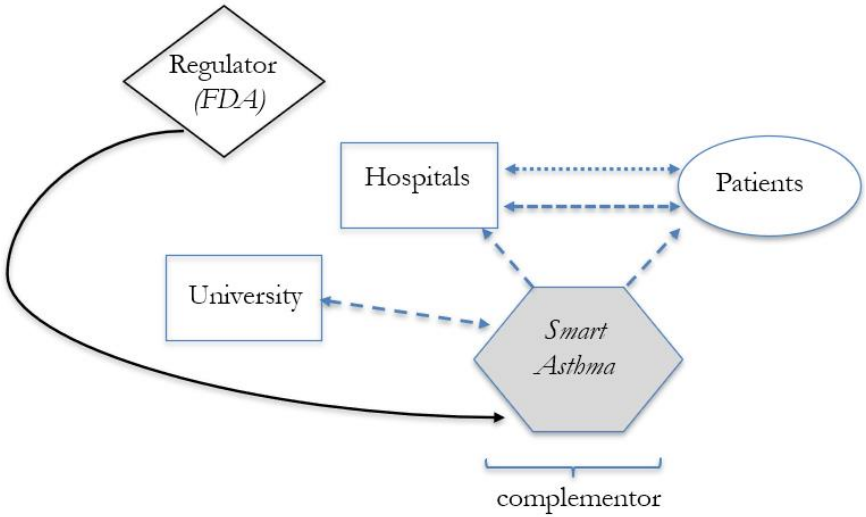
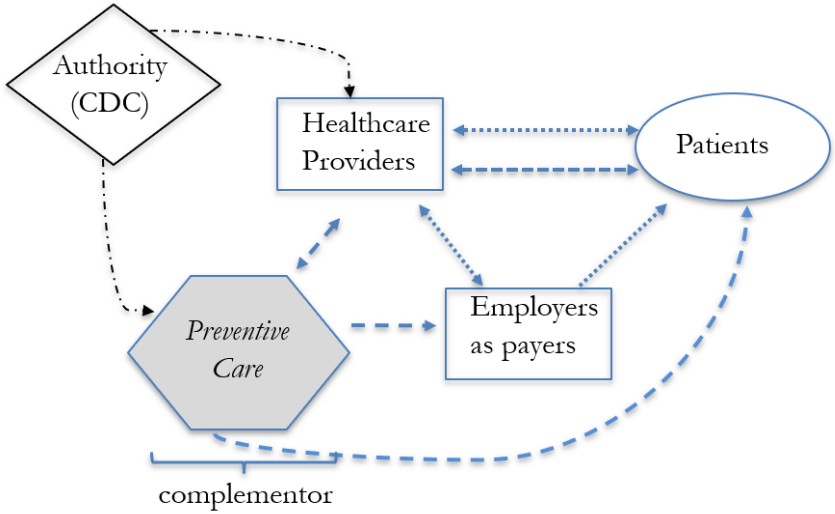


Figure 3d: PreventiveCare



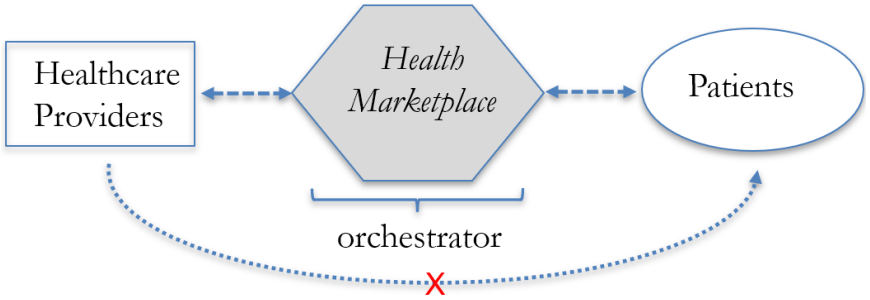


Figure 3e: HealthMarketplace

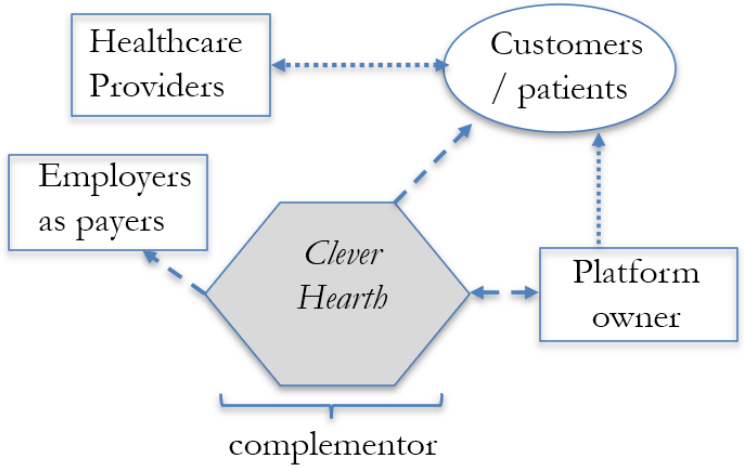


Figure 3f: CleverHeart

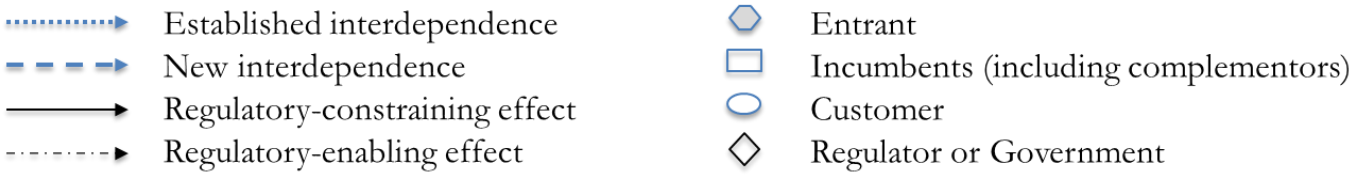
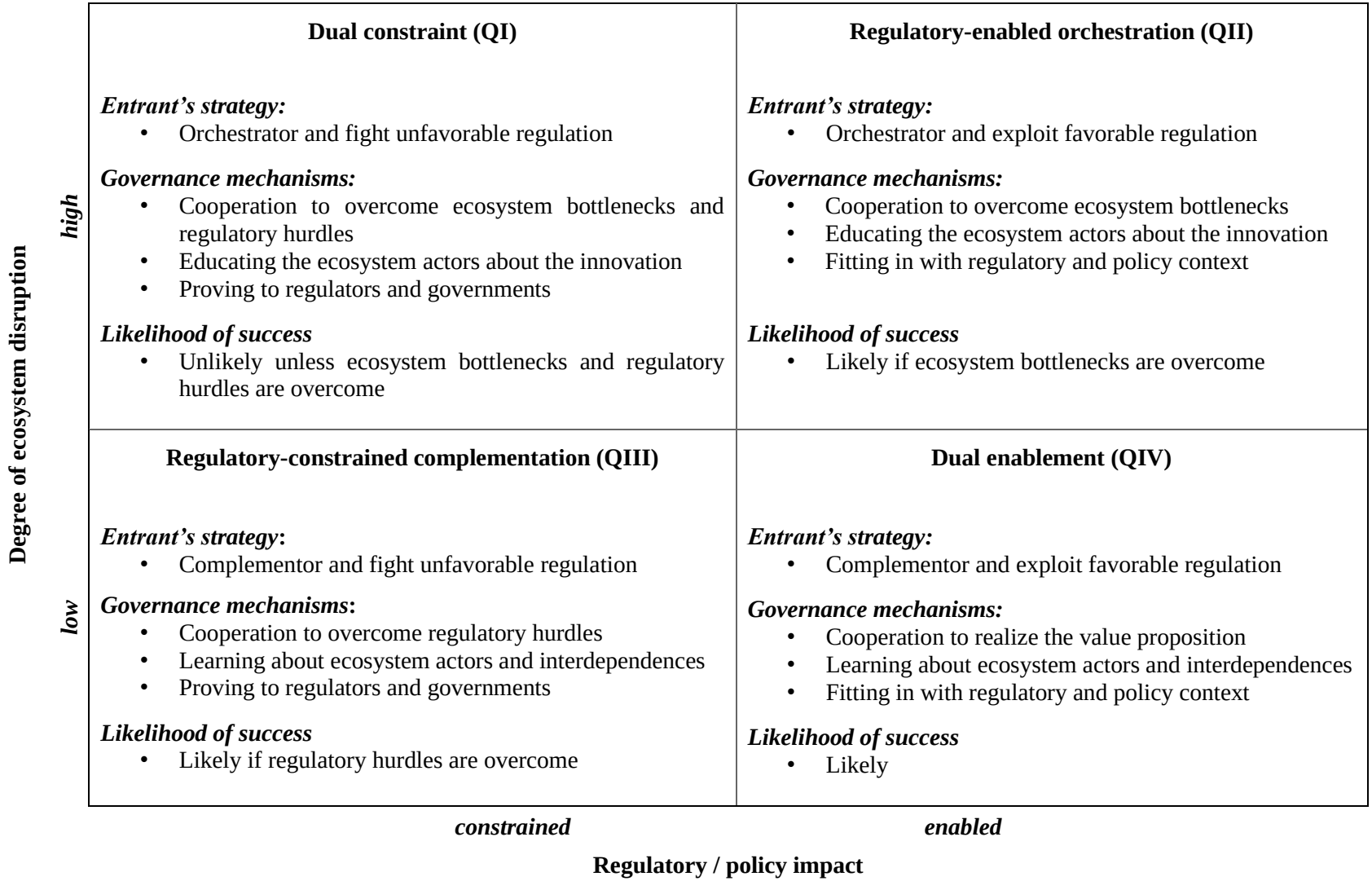


Figure 4. Framework of entry in an ecosystem based on ecosystem disruption and regulatory positioning



Examples of companies from our sample are: *DigitalMedicine* (for QI), *CollaborativeHealth* (for QII), *SmartAsthma* (for QIII), and *PreventiveCare* (QIV).