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Co-creating innovation ecosystems in contexts of absolute uncertainty: The case of low-cost heart valves in India

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Abstract

The development of innovations aimed at tackling grand challenges requires the support of an appropriate innovation ecosystem. However, there is a limited understanding of how such innovation ecosystems emerge in contexts of absolute uncertainty. We addressed this gap by examining the boundary work carried out by key actors in the creation of the biomedical innovation ecosystem in India that supported the development of a successful low-cost heart valve over the 1976–1995 period. We developed a process model demonstrating how the ecosystem leader co-created the innovation ecosystem that led to the development of a low-cost heart valve by engaging in three types of configuration boundary work: establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration. Our study contributes to the literature on innovations for grand challenges, innovation ecosystems, and boundary work.

KEYWORDS

boundary work, emerging markets, grand challenge, health, India, innovation ecosystem, institutional voids, medical device innovation

1 | INTRODUCTION

Affordable healthcare is identified as a grand challenge[1] given that many people, particularly the poor in emerging markets,[2] struggle to meet their healthcare needs owing to their expensive nature (World Bank, 2021). A key barrier to affordability is the high medical technology costs associated with new or improved devices, pharmaceutical products, and diagnostics, which often account for approximately two-thirds of the total (De Passe et al., 2016). Furthermore, medical technology development and sales are concentrated in developed countries, reducing access and increasing costs for people in emerging markets (Diaconu et al., 2014; EvaluateMedTech, 2018), thereby pushing more people into poverty. It is estimated that nearly 90 million people are impoverished by health expenses every year (World Bank, 2021). The alarming nature of this problem has therefore led to an increased research focus on innovations as a way to address this grand challenge (De Passe et al., 2016; George et al., 2012; Vakili & McGahan, 2016).

Innovation ecosystems are core to the development of innovations suited to address grand challenges (Nylund et al., 2021; Sahasranamam & Soundararajan, 2022). An innovation ecosystem—defined as "the evolving set of actors, activities, and artifacts, and the institutions and

[1]Grand challenges are defined as "*problems with significant implications and unknown solutions.*" (Eisenhardt et al., 2016, 1115). This includes challenges such as climate change, access to health care, hunger, and water shortages.
[2]As per the World Bank classification, an emerging market economy is as an economy with low to middle per capita income (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519).

relations, including complementary and substitute relations, that are important for the innovative performance of an actor or a population of actors" (Granstrand & Holgersson, 2020)—enables the collaborative efforts of varied actors and organizations toward collective value creation (Adner, 2017; Granstrand & Holgersson, 2020). Consequently, an extensive amount of research has focused on aspects such as collaboration between innovation ecosystem actors, ecosystem governance, and leadership within established innovation ecosystems (Klimas & Czakon, 2022b; Adner, 2006, 2017; Cobben et al., 2022).

Although research has explored the creation of innovation ecosystems (Autio & Thomas, 2018; Dedehayir et al., 2018; Foss et al., 2023; Holgersson et al., 2018; Pushpananthan & Elmquist, 2022), when it comes to innovations for grand challenges in emerging markets, there is a need to problematize our understanding of ecosystem creation. Such contexts involve different types of uncertainty owing to two reasons. First, grand challenges are wicked, complex, and evaluative (Ferraro et al., 2015), requiring solutions that are often unknown and intertwined with technical, political, and social aspects (George et al., 2016; Venkatesh et al., 2017). Grand challenges thus render innovating a demanding and arduous endeavor. Second, in emerging markets, this presents additional problems in the form of institutional voids. In such settings, institutional support structures are weak or nonexistent, posing uncertainties around resources, intellectual property, and regulation (Doh et al., 2017; Gao et al., 2017; Khanna et al., 2005).

This combination of uncertainty emanating from emerging technologies, grand challenges, and weak institutional structures gives rise to contexts that can be described as being of absolute uncertainty (Packard et al., 2017), wherein the available set of options and outcomes is open and often unforeseeable. This uncertainty makes it difficult to forecast and understand the expectations of heterogeneous ecosystem actors, even for experienced and resourceful ecosystem leaders (Subramaniam et al., 2015; Surie, 2017; Viswanathan & Sridharan, 2012). So, how does an ecosystem leader create an innovation ecosystem in contexts of absolute uncertainty? Beyond its theoretical significance, answering this research question is essential to understanding the development of innovations aimed at tackling grand challenges in emerging markets (Burda & Gavrikova, 2022; Chatterjee & Sahasranamam, 2018; Parente et al., 2021).

To answer the research question, we took a historical case study approach aimed at understanding how our case organization, the Sri Chitra Tirunal Institute for Medical Sciences and Technology (henceforth, SCTI) had acted as an ecosystem leader in co-creating a biomedical innovation ecosystem in India, enabling the development of affordable medical devices. We specifically focused on their first Class-III medical device—an implantable heart valve—and on the emergence of an innovation ecosystem around it over the 1976–1995 period. Driven by the data, we built on boundary work theory[3] to explore how the SCTI had configured the boundaries in the process of co-creating the first-of-its-kind biomedical innovation ecosystem to develop innovations aimed at tackling the grand challenge of affordable healthcare in India. Our study shows that the SCTI had engaged in a range of interconnected types of configurational boundary work, facilitating the ideation, experimentation, and translation processes of the low-cost heart valve.

Our study makes multiple contributions. First, it adds to the nascent theoretical and empirical understanding of the creation of innovation ecosystems amid the

Practitioner points

- In contexts of absolute uncertainty, wherein the available set of decision options and outcomes is open and often unforeseeable, the creation of an innovation ecosystem—the evolving set of actors, activities, artifacts, relationships, and institutions required for innovation—is complex.
- In such a context, ecosystem leaders need to appreciate the need for co-creation with other stakeholders and understand that the process will be dynamic and iterative.
- To cope with absolute uncertainty, ecosystem leaders need to employ different approaches in different stages of the co-creation journey. During the ideation stage, the focus of the co-creation effort needs to be on developing ideas with ample scope for course correction, as many aspects are likely to be unknown in the context of absolute uncertainty. During the experimentation phase, the ecosystem leader needs to create the space for bottom-up social practices to emerge that enable dialogue and experimentation. During the translation phase, the ecosystem leader needs to work across technical and commercial boundaries to engage in legitimizing activities through appropriate physical infrastructure, policies, systems, and processes.

[3]Boundary work refers to efforts undertaken by individuals or a collective to influence the social, symbolic, material or temporal boundaries, demarcations, and distinctions affecting groups, occupations, and organizations (Lamont & Molnár, 2002; Phillips & Lawrence, 2012).

uncertainties associated with the tackling of grand challenges in emerging markets (Klimas & Czakon, 2022b; Pushpananthan & Elmquist, 2022) by developing a process theoretical model that demonstrates how innovation ecosystems are co-created in contexts of absolute uncertainty. Second, it extends the research centered on the activities of ecosystem leaders (refer to Dedehayir et al. (2018) for a review of innovation ecosystem roles and activities) by highlighting that, in absolute uncertainty contexts, the ecosystem leader's role needs to extend beyond conventions to include boundary configuration activities. Third, our study elaborates on the existing research discussing mechanisms suited to overcome the uncertainties linked to tackling grand challenges in institutional void environments (Mair et al., 2012; Mair & Marti, 2009) by demonstrating configurational boundary work, wherein actors reshape the boundary landscape of others to orient their activities, as a distinctive mechanism adopted by emerging market organizations to tackle absolute uncertainty. Fourth, it adds to the boundary work literature (Barrett et al., 2012; Cartel et al., 2019; Langley et al., 2019) by developing a dynamic processual perspective of configurational boundary work that involves iterative interactions between different components in the creation of innovation ecosystems.

The rest of the paper is structured as follows. First, we review the literature on innovation ecosystems aimed at tackling grand challenges in emerging markets and boundary work. Second, we outline our historical case approach to the data collection. Subsequently, we outline the process by which the ecosystem leader had engaged in different types of boundary work to create an innovation ecosystem suited to tackling grand challenges in an institutional void context. Finally, we outline the contributions and implications of our study.

2 | LITERATURE REVIEW

2.1 | Innovation ecosystems for tackling grand challenges in emerging markets

Innovations are novel solutions that differ radically from any existing ones. Thus, the development and subsequent diffusion of innovations can be hindered by the uncertainty[4] created by the existing institutional arrangements or they can face resistance from entrenched players, customers, and end-users who might be unfamiliar with the adopted solutions (Dattee et al., 2018). Yet, as indicated by the extensive research on innovation development and diffusion, these challenges can be overcome (Cartel et al., 2019; Chiesa & Frattini, 2011) in the presence of an appropriate and supportive innovation ecosystem.

An innovation ecosystem comprises human capital (e.g., students, scientists) and material resources (e.g., equipment, financial sources) located within entities such as governments, universities, and industry (Oh et al., 2016). The system-level focus on collective value creation, including actors such as communities of interest and communities of users, is the characteristic that distinguishes innovation ecosystems from other types, such as business ecosystems (Thomas & Autio, 2014; de Vasconcelos Gomes et al., 2018). Cobben et al. (2022) highlighted the conceptual boundary conditions found in different types of ecosystems to highlight that competitive advantages for innovation ecosystems are relational—that is, they emanate from interdependencies between ecosystem actors—and aimed at realizing a shared value proposition.

Traditionally, it is assumed that the initiator of an innovation ecosystem assumes a leadership role during the creation phase, engaging in activities such as governing the ecosystem and forging partnerships (Dedehayir et al., 2018). This involves envisioning a compelling blueprint for the future of the ecosystem, engaging in developing the value proposition, identifying and coordinating with other relevant stakeholders, and developing the governance mechanisms for the engagement between actors (Adner, 2006, 2017). This envisioning of the future by the ecosystem leader is expected to reduce uncertainty and encourage other ecosystem actors to contribute to its development (Santos & Eisenhardt, 2009).

However, it is not always possible to develop a blueprint for an innovation ecosystem *ex-ante* (Dattee et al., 2018). During the creation phase, the ecosystem value proposition is unclear, volatile, and dependent upon the inputs of varied, independent stakeholders, which makes it difficult to develop a collective framework for actions (Almpanopoulou et al., 2019; Autio & Thomas, 2018). Consequently, such a phase is often marked by an absence of formal roles, processes, and resources and, as Markham et al. (2010) suggested, by a greater presence of informal roles and activities. Also, when the value proposition is unclear, ecosystem leaders are unable to gauge the effective knowledge distance (Afuah & Tucci, 2012), if any, between the knowledge possessed and that required to realize the value proposition (Lingens et al., 2021) and thus to identify the nature of the partners needed to support them.

Adding to this are the uncertainties imposed by grand challenges and institutional voids in emerging markets (Burda & Gavrikova, 2022; Chatterjee & Sahasranamam, 2018; Parente et al., 2021). First, grand challenges—

[4]Knight (1921) outlined the difference between uncertainty and risk; while risk applies to situations in which both the available options and their probability distribution are known, no such possibility exists in the case of uncertainty as the situation being dealt with is highly unique.

which are 'wicked problems' (e.g., poverty, global health, water crisis, and climate change) the nature, magnitude, and complexities of which create uncertainty—are highly significant yet potentially solvable (in the optimistic sense) (Gümüsay et al., 2020; Montgomery & Dacin, 2020). The fundamental principles underpinning the search for solutions to grand challenges are "the pursuit of bold ideas and the adoption of less conventional approaches to tackling large, unresolved problems" (Colquitt & George, 2011, 432). Grand challenges—which may be discrete and with clear end-points, like developing a vaccination for Ebola, or broad and open-ended, such as eradicating poverty (Eisenhardt et al., 2016)—are recognized as complex and evaluative (Ferraro et al., 2015), requiring solutions that are often unknown and intertwined with technical, political, and social aspects (George et al., 2016; Venkatesh et al., 2017). Hajer (2003) described any emerging technologies aimed at tackling grand challenges as falling into a void of their own, given that they are subject to few agreed governing structures or rules.

Second, an additional source of uncertainty stems from the institutional voids found in emerging markets, which uniquely constrain the creation of innovation ecosystems (Burda & Gavrikova, 2022; Chatterjee & Sahasranamam, 2018). Institutional voids "disturb the functioning of markets, enhancing the likelihood of opportunism (including corruption), excessive rents to a few actors (reducing entrepreneurship), and market power (discouraging competition)" (Doh et al., 2017, 294). In these contexts, innovators need to work with weak intellectual property rights, limited resources and capabilities, and high degrees of information asymmetry (Burda & Gavrikova, 2022; Chatterjee & Sahasranamam, 2018), which generate uncertainty (Khanna et al., 2005). These differ from the uncertainties faced in innovation ecosystems in developed market contexts. A case in point could be the emerging artificial intelligence technologies such as ChatGPT. Although their radical and emerging nature may pose uncertainties for certain actors in both emerging and developed economies, these differ from those arising from situations in which intellectual property safeguards are not institutionally guaranteed, as is often the case in emerging markets. This specificity may deter software programmers from joining and contributing to the development of such technologies. The challenges encountered in these situations do not relate only to the technological development itself, but also to addressing the uncertainties posed by the institutional voids. Burda and Gavrikova (2022) described the presence of higher technology uncertainty, limited resources, high market dynamism, and excessive state regulation as issues that influence the development of innovation ecosystems in emerging markets.

In addition to the uncertainties inherent to the innovation process per se, a combination of grand challenges and institutional voids can be characterized as what scholars have labeled contexts of "absolute uncertainty" (Packard et al., 2017). Knight (1921) made a seminal distinction between "risk," as probabilistic, and "uncertainty," as non-probabilistic. This distinction is based on whether the decision-makers know the sets of available options (potential means) and possible outcomes (potential ends). Packard et al. (2017) built on this to postulate that the nature of uncertainty depends on the openness and closedness of these sets and developed a related typology of uncertainty. In this typology, absolute uncertainty exists when both the option and outcome sets are open. First, this is the case when there are unlimited possibilities for addressing the need. Second, it is when the possible outcomes are unknown or unknowable, as environmental changes cannot be predetermined or foreseen. In such circumstances, one needs to proceed by committing resources to a perceived opportunity, not knowing how it will play out or whether specific solutions are even viable.

In such contexts, it is difficult for ecosystem leaders to create innovation ecosystems on their own (Sahasranamam & Soundararajan, 2022). Rather, they act as facilitators in the co-creation of innovation ecosystems by multiple actors coming together and sharing their knowledge, networks, and expertise. There is emerging research on the co-creation of an innovation ecosystem (Ketonen-Oksi & Valkokari, 2019; Klimas & Czakon, 2022a). Klimas and Czakon (2022a) highlighted that gaming innovation ecosystems operate with a collective leadership, rather than a focal firm leader. Further, they highlighted the distinct stages and roles found in the co-creation process. Ketonen-Oksi and Valkokari (2019) highlighted the importance of the facilitator's role in co-creation and the need to ensure that a shared value base exists among an ecosystem's actors. The presence of dynamic exchange capabilities helps to facilitate mutually beneficial knowledge and resource exchanges among the actors co-creating the ecosystem (Siaw & Sarpong, 2021).

However, research on innovation ecosystems does not yet offer any insights into how the ecosystem co-creation process unravels in the contexts of absolute uncertainty related to the tackling of grand challenges in institutional void settings. The co-creation of innovation ecosystems in contexts of absolute uncertainty necessitates challenging the existing established institutional structures (Ferraro et al., 2015; George et al., 2016) and transforming the underlying societal sub-systems (Walrave et al., 2018). In other words, such contexts necessitate system transformation (Mowery et al., 2010) and agility within the ecosystem (Sahasranamam & Soundararajan, 2022), requiring ecosystem leaders to work through the boundaries that divide actors and interests (Ozcan & Santos, 2015). As we argue in the following sub-section, research on boundary work provides a lens suited to understanding these issues.

2.2 | Boundary work

Boundary work refers to any efforts undertaken by individuals or a collective to influence the social, symbolic, material, or temporal boundaries, demarcations, and distinctions affecting groups, occupations, and organizations (Lamont & Molnár, 2002; Phillips & Lawrence, 2012). The concept of boundary work has important implications for the collaboration among and the inclusion and exclusion of actors, and for the power relations among them (Barrett et al., 2012; Zietsma & Lawrence, 2010).

In the context of innovations, the concept of boundary work has already been used to discuss aspects such as the reconfiguration of relationships, collaborations, and domains of knowledge (e.g., Barrett et al., 2012; Cartel et al., 2019). Barrett et al. (2012) discussed the role played by collaborative work among pharmacists, technicians, and assistants—and the reconfiguration of boundaries among them—in facilitating the use of robotic innovations in pharmacies. Based on the institutionalization of the European carbon market, Cartel et al. (2019) highlighted the importance of experimental spaces created through social and symbolic boundaries in initiating institutional innovation. Granqvist and Laurila (2011) discussed the emergence of nanotechnology by highlighting how futurists and scientists form boundaries around its definition. Velter et al. (2020) highlighted the need for mutual boundary changes in multi-stakeholder engagement to support sustainable business model innovations.

At the theoretical level, Langley et al. (2019) reviewed the literature on boundary work and divided it into three categories—namely, competitive, collaborative, and configurational. Competitive boundary work (work *for* boundaries) focuses on how actors "construct, defend, or extend boundaries to distinguish themselves from others, by defining an exclusive territory" (Langley et al., 2019, 706). The construction of boundaries or distinctions is often used to acquire resources or to reproduce power and social positions, wherein one side is often treated more favorably, to the exclusion of the other (Garud et al., 2014; Santos & Eisenhardt, 2005). Collaborative boundary work (work *at* boundaries) focuses on how actors "draw on, negotiate, blur, or realign boundaries in interaction with others in order to collaborate" (Langley et al., 2019, 707). Research on this topic discusses how such boundaries are negotiated, aligned, and accommodated in facilitating collaboration and developing coordination (Barrett et al., 2012). Nevertheless, although they may raise barriers, boundaries can also be seen as junctures for mutual understanding between actors on different sides (Quick & Feldman, 2014). Configurational boundary work (work *through* boundaries) focuses on how actors "design, organize, or rearrange the sets of boundaries influencing others' behaviors" (Langley et al., 2019, 707). Actors engage in reshaping "the boundary landscape of others to orient emerging patterns of competition and collaboration, often combining elements of both" (Langley et al., 2019: 720). This type of work helps transform taken-for-granted practices and power relationships by flexibly rearranging the physical, social, temporal, and symbolic boundaries isolating people and ideas (Stjerne & Svejenova, 2016).

Among these three types, configurational boundary work—which involves designing, organizing, and influencing ecosystem actors—is pertinent to this study for three reasons. First, in configurational boundary work, the locus of the agency is placed at a higher level (Langley et al., 2019), with actors, like ecosystem leaders, trying to create and influence the boundaries affecting others to co-create an innovation ecosystem. Second, configurational boundary work involves reshaping the boundary landscape based on patterns of integration and differentiation among sets of ideas or people within or around organizations to enable the collective action (Granqvist & Laurila, 2011; Howard-Grenville et al., 2017) required for innovation ecosystem co-creation. Third, the focus of innovation ecosystem creation is somewhat less on the boundaries themselves; rather, it is about developing and mobilizing the spaces defined by them to influence the activities happening within and around them, as in configurational boundary work (Lamont & Molnár, 2002). We thus built on insights drawn from the boundary work literature, especially configurational boundary work, to explore how the SCTI had facilitated the co-creation of a biomedical innovation ecosystem by specifically engaging in configurational boundary work (as informed by the data) to foster the development of a low-cost heart valve that has been saving thousands of poor people in India and elsewhere.

3 | METHODS

Theorizing the co-creation of an innovation ecosystem in contexts of absolute uncertainty, such as those related to grand challenges in emerging markets, requires a deeper understanding of a "significant phenomenon" or "exemplar organization" (Eisenhardt & Graebner, 2007). We thus took a single case study approach, as it enables "the creation of more complicated theories than multiple cases because single-case researchers can fit their theory exactly to the many details of a particular case" (Eisenhardt & Graebner, 2007, 30). We theoretically sampled the case of the SCTI and its development of a low-cost heart valve and its creation of a biomedical device innovation ecosystem in India. We selected the case because it is an exemplar and "unusually revelatory," and also because we had "unusual research access" (Eisenhardt & Graebner, 2007, 27).

The case that we examined was not a contemporary one. Rather, it was a long-drawn innovation endeavor that had been successfully concluded quite some time back; yet, it had the potential to offer deep insights into the co-creation of an innovation ecosystem. This pointed to the adoption of a historical approach to studying the phenomenon, which would enable us to draw "...extensively on historical data, methods, and knowledge, embedding organizing and organizations in their socio-historical context to generate historically informed theoretical narratives" (Maclean et al., 2016, 609). Historical analysis, as a methodology, has increasingly gained importance in organizational studies in recent years, prompting some scholars to note the "historical turn" (Godfrey et al., 2016) in organizational studies that recognizes the "temporal and spatial historical embeddedness of organizational phenomena" (Bansal et al., 2018, 1191). Historical methods are "...by definition, longitudinal ... change over time is at the heart of the historical enterprise, although the length of time covered can be measured in years, decades, or even centuries" (Yates, 2014, 274). This gave rise to an interesting predicament: on the one hand, a longitudinal study—in the sense of collecting data at different points in time—was not possible because of the time elapsed since the case events; on the other hand, it was important to capture the challenges faced by the innovators involved in the project, and how these had been resolved over time.

In most qualitative studies (including longitudinal ones), the evidential value of documents lies in their validation of interview accounts (Yates, 2014). However, those scholars who took a historical perspective on organizational studies (e.g., Lawrence, 2017; Zietsma & Lawrence, 2010) highlighted the need to rely primarily on document analysis, although interviews, in the form of oral histories and retrospective accounts, do supplement the understanding that researchers glean from documents. Therefore, in historical methods, retrospective accounts form an important part of the evidence, supplementing and complementing the data drawn from documents.

Retrospective accounts have previously been used in organizational research, especially in studies on change management and strategic management. They are particularly useful in situations that require capturing data over time, but where the researcher was not present (Glick et al., 1990). A retrospective account may involve the potential for recall bias. However, research suggests that, in a case like ours, recall bias would be relatively low. First, in recollecting major and vivid personal events, actors accurately draw upon episodic memory mental structures (Wheeler et al., 1997), and the development of the heart valve was one such defining professional event in the lives of the scientists and ecosystem actors involved. Second, research on self-based referencing structures highlights that such memories grow increasingly more accurate over time (Symons & Johnson, 1997). Third, a reanalysis of data aimed at assessing the accuracy of recall-based studies in organizational research suggests that retrospective data collection is not necessarily biased (Miller et al., 1997).

To further mitigate the risk of recall bias, we employed multiple additional practices in line with the approach often used in historical studies of organizations (Kipping & Üsdiken, 2014). First, we relied on archival materials to complement the interviews (Navis & Glynn, 2010). Second, we triangulated with multiple data sources and informants and sought factual—as opposed to judgmental—data from respondents with high levels of involvement (Huber & Power, 1985). Also, to develop an in-depth understanding of the actions taken by the ecosystem leader in developing the biomedical innovation ecosystem in India, we included interviewees who had been peripherally associated with the development of the ecosystem (Bhardwaj et al., 2006). Finally, we also approached certain key respondents for multiple rounds of interviews (Phillips et al., 2013).

3.1 | Research context

Our case organization, the SCTI, which was inaugurated in 1976, is situated in the city of Trivandrum, the capital of the state of Kerala in southern India. In Western countries, R&D in the healthcare sector is primarily undertaken by industries; however, in 1970s India, the healthcare industry was rudimentary, with virtually no research budgets. Therefore, the SCTI was set up with three main sections: a tertiary hospital specializing in advanced neurological and cardiac medicine and surgery; a center for research and training on public health; and a biomedical technology center for the research and development of biomedical devices for the Indian market.

We deliberately chose this institute because the traditional multi-faculty universities in India are not research-intensive (Altbach, 2009). Observers have noted that even the Indian Institutes of Technology—which are otherwise known for their excellence in teaching and the reach of their alum network in high-technology sectors across the world—shine in teaching rather than in research (Sen, 2010). On the other hand, there are publicly available records of some of the achievements of our case organization in innovating products and technologies that not only are considered highly relevant for the Indian market but are also technologically challenging. The SCTI has been granted 137 Indian and international patents, 41 design registrations, and eight trademarks.[5] The most prominent among the Institute's innovations is its "Sri Chitra Heart Valve," a low-cost heart valve that has received various national and international accolades (Raj, 2009). By tracing the development of this valve, we aimed to understand the creation of a biomedical device innovation ecosystem. This valve is a Class III medical device (i.e., a high-risk product for patients/users as it is meant to be implanted into the human body to sustain or support life[6]). Given the associated high risk, such medical devices are subject to the most stringent regulatory standards and are also prone to a high probability of project failure. At a time when no biomedical innovation ecosystem existed, the SCTI had managed to co-create an innovation ecosystem that supported the development of a high-risk product at a fraction of the cost of its imported counterparts, which made it affordable for patients in an emerging market context.

The heart valve's development took place between 1978 and 1995. In 2001, it received a National Award for the Successful Commercialization of Indigenous Technology. In 1995, imported valves cost over INR 40,000, while the Chitra valve was priced at INR 12,000 (India Today, 1995). As part of multi-centric trials conducted from 1992 to 1995, an evaluation of the patients who had received transplants with the SCTI heart valve revealed that, besides being cost-effective, it had "good haemodynamics with no structural failure and acceptable thromboembolic levels" (Muralidharan et al., 2011, 24).

3.2 | Data collection

The data collection process for this study initially drew from archival documents to understand the history of the institute, the key actors involved, and the technical background of the products. This was followed by interviews conducted with key actors identified from the archival documents (see Table 1 for a summary of the interview sources). One of the authors had been closely involved with the case organization for some years and the interviews were undertaken in multiple stages between 2014 and 2020. In 2014, an initial field visit was made to foster a working relationship with both the hospital and biomedical divisions of the SCTI. This also involved reading through different secondary sources, such as books and journal articles, to become appraised of the various biomedical innovations of the SCTI. In 2016, a second field visit was made to try to understand the relationship between the hospital and biomedical divisions. This involved discussions with doctors and scientists to explore their collaborative arrangements and practices. The data drawn from these initial field visits helped us understand the larger biomedical innovation context in India and brought to the fore the pioneering role that the SCTI had played in co-creating the innovation ecosystem for it. A third field visit made in December 2018 narrowed down the focus to the heart valve to gain an in-depth understanding of the ecosystem created around it. The final field visit, which was made in December 2019, involved discussions aimed at clarifying some aspects that had emerged from the earlier data collection activities, seeking elaborations on earlier inputs from the informants, and reflecting on the findings. The data collection process, which ended upon reaching theoretical saturation (Glaser & Strauss, 1967), followed all the necessary criteria suggested in the literature to ensure the truthfulness and rigor of the findings (Gibbert & Ruigrok, 2010; Guba & Lincoln, 1994; Yin, 2003).

TABLE 1 Interview sources.

Interview sources	Total
Scientists	14
Doctors	6
Ecosystem commercialization actors	8
Veterinary surgeon	1
Assistant	1

3.2.1 | Documents

The historical documents we used included books, annual reports, presentation notes of key actors, and newspaper articles. Our main source of initial data was a book—published by the SCTI to mark its silver jubilee anniversary—that detailed the history of the institute and its development of biomedical technologies. In addition, we also used the annual reports published by the Institute for every year of the period covered by the study. We also had access to the presentation notes of public

[5]*Source*: https://sctimst.ac.in/Academic%20and%20Research/Research/Intellectual%20Property%20Rights/ accessed on 22 January 2021.

[6]*Source*: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device accessed on 14 September 2020.

TABLE 2 Interview respondents.

Code name	Respondent's position during the 1976–1995 period	Respondent's position during data collection
Scientist 1	Scientist in heart valve project	Senior scientist at SCTI
Scientist 2	Scientist in heart valve project	Retired
Scientist 3	Leading the biomedical division of SCTI during the heart valve project	Retired
Scientist 4	Scientist who worked on Class 1 medical devices within SCTI	Retired
Scientist 5	Scientist who worked on Class 1 medical devices within SCTI	Retired
Scientist 6	Scientist who worked on Class 2 medical devices and was involved with the Techno-Prove facility	Senior scientist at SCTI
Scientist 7	Scientist who worked on Class 2 medical devices and was involved with the Techno-Prove facility	Retired
Scientist 8	Scientist who worked on Class 2 medical devices within SCTI	Professor at a university
Scientist 9	Not part of SCTI during the period, but was associated with the biomedical innovation ecosystem	Consultant at SCTI
Scientist 10	Part of SCTI since 1993	Led BMT division
Scientist 11	Not part of SCTI during the period, but was associated with the biomedical innovation ecosystem since 1993	Senior scientist at SCTI
Scientist 12	Scientist who worked on cellular and molecular cardiology	Senior scientist at SCTI
Scientist 13	Not part of SCTI during the period, but was associated with the biomedical innovation ecosystem	Scientist who worked on radiology and medical imaging
Scientist 14	Not part of SCTI during the period, but was associated with the biomedical innovation ecosystem	Scientist who worked on biostatistics and public health
Ecosystem commercialization actor 1	Technical leader of heart valve commercialization partner	Technical leader of heart valve commercialization partner
Ecosystem commercialization actor 2	Technical leader of heart valve commercialization partner	Technical leader of heart valve commercialization partner
Ecosystem commercialization actor 3	Technical support in the commercialization of medical devices	Retired
Ecosystem commercialization actor 4	Technical support in the commercialization of medical devices	Manager at the commercialization actor
Ecosystem commercialization actor 5	Trained at Techno-Prove facility for manufacturing medical devices	Technical support in the commercialization of medical devices
Ecosystem commercialization actor 6	Entrepreneur who commercialized medical devices	Retired
Ecosystem commercialization actor 7	Worked with the textile component supplier for heart valve	Worked with the textile component supplier for heart valve
Ecosystem commercialization actor 8	Led women's self-help group that was involved in the stitching of heart valve	Led women's self-help group that is involved in the stitching of heart valve
Veterinary surgeon	Led animal trials	Retired

TABLE 2 (Continued)

Code name	Respondent's position during the 1976–1995 period	Respondent's position during data collection
Doctor 1	Cardiac surgeon who had a leadership role in the heart valve project	Retired
Doctor 2	Cardiac surgeon involved in heart valve development and human trials	Retired
Doctor 3	Surgeon at SCTI	Professor
Doctor 4	Surgeon at SCTI	Professor
Doctor 5	Not part of SCTI during the period, but was associated with the medical ecosystem	Professor
Doctor 6	Not part of SCTI during the period, but was associated with the medical ecosystem	Surgeon at SCTI
Assistant	Administrative staff at SCTI during heart valve development	Retired

lectures given by the key actors involved in product development and library archives at the institute. We also used newspaper articles and documents drawn from Lexis Nexis about the institute and its products. In total, over 300 pages of data were collected.

3.2.2 | Interviews

We conducted in-depth, semi-structured interviews with a wide range of actors closely involved with the development of the biomedical innovation ecosystem. We took a purposive sampling approach and chose our interviewees based on their roles and involvement in the innovation ecosystem. We initially accessed some interviewees through the personal contacts of one of the authors. We then took a snowball sampling approach to identify and subsequently interview further actors. When the work on the heart valve had been conducted, the team leading the development of various biomedical devices at the SCTI had been small and had collaborated through regular discussions. This ensured that everyone in the team had first-hand information on the heart valve project, even though some members had been working on Class I and II medical device projects (e.g., Scientists 4, 5, and 8). In total, we conducted 38 interviews with 30 individuals, all of whom had been involved, connected to, or knowledgeable about the development of the SCTI and/or the heart valve project (see Table 2). The interviews lasted between 30 min and 2 h, and all but two were recorded and transcribed. For the two exceptions, extensive notes were taken both during and after. In total, this process produced over 500 pages of transcribed interview data. The interviews were carried out in a range of places, including the interviewees' homes or places of work, and over the phone or through Skype. The interviews were conducted either in English or Malayalam (the local vernacular language). The first author, who was leading the data collection, is well-versed in both languages. The interviews undertaken in Malayalam were translated into English and, to ensure accuracy, a selection of the transcripts was then back-translated into Malayalam by one of the authors not involved in the translation. We used a semi-structured interview guide with questions about the interviewees' roles, responsibilities, actions, and resources. The interview guide evolved over time and was different for different actors. Even though we only used a portion of the data generated, the range of the questions we asked and the topics we covered helped us develop a holistic understanding of the case. We stopped the interviews upon obtaining repetitive answers and reaching theoretical saturation (Glaser & Strauss, 1967).

3.3 | Data analysis

This study was aimed at understanding the historical practices and processes that had led to the co-creation of a biomedical innovation ecosystem in India through the invention and commercialization of a low-cost heart valve. To this end, we took an analytic approach appropriate for process research (Gioia et al., 2013; Lawrence, 2017) and adopted a contextualized explanation approach to theory development (Welch et al., 2011). We systematically coded the data utilizing established coding procedures (Gioia et al., 2013; Strauss & Corbin, 1990). First, we developed a base skeleton of the historical events that occurred between 1976 and 1995, from the conceptualization to the commercialization of the heart valve. We consulted key informants to ensure the accuracy of the timeline.[7] Second, using interviews and archival data, we developed a detailed case narrative on the ecosystem leader and innovation ecosystem. By iteratively reading the narratives, we first noticed the presence of boundaries broadly defined as distinctions among groups and people (Zietsma & Lawrence, 2010); these included disciplinary, symbolic, and specific task-related boundaries. We also observed the boundary work practices undertaken by the ecosystem leader in configuring the innovation ecosystem by working through the boundaries. The narrative also provided information on the different actors involved in the ecosystem, their activities, their involvement in its co-creation, the events that occurred, and the evolution of the ecosystem around the different phases of the product. Third, to guide our analysis, we consulted the literature on innovation ecosystems (Autio & Thomas, 2013; Klimas & Czakon, 2022b) and boundary work (Langley et al., 2019), and held discussions among us for theory inspiration, while remaining open to emergent phenomena. Through the innovation literature (Bocken & Snihur, 2020; Randhawa et al., 2021), we identified the phases of innovation development—namely, ideation, experimentation, and translation. Fourth, we open-coded the raw data to understand the boundary work practices enacted by the ecosystem leader. This yielded broad first-order concepts that we labeled for further analysis (see Table 3). When possible, we labeled the concepts using the informants' terms (Gioia et al., 2013). Fifth, we performed axial coding on the first-order codes to develop meaningful second-order themes such as "setting ecosystem boundaries" and "creating active experimental spaces." We then examined the data from a theoretical perspective to identify any distinct patterns of understanding. This process enabled us to expand the relationships beyond the immediate scope of our study to develop meaningful insights for other researchers (Gioia et al., 2013). The second-order analysis involved the extraction of theoretical explanatory dimensions from the emerging patterns and the consolidation of such patterns into a conceptual model. We grouped the second-order themes into three abstract theoretical categories—namely, establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration. We consulted the historical timeline and innovation phases we had identified and placed the constructs on the skeleton to develop the process model. Based on Langley's (1999) suggestions, we played with various ways to present the conceptual model, and, following multiple iterations, we arrived at the one presented in Figure 1. Finally, we reviewed the raw data to check for additional codes or constructs. We re-read the narrative and raw data, consulted with some key informants a second time, and held iterative discussions among ourselves to examine internal homogeneity and external heterogeneity (Patton, 2002) and to ensure the "trustworthiness" (Guba & Lincoln, 1994) of the theoretical constructs. We also ensured inter-coder consistency (Hemmler et al., 2022) by consensually developing a coding scheme and iteratively developing the codes and constructs based on constant discussions among ourselves. See Table 3 for a demonstration of the coding process, which, consistent with Gioia et al. (2013), comprises the first-order concepts, second-order themes, and aggregate theoretical dimensions.

[7]We consulted several key participants (e.g., Scientist 1, Scientist 3, Scientist 6) a second time in person (Scientist 1) or through email/phone (Scientist 3, Scientist 6) to discuss the information we had captured and to ask for feedback. With regard to the dates and chronology of the events, the participants confirmed the information we had captured from the archival data. This follow-up consultation discussion also provided the participant with an opportunity to add further details to their initial conversation, offering us more clarity.

4 | THE DEVELOPMENT OF THE BIOMEDICAL DEVICE INNOVATION ECOSYSTEM

Our findings illustrate the boundary work undertaken by the SCTI, as the ecosystem leader—namely, establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration—to co-create the biomedical device innovation ecosystem that had led to the development of the heart valve. This configurational work involved designing, arranging, and shaping boundaries within the ecosystem to influence the behaviors of other actors in it to realize the value proposition of creating biomedical devices. We present the coding process in Table 3.

4.1 | Ideation (1978–1980): Establishing ecosystem configuration

In 1976, when the SCTI hospital division had been established, open-heart surgery was not performed in the state of Kerala (Valiathan, 2018). The hospital soon found itself with many patients with valvular heart disease needing valve replacement. The grant fund available was insufficient to buy imported valves; this, in 1978, led to the conscious decision to develop an artificial heart valve. However, the ecosystem necessary to develop the product was non-existent.

Between 1978 and 1980, the SCTI engaged with other actors in establishing a configuration aimed at initiating the co-creation of an ecosystem suited to help in the

TABLE 3 Coding process on boundary work.

First-order codes	Second-order themes	Aggregate theoretical dimensions
Affordable to poor patients Technology commercialization focus	Setting ecosystem boundaries	Establishing ecosystem configuration
Polymer research group – developing polymer processing technologies like coating and surface treatment were not available in India and expensive from abroad Engineering services division—developing machining facility and precision tool room for metal components	Differentiating specialized sub-groups	
Connecting to scientific organizations from different disciplines Lack of human capital specific to the sector, augmented by individuals with skillsets from other industries Regular meetings between multidisciplinary stakeholders—polymer processing, engineering division, doctors	Integrating across disciplinary boundaries	
Experiments in materials for developing the valve with partners (e.g., HAL, Keltron, SITRA, and NAL) Experiments in product testing (e.g., using equipment of partners) Experiments in animal testing	Creating active experimental spaces	Modeling ecosystem configuration
CNC machines were expensive and experiments using available resources (copper electrodes and pantograph milling machine) Developing performance testing equipment at less than 1/10th cost	Creating frugal experimental spaces	
Training on procedures specific to medical devices (e.g., contamination control, clean room) Developing process knowledge that was not available from technical documentation Communicating the social value of solving the grand challenge to ecosystem partners	Creating ecosystem learning spaces	
Technical Advisory Committee involving prominent scientists from across India for advice and support Regulator mechanism Independent ethics committee Animal care committee Detailed documentation of experiments and their outcomes	Establishing governance of experimental spaces	
Convincing multiple centers for clinical trials Establishing confidence with surgeons, who are customers and influencers for using the valve Marketing the valve in the SCTI name Independent monitoring committee led by a senior cardiac surgeon for clinical evaluation	Legitimizing across technical and commercial boundaries	Expanding ecosystem configuration
Use of personal connections in identifying partners for product commercialization Techno prove facility Training in medical device production on a commercial scale	Bridging technical and commercial boundaries	
Movement of personnel from SCTI to commercialization partners Detailed technology transfer document Understanding on nature of follow-up intervention Practices of SCTI extended to national-level standards and practices	Scaling-up across boundaries	

development of the heart valve. This boundary work involved the SCTI identifying, deliberating, and developing ideas suited to solve problems within the domain of biomedical devices. The SCTI had engaged in the configurational boundary work of establishing an ecosystem configuration through three practices: (a) setting ecosystem boundaries, (b) differentiating specialized sub-groups, and (c) integrating across disciplinary boundaries.

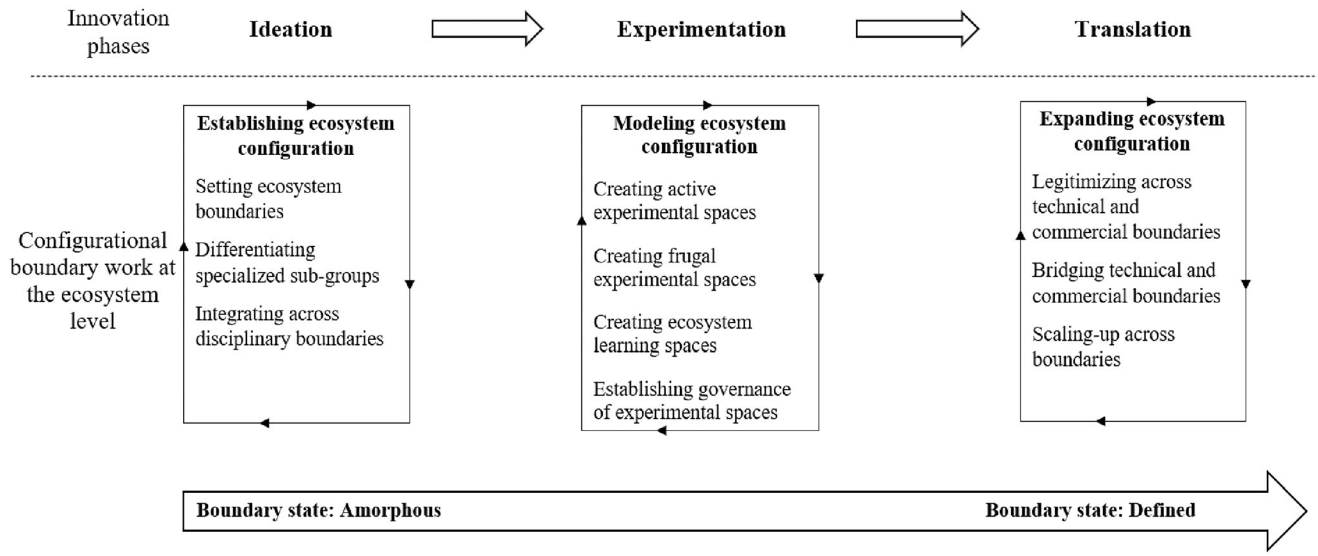

FIGURE 1 Conceptual model.

4.1.1 | Setting ecosystem boundaries

The affordability of the heart valve among poor communities had been set as a key boundary for the ecosystem. An artificial heart valve could substantially extend the lives of young people with rheumatic heart disease. While over 1.2 million young people were at risk of such diseases (Muraleedharan & Bhuvaneshwar, 2004), only 4000 heart valve replacements were being undertaken annually in India, primarily owing to the very high costs. This criterion had been a key driver of the project. Thus, two of the key scientists who had been involved in the project wrote:

> "The valves needed to be imported at a very high cost and were not affordable to most of the needy. Therefore, it was clear that India's need for artificial valves was too large, critical, and uneconomical to be left alone for imports and imported technology... It was in this context that the Institute put together a multidisciplinary team to take up the development challenge." (Muraleedharan & Bhuvaneshwar, 2004: 82).

Of equal importance had been the emphasis on commercialization from the very beginning of the project. At a senior management level, from the very start, discussions had been held with other ecosystem partners on windows of opportunity, technology proving, and commercialization. For instance, Scientist 3 commented: "Even from the initial days, Mr. R [anonymized], Doctor 1 [anonymized], and I were constantly talking about the commercialization of technology." This commercialization vision had set a symbolic boundary for the ecosystem to focus on translating the device development from lab to market. To summarize, the SCTI outlined the material and symbolic boundaries for the ecosystem by setting the affordability criterion and commercialization plan, respectively.

4.1.2 | Differentiating specialized sub-groups

The SCTI had focused on developing specialized sub-groups differentiated by technical boundaries to develop enabling technologies within the ecosystem. During the 1978–1980 period, India had significant regulatory caps on the import of items, and very high taxes were levied on imports (Panagariya, 2004). This meant that sourcing materials and equipment from abroad was difficult and expensive. Similarly, the process of sending the materials outside the country for testing each time involved long delays and excessive costs, making it inapplicable to the development of an affordable product. This meant that the SCTI had to invest its time and resources in developing such capabilities indigenously. So, it created sub-groups differentiated by technical specialization for enabling technologies. Scientist 1 commented: "...we needed different development teams also on the enabling technologies like coating, surface treatment, and enhancement of properties." The heart valve involved three types of materials—polymer, metal, and textile. Specialized manufacturing and polishing processes were important for the metal, which required a machining facility and precision tool room; to this end, the SCTI had to create a sub-group with a technical focus on engineering services (Ramani, 1991).

4.1.3 | Integrating across disciplinary boundaries

The crucial part of the initial phase of the valve's development was R&D aimed at identifying the biocompatible materials that could be used. The absence of a medical device ecosystem in India meant that there was a limited number of experienced individuals who could undertake such research. The SCTI tackled this lack of human capital by crossing the disciplinary boundaries of biomedical science by reaching out to individuals from other industries and training them. For instance, a scientist who had been part of this initial team recalled:

> "From the industry, it may not be the medical device skill-set which was coming up; a basic industrial skill-set was coming up, and our role was to refine this industrial skill-set and make it suitable for the medical device development." – Scientist 1.

Relevant state-of-art expertise was needed to undertake research into materials. Here again, the SCTI had engaged in working across disciplinary boundaries and had tapped the expertise of organizations like the Vikram Sarabhai Space Center (VSSC) and the National Aeronautics Laboratory (NAL), the core disciplines of which were space and aeronautical engineering, respectively. Furthermore, to facilitate the exchange of knowledge among the different teams (polymer processing, engineering services, and doctors) involved in the ecosystem, interdisciplinary weekly meetings had been scheduled, as recalled by Scientist 1:

> "Here actually that was quite effective, in the sense that all the groups used to have what we called Friday meetings, those regular meetings were quite good ... In fact, it was a small team." – Scientist 1.

During the ideation phase, there was a need for creativity amid uncertainty, as the domain needs were not fully understood (Gemmell et al., 2012; Kock et al., 2015; Page & Schirr, 2008). We found that, by establishing the configuration of the ecosystem through the arrangement, reshaping, and integration of boundaries, the SCTI had managed to navigate the uncertainties present during the ideation phase. This enabled the setting of a grand-challenge-oriented vision as a core ecosystem boundary while, at the same time, providing scope for creativity and flexibility through sub-group specialization and cross-boundary integration. The instances we describe show that, while one aspect of the progression of innovation had involved drawing up new sub-group boundaries around specialized expertise, attempts had simultaneously been made to integrate across them. Establishing such flexibility in ecosystem configuration had been crucial to the ideation of a product that, at the time, was technologically complex and novel for SCTI and India.

4.2 | Experimentation (1980–1990): Modeling ecosystem configuration

The SCTI had engaged in modeling ecosystem configuration as configurational boundary work aimed at modeling and supporting the experimental spaces suited to develop new practices for the ecosystem that would support the development of product prototypes. The SCTI performed this work through four practices: (a) creating active experimental spaces, (b) creating frugal experimental spaces, (c) creating ecosystem learning spaces, and (d) establishing the governance of the experimental spaces.

4.2.1 | Creating active experimental spaces

The first experimental variant of the heart valve was a tilting disc model that featured a valve housing made of titanium, a disc fabricated of polyacetal (Delrin), and a sewing ring of polyester fabric. The electron beam welding of the struts in the valve housing for this had been done by Hindustan Aeronautics Limited (HAL); the molding facility at Keltron Counters Ltd had been used for injection molding; knitting of the polyester yarn for the sewing ring had been done by the South India Textile Research Association (SITRA); and the polyacetal material had been provided by DuPont free of cost. This model had failed during performance tests, and the weld fracture found in it had been analyzed by the National Aeronautic Laboratory (NAL). The lessons learned from the first experimental model led to a variant with an integral housing of titanium and a single crystal sapphire disc developed with the support of partner organizations. This also failed the performance tests. Another variant, which had used Haynes 25 as the housing material with a sapphire disc, had failed during animal testing. Such trial-and-error learning within the active experimental space led to the eventual final variant of the heart valve with a housing of Haynes 25, a disc of ultra-high-molecular-weight polyethylene (UHMWPE), and a sewing ring of knitted polyester cloth. The suggestion of using a UHMWPE disc, which had no precedent use in medical applications, had been made by the National Chemical

Laboratory (NCL), which had been part of the multidisciplinary active experimental space. Thus, the SCTI created active experimental spaces with partner organizations such as HAL and the SITRA (Muraleedharan & Bhuvaneshwar, 2004) for heart valve prototype development and testing.

4.2.2 | Creating frugal experimental spaces

The integral housing of the valve required CNC machines, which were expensive and not easily available within India at that time. This issue was resolved by experimenting with various frugal approaches involving the resources available within the ecosystem. This experimentation led to the use of copper electrodes and a pantograph milling machine available in the engineering services division (Valiathan, 2018). Similarly, to test the valve's performance within the lab, pulse duplicators were needed. In Western countries, Laser Doppler Anemometry (LDA) was used, which cost over INR 10 million in the 1980s. Subsequently, the same measurement was done by a Pulse Ultrasound Doppler Velocimeter" (PUDVEL) designed and built by actors within the ecosystem at one-tenth the cost (Valiathan, 2018). To summarize, to stay within the material boundary set for the ecosystem while ensuring the affordability of medical devices for poor patients, the SCTI engaged in the creation of frugal experimental spaces that brought together multiple actors to develop low-cost manufacturing and testing processes within the ecosystem.

4.2.3 | Creating ecosystem learning spaces

In the nascent phase of the biomedical innovation ecosystem in India, there was a need to create a learning space in which one could identify potential partners, engage with them, and train them to support the manufacture of medical devices. For instance, Scientist 5 highlighted the learning about the importance of cleanrooms:

> "…the hospital staff, they were all trained (on the importance of a clean environment) at the beginning itself. But then you get people like us [scientists] who have never been trained to do this. That is a big training. Use this, use that, and keep it neat and clean. If something falls, it should not be taken and used."

The creation of a learning space had also been important for communicating the social value and impact of the product to different partners. For instance, the SCTI had engaged in communicating the expectations of the ecosystem around the affordability and social value of the product to its partners, as this quote suggests:

> "Most of the people we were dealing with, they were supporting us as a kind of service and not just for profit. This involved a lot of convincing from our side to communicate our intention, commitment, passion, national interest, and everything." – Scientist 5.

Similarly, although technical documentation about the product did exist in the Western country context, there was limited process-level information on how it had been developed. The learning space facilitated in creation, almost from scratch, of a contextualized process knowledge base within the ecosystem. For instance, Scientist 1 commented:

> "Processing information is like when you have a particular product being made, there will be certain processing steps involved, and that information will not be public … like actually what should be the process? … So, the process information had to be generated in-house … There [in cleaning] we could get help from the NCL and the NAL because they had the knowledge, so we could tap into those knowledge pools."

To summarize, the ecosystem leader had created learning spaces by arranging knowledge boundaries suited to develop products and process information about biomedical innovations, as well as to communicate the larger mission and social value of the innovation.

4.2.4 | Establishing the governance of the experimental spaces

First, during the experimentation process, the ecosystem actors were asked to adhere to established regulatory standards such as ANSI, AAMI, and so forth. In the case of animal testing, the Principles for Biomedical Research Involving Animals from the Council for International Organizations of Medical Sciences (CIOMS) were followed. Second, the SCTI created advisory and regulatory mechanisms for the ecosystem, such as a Technical Advisory Committee involving prominent scientists from across India, as outlined by one participant:

> "Basically, we have a system here and we ourselves have to take up the role of the

> regulator. As there is nobody who has the technical competence to assess this in India … people from abroad are not going to be cost-effective for a number of reasons, so we had to take up the role of regulator within the team itself." – Scientist 1.

The SCTI had also constituted an independent ethics committee, drawing on the international practice of such committees. This committee was chaired by a High Court judge and included members from various fields of the social and medical sciences, including a cardiac surgeon as the subject expert. They approved the first phase of the clinical trial of the heart valve in October 1990 (Muraleedharan & Bhuvaneshwar, 2004). For animal testing, the SCTI had set up an animal care committee to authorize and supervise the studies.

Third, the governance of the experimental spaces involved a focus on detailed documentation. The SCTI had made a conscious effort to ensure that all actors would document the different experiments and their outcomes, irrespective of whether they were positive or negative. This eventually became a standard operating procedure for the subsequent stages of valve development and testing. This ensured the generalizability and replicability of the development process, as outlined by one respondent:

> "We had to write down the process—our operational procedure—that raw data was valuable data. We always scribbled it down, rather than putting it in our mind … it became a record … When we had that raw data, we could easily find the reason for a failure, where we had gone wrong, and so forth." – Veterinary surgeon.

To summarize, modeling ecosystem configuration is a key boundary work for supporting experimentation within an innovation ecosystem in contexts of absolute uncertainty. We found that, in such contexts, the ecosystem leader needs to not just model boundary arrangements suited to create spaces for experimentation and learning, but also model governance structures for the activities that take place within those boundaries. For instance, the SCTI had to deal with the absence of any medical device regulations or overseeing authority tasked with approving and validating the lab and animal testing in India by establishing a governance process for the experimental spaces. Without such a process, it would have been difficult for the ecosystem leader to legitimize the product for use in a critical medical application.

4.3 | Translation (1990–1995): Expanding ecosystem configuration

During the later stages, the SCTI engaged in the configurational boundary work of expanding the ecosystem configuration aimed at extending its boundaries beyond the technical domain to include commercial and customer aspects. It carried out this boundary work by (a) legitimizing across technical and commercial boundaries, (b) bridging technical and commercial boundaries, and (c) scaling up across boundaries.

4.3.1 | Legitimizing across technical and commercial boundaries

The boundary work of establishing and modeling ecosystem configuration had been primarily restricted to its technical boundaries. However, given their potentially life-saving nature, the commercialization of medical device innovations poses a unique challenge, as it is subject to multiple stages of clinical trials aimed at establishing legitimacy with customers and commercial actors (e.g., doctors). The following quote highlights the importance of establishing legitimacy with doctors:

> "The end customer for the valve is of concern to the surgeon. We don't see the patient. The surgeon decides which valve to use. The first question s/he will ask is: 'Why should I risk my reputation by using this valve?' So, the device needs to have credibility." – Ecosystem commercialization actor 2.

The SCTI had to risk its reputation in trying to establish legitimacy with doctors and commercialization partners by marketing the valve under its name, as this quote revealed:

> "The SCTI helped in doing multi-centric clinical trials in six major hospitals … cardiac surgeries used the valve developed by the SCTI under its own name, not under that of a commercialization partner." – Scientist 3.

An important part of this legitimizing had been the search for wider stakeholder participation. For this, the SCTI had also established an independent monitoring committee tasked with evaluating multi-center trials. To build confidence among doctors and patients, this committee included people of high repute from different walks of life, as revealed by Scientist 1:

> "…a monitoring committee that was chaired by a senior cardiac surgeon, and included people from all walks of cardiac surgery and medical statistics … the entire data were verified by a team from the Indian Statistical Institute."

Thus, in the translation process, it was important to reshape the existing technical boundaries by legitimizing the activities for commercialization. This involved a process aimed at influencing relevant stakeholders by rearranging the existing boundaries (cf. Langley et al., 2019) that had developed around the product technologies and bringing in other stakeholders in the process of establishing the clinical viability of the product. The aim had been to build trust and legitimacy with a wider set of stakeholders such as users (the patients who needed the valve and the doctors who would recommend and use it) and commercialization partners.

4.3.2 | Bridging technical and commercial boundaries

In its efforts to transition the product from the lab to an industrial scale, the SCTI had bridged the boundaries between technical and commercial domains to enable collaboration between scientists and commercial actors, who had different interests. The SCTI had invested in setting up a technology-proving facility (Techno-Prove), the first of its type in India, tasked with qualifying the technology on a commercial scale and providing facilities for medical device development, such as clean rooms. Using this facility, the SCTI also trained the commercialization partner on product and quality assurance aspects. The commercialization partner had used this facility to manufacture the initial 1000 valves before setting up a dedicated industrial one (Nagesh & Bhuvaneshwar, 2004). This interface period was used to fine-tune the production process and finalize the quality assurance and acceptance criteria. This had been important in managing the transition of a high-risk medical product in an emerging innovation ecosystem together with a commercial partner, as this comment suggests:

> "…During the 1992 to 1995 period, we were doing production there [the Techno-Prove facility]. In the transfer of technology for a critical medical device, you cannot just deliver documentation. It has to be a hand-holding, joint activity by the research group and the industry … It's not like making a single valve; when you make 10, you will encounter various production-related issues." – Ecosystem commercialization actor 1.

The SCTI had also tried to mediate between technical and commercial actors through personal networking and conversations between its senior team and potential commercialization partners. For instance, to commercialize the heart valve in the absence of an established biomedical device manufacturing industry, the SCTI had had to engage with an unrelated commercialization partner the core business of which was the manufacture of pressure cookers:

> "Scientist 3 [anonymized] realized that an executive in the commercialization partner [anonymized] had been a student of his … he found that the partner had excellent tool room facilities because it made pressure cooker release valves." – Scientist 7.

4.3.3 | Scaling up across boundaries

As part of the scaling up of production, it had been important to engage with manufacturing partners capable of processing the different components of the heart valve, such as metals and textiles, on an industrial scale. The commercialization partner's existing tool room facility had been repurposed for the metal component, as this comment suggests:

> "So, he set up a whole lot of tool room activities in the pressure cooker factory … 300 valves were made by the commercialization partner's [anonymized] pressure cooker factory" – Scientist 3.

As part of the technology transfer, a document consisting of multiple sections had been handed over to the partner. This document contained sub-sections like the policy of the process, equipment input, standard operating procedure, and so forth. Given that no biomedical devices had hitherto been commercialized in India, there was significant apprehension on the part of the commercialization partner. So, in addition to bridging the technical and commercial domains through personal networking and persuasion, it had been necessary to relocate one of the lead scientists involved in the product's development to the commercialization partner to set up the production on an industrial scale, as this quote revealed:

> "By 1995, after the clinical trials, there was the need for commercial production, but nobody wanted to do it … Mr. N [anonymized] said, *OK, I will take it, provided you*

come with the technology. I said, *I cannot just leave like that; I need some time*. He replied, *No, no, no, if you want me to take it, you come with me*." – Scientist 3.

As part of the scaling-up process, the SCTI also publicized the product at conferences and in articles published in medical journals based on the results of the multicenter trials (e.g., Bhuvaneshwar et al., 1991). The SCTI also conducted regular check-ups with patients who had undergone the heart valve implantation, to check on their health and the valve's functionality, thereby establishing trust with patients and the larger community.

Eventually, many of the processes, standards, and practices developed by the SCTI became the established norms of the wider biomedical device innovation ecosystem in the country. For instance, the SCTI's technology transfer committee was asked to take over the technology transfer functions of other Indian science and technology labs. Similarly, the concept of the independent ethics committee was replicated by other R&D organizations in India. The national framework for the lifecycle and technology readiness of medical devices also used the guidelines developed by the SCTI, as revealed by Scientist 1:

"Even the medical device development strategy, the entire nation follows our model … all the Department of Science and Technology (DST) labs and national organizations now use our model, and that is being propagated." – Scientist 1.

The activities carried out to scale up across boundaries included the transfer of both knowledge and human capital, alongside the creation of a structure and design suited to commercialize emerging technologies in contexts of absolute uncertainty. This involved going beyond merely setting the conditions for networking and collaboration between technological and commercial actors.

To summarize, to navigate the uncertainties between technical and commercial actors, the ecosystem leader had to engage in expanding the ecosystem configuration. This had involved going beyond shaping technical boundaries, to shaping commercial and customer ones. It required the ecosystem leader to engage in legitimization, bridging, and scaling-up activities. We found that, in contexts of absolute uncertainty, the ecosystem leader had to go beyond the transfer of technical documentation, to setting up technology-proving facilities for commercial trials and allowing the relocation of human capital (i.e., a lead scientist) to the commercial partner to support the commercialization of the technology.

5 | THE CO-CREATION OF INNOVATION ECOSYSTEMS IN CONTEXTS OF ABSOLUTE UNCERTAINTY: A THEORETICAL MODEL

In this section, by illustrating and explaining the linkages and relationships among the concepts, we present the development of a model of co-creation of innovation ecosystems in contexts of absolute uncertainty (Gioia et al., 2013). Figure 1 illustrates the dynamism that characterizes the relationships between the key concepts and how, over time, they influence the development of innovation. The transitions between the innovation phases of ideation, experimentation, and translation are marked through the process at the top of Figure 1.

The ideation phase of innovation is characterized by: (a) the need to make decisions even when there is insufficient understanding of the domain needs, (b) high levels of creativity, (c) the need for problem engagement and insights into selecting ideas, and (d) the need to develop processes and infrastructure suited to support the ideas (Gemmell et al., 2012; Kock et al., 2015; Page & Schirr, 2008). This requires the innovation ecosystem leader to begin the creation process by acting from a distance, with a locus of agency at a higher level, by setting the core ecosystem boundaries. In contexts of absolute uncertainty, the ecosystem leader needs to set and communicate boundaries aligned with a grand challenge vision. In our case, we observed this aspect being framed around a nation-building motive of affordable improved healthcare. To refocus interactions on doing new things, the leader also needs to collaboratively arrange the boundaries based on patterns of differentiation and integration among sets of people and ideas (Granqvist & Laurila, 2011). This involves the setting of temporary boundaries that enable a focus on specialized actions (Cartel et al., 2019). For instance, the Indian policy environment of the 1980s (Panagariya, 2004) featured voids that posed restrictions on the sourcing of knowledge and materials for biomedical innovation. The ecosystem leader had worked around this by engaging in practices of differentiation and integration across boundaries. Specialized sub-groups had been differentiated by technical boundaries, such as the polymer research group and the engineering services division that existed within the SCTI and other external sub-groups that possessed expertise that was not available in-house (e.g., the NAL). Over time, the sub-groups developed further specialized expertise and knowledge (e.g., internal animal testing and external development of the sewing ring). Ideas and human capital from across disciplinary boundaries had also been integrated both internally and in partnership with multiple actors such as the VSSC and the NAL (e.g., drawing ideas and talent from other disciplines like space and chemistry).

Experimentation phases involve trial and error learning and the need to accept success and failure (Sosna et al., 2010; Wiklund & Shepherd, 2011). A key feature of configurational boundary work involves the development and mobilization of spaces intending to influence the activities carried out within them to serve collective purposes (Lamont & Molnár, 2002; Zietsma & Lawrence, 2010). In the context of meeting grand challenges in institutional void environments—which are characterized by uncertainty and complexity—these spaces need to be protected to allow for robust dialogue and experimentation so that bottom-up initiatives can occur through collaboration and the interaction of the resources at hand (Bollier & Helfrich, 2012). Through this provisioning of space, the ecosystem leader can enable the actors to engage in bottom-up social practices aimed at discovering and implementing new ways of doing things in a decentralized manner. We saw this happening in the active and frugal experimental spaces. We also saw the establishment of a governance process for these spaces through the setting up of ethics and advisory committees that included experts from different sectors to ensure accountability.

The translation of innovation requires a set of strategic and operational decisions to define the new product's positioning and the associated processes to manufacture it at scale and market it (Chiesa & Frattini, 2011; Hultink et al., 2000). Commercialization or translation requires working across technical and commercial boundaries, and thus the expansion of the ecosystem configuration. During this phase, the ecosystem leader needs to legitimize the activities carried out in the technical space into the commercial space to ensure the acceptance of innovation as legitimate by a wider set of actors. The ecosystem leader needs to engage in practices suited to establish the credibility of the emerging field to stakeholders located outside the laboratory or experimental scope of the product; this includes engaging with customers and suppliers, proving the technology for commercial use, and transferring knowledge and processes from the laboratory to an industrial scale (Slater & Mohr, 2006; Snow et al., 2011). In this regard, to establish credibility with doctors and commercial partners, the SCTI engaged in developing collaborative research publications, networking, and setting up an independent monitoring committee made up of reputed professionals. The ecosystem leader also needs to engage in bridging boundaries to accommodate collaboration between scientists and commercial entrepreneurs, who have differing interests. This can be achieved by establishing boundary organizations, such as the Techno-Prove, as a means to translate the scientific advancements attained in the lab into commercial medical products. Mørk et al. (2012) illustrated a similar example of the creation of a new R&D department in a Norwegian hospital tasked with transforming scientific breakthroughs into medical practices.

The process involved in configuring an ecosystem is not a linear one. Rather, it involves iterative practices within each of the ecosystem's configurational boundary work activities. In Figure 1, we highlight this iterative process through the circular arrows around each of the three configurational boundary work activities. For instance, in establishing the ecosystem configuration, every time a potential new material was identified for the heart valve, it first had to meet material boundary conditions of affordability. This had been followed by the verification of its suitability by a sub-group, and then by validation and testing carried out by drawing on expertise from across boundaries. Similarly, we observed the creation, at the intersection of the technical and commercial boundaries, of bridging structures aimed at facilitating iterative boundary work during the transition from lab to commercialization. For instance, Techno-Prove, the technology-proving facility created by the SCTI, enabled the commercial partner to co-learn and co-iterate the transition.

Further, in each of the three configurational boundary work activities, we saw various ecosystem stakeholders being engaged in an iterative dialogue to uncover the challenges faced by the ecosystem at various points in time. This dialogue process is crucial for ecosystem creation in contexts of absolute uncertainty because the potential outcomes are not predetermined; they only manifest themselves in the process of engaging with innovation. The iterative dialogue enabled the stakeholders to rearrange and reshape boundaries in response to evolving situations. For example, we saw active experimental spaces being reshaped to form frugal ones for the development of certain enabling technologies, like pulse duplicators.

As the innovation moved from the ideation to the translation phase, we also saw a dynamism in the state of the boundaries, which had evolved from amorphous to defined due to different types of configurational boundary work activities. During the ideation phase—considering the absolute uncertainties surrounding emerging technologies, grand challenges, and emerging markets—the boundaries within the ecosystem and its actors had been amorphous. The roles had been provisional and open to change. For instance, when the SCTI included diverse actors from sectors such as space (VSSC) and textiles (SITRA), which were beyond the immediate scope of biomedical technology, their roles were ambiguous. Over time, their roles had changed from offering material suggestions to sharing a physical space for technology development, to becoming supply chain vendors for heart valve production. The ecosystem leader had also engaged in mediating between the activities of other ecosystem actors, such as those from the engineering, medical, and material sciences, which would have otherwise remained isolated within the system in the absence of clearly defined boundaries. However, as the uncertainty around the innovation and context had decreased with technology evolution and with the ecosystem leader establishing networks and legitimacy, the boundaries had become more structured and defined. For instance, there had been a demarcation of technical boundaries about what each ecosystem actor needed to engage in (e.g., polishing or tooling) to develop biomedical innovation. The boundaries between the technical and commercial actors had also been defined in relation to setting up the technology-proving facility. Thus, we found that the evolution in the state of the boundaries within the ecosystem had gone hand in hand with changes to the extant state of uncertainty. We illustrate this through the large panel arrow at the bottom of Figure 1.

6 | DISCUSSION

Innovation ecosystems are key to the development of innovations. While their creation is always challenging, contexts of absolute uncertainty (Packard et al., 2017), such as those related to grand challenges in institutional void settings, can make it significantly more so. So, how are ecosystems created in such contexts? Our in-depth analysis of the SCTI's involvement in the creation of the Indian biomedical innovation ecosystem that had supported the development of low-cost heart valves enabled us to develop a theoretical model for the co-creation of innovation ecosystems in contexts of absolute uncertainty. Our study shows how the SCTI, as the ecosystem leader, had needed to extend its role to engage in activities that had gone beyond the conventional ones expected of a leader (cf. Dedehayir et al., 2018) to deal with absolute uncertainty by engaging in boundary configuration activities. These involved establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration. We now elaborate on how our study contributes to and extends the existing literature on innovations for grand challenges and innovation ecosystem creation.

6.1 | Theoretical contributions

Our study makes four key theoretical contributions. First, the extant literature acknowledges the importance of innovation ecosystems for developing innovations aimed at tackling grand challenges (Nylund et al., 2021; Sahasranamam & Soundararajan, 2022). However, there is very little theoretical and empirical understanding of the creation of innovation ecosystems under the conditions of absolute uncertainty associated with the tackling of grand challenges in emerging markets (Klimas & Czakon, 2022b; Pushpananthan & Elmquist, 2022). Based on an in-depth study of the emergence of a biomedical innovation ecosystem in India, we developed a theoretical process model that demonstrates how, in contexts of absolute uncertainty, innovation ecosystems are co-created by the ecosystem leader and other stakeholders. We elaborated on our understanding of innovation ecosystem creation by doubling down on the nature of the activities undertaken within each of the three phases of innovation—namely, ideation, experimentation, and translation. During the ideation phase, the ecosystem leader needs to engage in establishing the ecosystem configuration. In the experimentation phase, the focus is on modeling the ecosystem configuration, and in the translation phase, it is on expanding the ecosystem configuration. These insights shed more light on the role played by uncertainty in ecosystem design (Lingens et al., 2021).

Second, prior research has discussed the activities of ecosystem leaders, such as governance, value management, and partnership building (refer to Dedehayir et al. (2018) for details on innovation ecosystem roles and activities). Ecosystem leaders are key to the coordination and cooperation among the actors in the ecosystem (Foss et al., 2023). Our study demonstrates that, for innovation ecosystems in contexts of absolute uncertainty, the ecosystem leader's role needs to extend to cover activities that go beyond the conventional ones highlighted in the literature (cf. Dedehayir et al., 2018). In such settings, the ecosystem leader is unable to foresee any options and outcomes, and set a blueprint for the ecosystem. Rather, they have to be adaptive and flexible enough to react to changes in the environment while developing the ecosystem (Lingens et al., 2021). In contrast to leading and acting within pre-configured boundaries, they need to engage in configuring them, which involves activities such as establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration. Moreover, it is worth highlighting the dynamic nature of the roles engendered by the iterative character of the activities we identified. Rather than the static ecosystem roles discussed in earlier research (Dedehayir et al., 2018), the absolute uncertainty associated with the development of technology products aimed at tackling grand challenges in emerging markets requires ecosystem actors to be dynamic in performing a range of ad-hoc roles.

Third, our research addresses the call for a focus on contextualized theory development in innovation research (Kolk et al., 2014; Nakata & Weidner, 2012; Prahalad, 2012), particularly with an emerging market focus (Chatterjee & Sahasranamam, 2018; Subramaniam et al., 2015). Extant organizational-level research has explored the mechanisms adopted by emerging market firms and intermediaries to tackle the uncertainties associated with institutional voids and grand challenges (Dutt et al., 2016; Mair et al., 2012). These mechanisms include network benefits, reputation (Gao et al., 2017; Khanna et al., 2005), and engagement in bridging activities (Parmigiani & Rivera-Santos, 2015). We highlighted configurational boundary work—wherein actors reshape the boundary landscape of others to orient their activities—as a distinctive mechanism adopted by emerging market organizations to tackle absolute uncertainty. We found that boundary configuration not only leverages aspects of networks but also focuses on creating bounded spaces for robust dialogue and experimentation. This enables actors to co-create dynamically and flexibly through bottom-up practices. We stress that the boundary configuration activities of the ecosystem leader—such as the creation of frugal experimental and learning spaces, the establishment of governance of the experimental spaces, and the bridging of the technical and commercial boundaries are relevant in contexts of absolute uncertainty because they compensate for key deficiencies. For instance, given the absence of mechanisms for the testing and approval of biomedical devices in India, the ecosystem leader had engaged in establishing governance mechanisms for the experimental spaces, such as ethics committees endowed with contextual knowledge expertise. Similarly, given the weak intellectual property rights and limited commercialization support (George et al., 2012; Sahasranamam et al., 2019), the ecosystem leader had engaged in bridging activities such as the creation of boundary organization (i.e., Techno Prove) and the relocation of key personnel across boundaries (from ecosystem leader to commercialization partner). Thus, in the absence of such specific attention to configuration activities, neither of the ecosystem actors would have been able to work in tandem, nor would the output have garnered legitimacy and acceptance.

Finally, the extant research illustrates the value of boundary work for the development of innovations for grand challenges. For instance, Cartel et al. (2019) discussed the importance of experimental spaces in initiating institutional innovation, while Zietsma and Lawrence (2010) addressed the importance of boundary breaching, bolstering, creating, and connecting activities in supporting innovation. However, most of the configurational boundary work literature on organizing considers "boundaries as subject to 'work' but regards boundaries as fixed and immobile" (Langley et al., 2019, 721), ignoring a dynamic processual perspective, despite the value of the concept to fluid and open-ended theorizing. For example, in the context of organizational design, Oldenhof et al. (2016) highlighted how organizational classifications are produced, renegotiated, and accepted over time. We addressed this gap by developing a dynamic processual perspective of configurational boundary work that involves iterative interactions between various boundary work components in innovation ecosystem creation. As discussed earlier, within each phase of innovation, we observed an iterative play of configurational boundary components that involved their arrangement and reshaping according to the needs of the innovation. This had been complemented by an iterative dialogue among the ecosystem actors. This enabled the actors to deal with the conditions of absolute uncertainty, wherein the boundaries had initially been amorphous, and the actors had played fluid roles subject to change. During this period, the ecosystem leader had arranged boundaries and created temporary bounded spaces to support ideation and experimentation within the ecosystem. As the uncertainty around the innovation and context had decreased, the ecosystem leader had been able to better structure and define the boundaries. To summarize, to illustrate both the iterative and evolutionary aspects that change depending on the nature of uncertainty, we developed a dynamic processual perspective of configurational boundary work.

6.2 | Practical implications

Our research has important practical implications for policymakers, innovators, and other innovation ecosystem actors. The first is that the process of innovation ecosystem creation for grand challenges in emerging markets involves a set of steps, each of which is likely to be highly uncertain in its outcome. This requires the ecosystem actors to engage in an iterative, non-linear, and decentralized set of actions. Thus, a key practical requirement for those trying to create innovative ecosystems in contexts of absolute uncertainty is to understand the dynamic and iterative nature of the process involved.

A second practical implication that arises from the temporal and multi-disciplinary nature of innovation ecosystem creation is that such processes are likely to require the involvement of a wide variety of actors who may not traditionally collaborate or even understand each other well. This requires the ecosystem actors to work across disciplinary boundaries. Ecosystem leaders thus need to foster collective action among different actors by creating spaces for dialogue and by communicating the grand-challenge-oriented vision of the innovation.

Third, we offer ecosystem leaders insights into the managerial actions to be taken during the different phases of innovation development. During the ideation stage, the focus of the co-creation effort is on developing ideas with ample scope for course correction, as many aspects are likely to be unknown in the context of addressing the grand challenge in an emerging market. Hence, managerial policies should allow ample scope for scientists and engineers, not just for laboratory-level development, but also for new boundary configurations, both internal and external to the organization. Therefore, during this phase, the actors engaged in innovation activities need to be sensitized to work within amorphous and uncertain boundaries. During the experimentation phase, the leader needs to provide the space for the creation of bottom-up social practices that enable dialogue and experimentation. It is therefore important for the ecosystem leader to create spaces in which experimentation can take place across different types of boundaries. Finally, an important task in the translation phase pertains to the establishment of legitimacy. The ecosystem leader needs to create spaces suited to encourage key actors to engage in legitimizing activities across boundaries through appropriate physical infrastructure, policies, systems, and processes. For instance, in a context that is constrained by institutional voids, the leader may have to forgo the temptation of withholding crucial process knowledge from certain stakeholders, and rather encourage innovation developers to reach out to significant external stakeholders.

Finally, our study offers policy implications for governments to support innovation ecosystem development in emerging market contexts. As mentioned earlier, the presence of institutional voids alongside the complexities of grand challenges may cause uncertain outcomes and difficulties in envisioning, *ex-ante*, a pathway for ecosystem emergence. The SCTI, as an innovation ecosystem leader, had been able to navigate these barriers through configurational boundary work, presenting an alternative. In such contexts, government policy, could therefore focus less on policy interventions in the form of legislation and policy guidelines, and more on creating and supporting those organizations that might take on the role of ecosystem leaders. This would entail two interventions. First, a deep dive into talent identification to encourage entrepreneurial individuals to take up leadership roles in such organizations. Second, a close interaction between the government and such organizations enables the formulation of supporting policies and interventions as and when contingencies arise. In the case of the SCTI, for example, the necessary standards related to biomedical devices in India had been implemented at different stages of the device development process.

6.3 | Limitations and future research

Despite its multiple contributions, the scope of this research was limited by its focus on a single historical case study. Considering the limited extant research on the creation of innovation ecosystems for tackling grand challenges in institutional void settings, our key thrust was on context-based theory development using historical data. Although we engaged in providing detailed, thick descriptions of the data to increase the transferability of our findings (Guba & Lincoln, 1994), we are unable to offer empirical generalizations to other contexts, as the governance of innovation ecosystems differs. However, our study enables similarly placed actors (e.g., innovation ecosystem leaders tackling grand challenges in other emerging markets) to abstract and transfer insights into their specific settings (Langley, 1999). Future research could study the creation of multiple innovation ecosystems for tackling grand challenges to develop more generalized insights and theoretical propositions.

Second, we primarily focused on the activities and practices enacted by the ecosystem leader in shaping the emergence. Future research could draw upon role theory and research different innovation ecosystem roles (Dedehayir et al., 2018) to understand the practices in which other ecosystem actors engage during the creation of an innovation ecosystem. In this regard, the rise of maker spaces and community-driven open innovation initiatives offers an interesting opportunity to understand the boundary work done by communities in creating innovation ecosystems. This could complement the emerging research that discusses concepts such as ecocentric innovation ecosystems (Sahasranamam & Soundararajan, 2022) and open innovation ecosystems (Alam et al., 2022).

Third, our research is among the few to have hitherto focused on the indigenous development of product innovation aimed at tackling grand challenges to theorize on contextual aspects. Further research focused on such unexplored settings is needed at both the product and ecosystem levels to understand the capabilities and processes needed to develop contextualized innovations aimed at tackling grand challenges (c.f. Chatterjee & Sahasranamam (2018) for research questions).

To conclude, with our research, we developed a conceptual framework suited to understanding the processes and practices in which ecosystem leaders engage to create innovation ecosystems in contexts of absolute uncertainty, such as those aimed at tackling grand challenges in institutional void contexts. We highlighted how our case ecosystem leader had engaged in three types of configurational boundary work—namely, establishing ecosystem configuration, modeling ecosystem configuration, and expanding ecosystem configuration—to deal with contexts of absolute uncertainty. This may serve as a valuable guiding tool for innovators, other ecosystem actors, and policymakers engaged in developing innovation ecosystems aimed at tackling grand challenges in institutional void settings.

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