R&D MANAGEMENT

From laboratory to clinic: science commercialization within university-centered entrepreneurial ecosystems

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The commercialization of scientific discoveries within the university-industry nexus is multi-faceted and complex, characterized by dynamic interactions between multiple agents, organizations, and institutions. These interactions support a university-centered entrepreneurial ecosystem (UCEE). Our study investigates agent-institution dynamics within the UCEE to explore how individual agents seek to commercialize their scientific discoveries. Specifically, relying on 47 narrative interviews, we explore how UCEE agents across three UCEEs in the United States, United Kingdom, and Russia respond and adapt to institutional commercialization mandates during commercialization of their stem cell-based regenerative medicine discoveries. Our findings emphasize the bi-directional relationship between individual agents and institutions within a UCEE, facilitating a much-needed multi-level perspective on academic entrepreneurship research. We extend recent frameworks that propose how the formative stages of the entrepreneurial process – opportunity evolution – influences ecosystem emergence. Specifically, by investigating the latter stages of the entrepreneurial process – how (science-based) opportunities are commercialized within UCEEs – we reveal distinct behavioral responses to science commercialization mandates, which underscore how UCEEs evolve. Furthermore, by explicating the importance of UCEE agent behavior during science commercialization, our study shines an important spotlight onto the microfoundations of science commercialization and UCEEs. Our research imparts important policy implications for institutions tasked with commercializing scientific discoveries and policy makers challenged with developing high growth, sustainable UCEEs.

1. Introduction

Commercializing scientific discoveries are a complex process. Taking these discoveries from the laboratory to the clinic, especially for life science inventions, involves commitment from and interactions by individual agents with a myriad of organizational support entities and institutions. Scientific discoveries often emanate from universities (i.e., institutions); technology transfer offices (TTOs) (i.e., organizational support entities) working alongside academics (i.e., individual agents) facilitate the translation of these discoveries across the university-industry boundary to the marketplace (Rothaermel et al., 2007). This interplay of individual agents, organizational support entities, and institutions form the basis of a university-centered entrepreneurial ecosystem (UCEE).

Research on UCEEs as a distinctive entity remains scarce, especially their role as a facilitator of or obstructer to possible commercialization pathways. Since science commercialization is characterized by multifaceted agent-organization-institution interactions, studying science commercialization from a UCEE perspective is critical. UCEEs have been described as a fulcrum for commercial activity, characterized by the dynamic relationship between agents, organizations, and institutions, which facilitates technology transfer activities (Johnson et al., 2019). This multitude of agents, organizational support entities, and institutions within UCEEs suggests the need for richer theory (Chang et al., 2016; Fini et al., 2017), which can model their divergent interactions, particularly when commercialization uncertainties exist (Neves and Franco, 2016; Johnson and Bock, 2017).

To account for these agent-organization-institution interactions, research has expanded beyond *single-level* studies to investigate *multi-level* studies. Recent research has investigated the complex relationship between individual and university institutional factors on entrepreneurial behavior and commercial activity (Huyghe and Knockaert, 2015; Wu et al., 2015; Eesley et al., 2016). Yet, this research has limits since it generally considers individual and university institutional factors in isolation, failing to recognize the bi-directional relationship of academic entrepreneurship. We address the limitations of both single- and multi-level research by investigating the bi-directional relationship between individual agents and their institutional environments to understand how this influences science commercialization within UCEEs. This bi-directional relationship is important, and our multi-level study affords us the opportunity to unpack both sides of UCEE engagement, specifically, how institutions act on agents *and* how agents act on institutions. While empirical research has confirmed how entrepreneurial institutions act on agents to promote or hinder science commercialization activities (Rothaermel et al., 2007), less is known about the other side of this dynamic relationship – how UCEE agents act on institutions. Accordingly, we ask: *how do UCEE agents respond and adapt to institutional commercialization mandates during science commercialization?*

Scholars have emphasized the importance of science commercialization as a rich context to develop and test theory (Fini et al., 2019), including the critical role of individual agents in science commercialization (Hmieleski and Powell, 2018). Therefore, we focus our study on a cross-national investigation of regenerative medicine commercialization. To address our research question, we employ an inductive, qualitative methodology consisting of 47 narrative interviews with a variety of agents – that is, scientists, entrepreneurs, executive-level individuals from organizational support entities – embedded in a UCEE and involved in the commercialization of regenerative medicine across three universities, one each in the United States (US), United Kingdom (UK), and Russia.

Our study makes two important contributions to the academic entrepreneurship and science commercialization literature. First, it highlights the dynamic interactions between UCEE agents and institutions during science commercialization within UCEEs. This bi-directional relationship between individual agents and institutions, as well as a focus on UCEEs, facilitates a much-needed multi-level perspective on academic entrepreneurship research (Klingbeil et al., 2019). We reveal how UCEE agents respond and adapt to institutional science commercialization mandates. Specifically, we show how UCEE agents act on institutions through a variety of behavioral responses to prevailing rules and norms ranging from *adhering* (i.e., strictly following), *sidestepping* (i.e., partly following), to *violating* them (i.e., strictly ignoring). This enables UCEE agents to pursue an established or create a new path toward science commercialization. This provides us with the opportunity to delineate how aligned agent-institution engagements within UCEEs reflects an ecosystem that is engineered while misaligned agent-institution engagements underscore an ecosystem that co-evolves (Ritala and Almpanopoulou, 2017).

Second, our focus on UCEE agents affords us the opportunity to address the limited efforts to unpack the microfoundations of science commercialization (Fini et al., 2018; Hmieleski and Powell, 2018) and entrepreneurial ecosystems (Wurth et al., 2021), as

well as bring multiple agent voices from within the UCEE to the forefront of ecosystem research (Hakala et al., 2020). We reveal how behavioral responses by UCEE agents to institutional influences (e.g., constraints) related to commercialization support mechanisms affect science venturing. This is important since these behavioral responses influence the science commercial pathway chosen and entrepreneurial pursuits within UCEEs. Further, these behavioral responses provide feedback to UCEE institutions, which act as signals to adapt its structures, processes, and governance mechanisms. This finding builds upon prior research connecting entrepreneurial processes with entrepreneurial ecosystems (O'Shea et al., 2021). In particular, O'Shea et al. (2021) suggests that entrepreneurial ecosystem formation is centered on a process of opportunity co-evolution. We extend their framework by moving beyond the earlier opportunity evolution stage of the entrepreneurial process and, instead, explore the latter stages of the entrepreneurial process – how (science-based) opportunities are commercialized within UCEEs.

In the next section, we review the literature on science commercialization within UCEEs. Next, we detail the methods and data utilized to address our research question. Following this, we present our study findings. We further elaborate upon these observations in our discussion and advance our contributions to theory. Finally, we consider the implications of our findings and provide areas for future research.

2. Literature review and theoretical framing

2.1. *Entrepreneurial ecosystems: toward a UCEE*

Commercializing science is an inherently risky process; it involves multiple parties with divergent goals that operate across organizational boundaries. Only a few exemplar studies fully describe and explain how entrepreneurial agents act during this process, especially within diverse UCEE settings (*cf.* Johnson et al., 2019). Investigating the distinctive characteristics of science commercialization associated with entrepreneurial behavior within a UCEE is timely because it helps to explain the complex dynamics of various agents and institutions.

The evolution and performance of an entrepreneurial ecosystem is dependent upon the interactions between three critical components – individual agents, organizations (including their organizational agents), and institutions (Brown and Mason, 2017; Spigel, 2017). The behavior and actions of individual agents are central to explaining how entrepreneurial ecosystems function (Stam, 2015; Wurth et al., 2021). Investigating how individual agents dynamically interact with institutions is important to our understanding of entrepreneurial ecosystem evolution. Unfortunately, the interactions between agents, organizations, and institutions remains fuzzy (Alvedalen and Boschma, 2017).

The evolutionary pathway of an entrepreneurial ecosystem depends heavily on individual ecosystem agents but emerges from a highly institutionalized framework. Despite their importance, the dynamics and evolution of entrepreneurial ecosystems are poorly understood (Cho et al., 2021; Dedehayir et al., 2018). Of particular interest, is a greater understanding of *'which parts of the ecosystem are (and can be) engineered and which parts are self-organized or co-evolve'* (Ritala and Almpanopoulou, 2017, p. 41). Understanding the role of ecosystems agents in shaping ecosystem evolution is, therefore, timely. While research exploring entrepreneurial ecosystems has been the subject of recent conversations (c.f. Alvedalen and Boschma, 2017; Spigel, 2017; Cho et al., 2021; Wurth et al., 2021), with a few exceptions (c.f. Miller and Acs, 2017; Hayter et al., 2018; Johnson et al., 2019), studies investigating UCEEs are limited. Given the importance of UCEEs to science commercialization activities (Johnson et al., 2019), this limited understanding of UCEEs is problematic.

Science commercialization is, generally, characterized by specialized knowledge requirements, high discovery costs, technological uncertainties, and long gestation periods. Accordingly, science commercialization favors centralization, especially around research universities. UCEEs are embedded networks of agents, supporting organizations, and institutions that reinforce specific technologies. A UCEE forms when these embedded networks of agents, supporting organizations, and institutions respond to (and possibly adapt) institutional commercialization mandates and engage in technology transfer, driving science commercialization and a cluster of new ventures (Johnson et al. 2019).

In knowledge-intensive sectors, such as regenerative medicine, technology transfer activities are challenging (Bock and Johnson, 2018). To make scientific and commercial progress, UCEE agents must navigate institutional mandates. While institutional mandates have been shown to influence UCEE agents to drive science commercialization (Rothaermel et al., 2007), it is unclear how UCEEs remain vibrant and evolve when individual efforts appear frustrated or are deadlocked. We have limited

knowledge of how UCEE agents act on institutional mandates when they challenge, or are perceived to challenge, science commercialization. Research has detailed how agents operating in suboptimal institutional environments can still act entrepreneurially to drive commercial activity (Lucas and Fuller, 2017), including strategies to bypass institutional mandates (Gianiodis et al., 2016) and directly engage agents with the UCEE/region (Pugh et al., 2018). Similarly, in some instances of R&D activity, like-minded agents may escape the constraints of institutional mandates, or break with institutional norms, to act entrepreneurially *via* bootlegging efforts (Criscuolo et al., 2014). Therefore, to understand how UCEE agents respond and adapt to institutional commercialization mandates during science commercialization, a multi-level approach is required.

2.2. *Multi-level relationships within UCEEs*

Entrepreneurial ecosystems evolve based on the dynamic characteristics and interactions between and among agents and institutions (Pitelis, 2012). In this study, we apply a systems view to the behavior of UCEE agents and their interactions with UCEE institutions. Building upon Hakala et al. (2020), we *bring in multiple voices and more main characters* from within *multiple* ecosystems. Specifically, we take a much-needed microfoundations approach to entrepreneurial ecosystems (Wurth et al., 2021) to understand how UCEE agents interact with institutions during science commercialization activities.

From an individual-level perspective, behaviors and attitudes of the academic scientist are important in predicting commercialization outcomes (Azagra-Caro and Llopis, 2017; Holley and Watson, 2017). There is an extensive literature that investigates how individual agents influence science commercialization, especially within a university setting (*cf.* Perkmann et al., 2013; Hmieleski and Powell, 2018; Civera et al., 2020). How individual scientists perceive institutional support may influence their entrepreneurial intention to engage in science commercialization.

At the organizational level, science commercialization is dependent on support functions and intermediaries (Villani et al., 2017; Clayton et al., 2018; Iacobucci et al., 2020). While the literature relies heavily on the study of formal mechanisms, more recent research suggests that commercialization can occur *via* informal 'back-door' mechanisms, when individuals bypass established TTO commercialization pathways (Markman, 2015; Gianiodis et al., 2016), or *via* bootlegging activities (Criscuolo et al., 2014).

From an institutional-level perspective, we adopt the approach of Huyghe and Knockaert (2015) and view the organization as institution. In doing so, we recognize that institutional elements surface from within the organization itself and operate across multiple levels (Zucker, 1987; Scott, 2008). At each of these levels – e.g., the UCEE (Johnson et al., 2019), the university (Huyghe and Knockaert, 2015), individual university departments (Rasmussen et al., 2014), or the TTO (Baglieri et al., 2018) – there is either support or barriers to science commercialization activity.

Within UCEEs, universities implement institutional policies, processes, norms, and mandates that seek to support science commercialization in theory but may not always in practice. Despite institutional science commercialization barriers (Bock and Johnson, 2016), research has also found that, even in institutional challenging contexts, scientists still find ways to pursue entrepreneurial activities (Meoli and Vismara, 2016). This suggests that while institutions affect entrepreneurial behavior, individual entrepreneurial activity both influences the institutional environment and/or overcomes its limitations (Lucas and Fuller, 2017). Yet, our understanding of this bi-directional relationship within a UCEE remains limited, especially within the context of academic entrepreneurship. Given this gap in knowledge, our departure is centered on the dynamic between institutions influencing entrepreneurial behavior and institutions *being* influenced by individual agents.

3. Methodology

To explore agent-institution dynamics, we investigated science commercialization in the field of stem cell-based regenerative medicine. Since regenerative medicine research is predominantly situated within research institutions, and involves interactions between multiple agents, organizational stakeholders, and institutions, this provided the necessary conditions to explore agent-institution dynamics within a UCEE. At the same time, given the scientific and translational complexities inherent to science commercialization in this field (see Bock and Johnson, 2018), regenerative medicine commercialization represents an excellent context for building and testing theory predicting science commercialization outcomes.

We studied regenerative medicine commercialization activity across three research-intensive universities within three countries: the United States,

the United Kingdom, and Russia. To preserve the anonymity of the UCEEs under investigation, we do not directly identify them. The UCEEs that we studied included a large US research institution and its associated UCEE (UCEE US); a large UK research institution and its associated UCEE (UCEE UK); and a large Russian research institution and its associated UCEE (UCEE Russia). We provide further information relating to the selection of UCEEs in Appendix A.

3.1. Data collection: narrative interviews

We employed a long-form narrative interview format (McCraken, 1988; Jovchelovitch and Bauer, 2000). A narrative interview approach was particularly suited to this inductive investigation since it enabled reflective meaning-making (Jovchelovitch and Bauer, 2000) and deeper theorizing (Larty and Hamilton, 2011). Selection of informants was purpose-based (Morse et al., 2002), focusing on informants that were directly involved in regenerative medicine commercialization activities and had close connections with their respective UCEE. This resulted in three categories of UCEE agents: (1) regenerative medicine entrepreneurs (ENT); (2) regenerative medicine academic scientists (AS); and (3) executive-level agents from regenerative medicine supporting entities (SEA) who were directly involved in science commercialization activities. Further information relating to the three categories of UCEE agents is provided in Appendix A.

Consistent with a narrative interview approach, target informants were asked to *'describe your role in regenerative medicine commercialization'*. Across the three UCEEs, the lead author conducted 47 narrative interviews between November 2012 and May 2015. A full list of informants is reported in Table 1.

3.2. Data analysis procedures

Our data analysis began with a fine-grained review of the transcripts. The analysis involved three phases following prior inductive methods (Strauss and Corbin, 1990; Charmaz, 2006; Gioia et al., 2012). All coding was performed using NVIVO software.

Phase I. We began by carefully reviewing the transcripts, along with the field notes. Initially, we open-coded the data developing first-order codes (Strauss and Corbin, 1990). As themes emerged, we compared them both within and across transcripts, and with the field notes. Throughout this process, we were careful not to lose sight of the intact narratives and strove to preserve their depth and richness by staying close to informants' interpretations.

Phase II. We then progressed with axial-coding. This involved structuring the first-order codes into second-order themes, which relied on searching for relationships between codes and grouping them into common themes (Strauss and Corbin, 1990). We moved back and forth between our data and extant theory to develop themes that were grounded in our data but expanded upon with the help of existing concepts. During this process, we employed the constant comparative method (Glaser, 1965).

Phase III. The final phase of data analysis involved the identification of theoretical dimensions from the second-order themes. In developing these dimensions, we engaged in inductive and deductive reasoning, connecting our inductive codes and themes with extant concepts and frameworks.

4. Findings

Figure 1 illustrates the data structure that emerged from our analysis of the 47 narrative interviews. In Appendix B, we show 'proof' quotes (Pratt, 2008) from the interview narratives that led to the development of the second-order themes and theoretical dimensions. We discuss our findings, paying close attention to the theoretical dimensions that surface the *institutional science commercialization support mechanisms*, *UCEE science venturing*, and most importantly, *UCEE agent-institution dynamics*.

4.1. Institutional science commercialization support mechanisms

Commercialization support mechanisms are critical for science commercialization activities. Across the three UCEEs, we witnessed significant differences between their commercialization policies and processes. Yet, consistent across the UCEEs, was that each research institution had strong mandates to commercialize regenerative medicine. For example, the creation of purpose-built regenerative medicine centers within each UCEE, whose core mission is to foster science commercialization and translate stem cell research from the laboratory to the clinic/market, further supported institutional-wide mandates and commercialization activities. In addition, there were numerous entrepreneurial training and educational programs across the UCEEs. Some of these programs were embedded at the university-level, where we witnessed programs offered by the university's TTO or Business School. Other programs were focused at the UCEE-level and were typically overseen by state-funded innovation organizations.

Table 1. Informant information

Informant #		Category[1]	Informant role	Organization type
UCEE UK	1	SEA	Executive	Government-backed org. Supporting regenerative medicine community
	2	ENT	Founder	Operating in tools/diagnostics, but offering services too
	3	ENT	Founder	Provides regenerative medicine technical support & services
	4	ENT[2]	Founder	Primarily involved in stem cell training & consultancy
	5	AS	Manager	University academic scientist (Principal Investigator)
	6	SEA	Manager	Government-backed org. Fostering economic growth
	7	SEA	Executive	Supports academic innovation & commercialization
	8	SEA	Manager	Supports technology transfer activities & innovation
	9	AS	Executive	University academic scientist (Principal Investigator)
	10	ENT	Founder	Regenerative medicine products & services organization
	11	SEA	Manager	Supports life science community & regional growth
	12	SEA	Manager	Supports UK healthcare community & fosters innovation
	13	ENT	Founder	Operates in the RM tools & diagnostics space
	14	ENT	Founder	Biotechnology & stem cell services organization
	15	SEA	Executive	Creating a cell therapy industry & community
	16	ENT	Founder	Provides products & services to the stem cell sector
	17	SEA	Manager	Encourages innovation & economic development
	18	SEA	Manager	Supports regional economic growth
	19	ENT	Founder	Regenerative medicine diagnostics venture
	20	SEA	Executive	Promotes life science commercialization & collaboration
	21	SEA	Executive	Promotes technology transfer & venture formation
	22	AS	Executive	University academic scientist (Principal Investigator)
	23	SEA	Executive	Promotes technology transfer & venture formation
UCEE US	24	SEA	Manager	Promotes technology transfer & venture formation
	25	ENT[2]	Founder	De novo regenerative medicine tools & therapeutics venture
	26	ENT[2]	Founder	De novo regenerative medicine tools & therapeutics venture
	27	SEA	Manager	Fosters regional economic growth
	28	SEA	Executive	Promotes scientific & technological innovation
	29	SEA	Executive	Supports new venture creation & growth
	30	ENT	Founder	De novo regenerative medicine tools, diagnostics & therapeutics venture
	31	SEA	Manager	Promotes technology transfer & innovation
	32	AS	Executive	University academic scientist (Principal Investigator)
	33	ENT[2]	Founder	De novo regenerative medicine tools & therapeutics venture
	34	SEA	Executive	Promotes technology transfer & innovation
	35	SEA	Manager	Supports venture investments
	36	SEA	Manager	Supports venture investments
UCEE Russia	37	ENT	Founder	Regenerative medicine therapeutics, tools, diagnostics, & services
	38	AS	Executive	University academic scientist (Principal Investigator)
	39	ENT[2]	Founder	De novo regenerative medicine tools venture
	40	SEA	Manager	Supports tech. Commercialization & new venture formation
	41	AS	Executive	University academic scientist (Principal Investigator)
	42	SEA	Executive	Supports tech. Commercialization & new venture formation
	43	SEA	Executive	Supports biomed commercialization & venture development
	44	AS	Executive	University academic scientist (Principal Investigator)
	45	SEA	Manager	Supports licensing & technology transfer
	46	ENT	Founder	Stem cell services venture
	47	ENT	Founder	Regenerative medicine therapeutics, tools, diagnostics, & services

[1]AS: Academic Scientist; ENT: Entrepreneur; SEA: Support Entity Agent.
[2]Indicates instances where the entrepreneur was a prior academic scientist.

1st Order Codes	*2nd Order Categories*	*Theoretical Dimensions*
Academic engagement in commercialization activities Tensions between scientific research and commercialization activities	Academic entrepreneurs	***Institutional science commercialization support mechanisms***
University/TTO policies, processes, metrics, and commercialization models Institutional support and training for commercialization activities Promotion of new/enhanced commercialization approaches	Technology transfer	
Institutional translation facilities Science commercialization centers Science Parks Laboratories Incubators Accelerators	Institutional supporting infrastructure	
Current or future unknowns	Uncertain venturing landscape	***UCEE science venturing***
Physical resources Financial and human capital Knowledge and capabilities	Tangible and intangible resources	
Establishing trust Validating current or future science commercialization models and/or innovation Influencing key stakeholders Aligning science commercialization activities with established norms	Venture legitimacy	
Business models and spin-out venture formation Commercialization timeframes Regional economics Visioning and goal setting	Science commercialization activities	
Collaborations and partnerships to progress scientific innovations and the venture's science commercialization activities Individual and organizational learning as a consequence of collaborations and partnerships Networks	Knowledge capabilities	
Translation of scientific innovations within existing technology transfer and commercialization structures and policies	Adhering	***UCEE agent-institution dynamics***
Translation of scientific innovations through political means and lobbying to change/adapt/shape existing technology transfer and commercialization structures and policies	Sidestepping	
Translation of scientific innovations by operating and engaging in science commercialization activities outside the existing technology transfer and commercialization structures and policies	Violating	

Figure 1. Data structure.

Table 2. Institutional science commercialization support mechanisms: UCEE agent quotes

Example	UCEE agent quote
A	'*…I find that extremely difficult to encourage…spinouts take a lot of time and a huge amount of work… academics are judged by their papers and grants, not commercial activities*. (Informant #9 – UCEE UK AS)
B	'*…they have funded very significantly our research and we could take this research into the clinic…it is surprising because we have everything, we have all the technology to create, for example, tissue banks, skin banks, or draft banks…and I do not know why they do not want to help commercialize, I cannot answer this question…they have funds and the policies, but they do not support the commercialization of this scientific work.*' (Informant #41 – UCEE Russia AS)
C	'*…And I view that as being critical because the way that our scientific environment is structured, we publish papers, research, and get proposals funded…we cannot have impact…we are unable to commercialize fundamental discoveries…*' (Informant #33 – UCEE US ENT)

Additionally, each UCEE offered various platforms to support science commercialization activities. Informants talked about translational programs and proof-of-concept programs to assist regenerative medicine commercialization activities. Others talked about physical infrastructure, including platforms such as incubators or accelerators, as a support during the long gestation period. Despite these mechanisms and platforms, we observed deviances from commercialization mandates across the UCEEs, with agents in the form of some senior academics discouraging science commercialization activities – see Table 2, example A. Others spoke about institutional mandates to engage in commercialization activities as being nothing more than 'lip-service' – see Table 2, example B. This provided evidence of goal misalignment across the UCEEs, which created potential conflicts for agents engaging in commercializing activities, as highlighted in Table 2, example C. In example C, we observe a scientist-turned-entrepreneur utilizing

language (e.g., publications, research, and grant funding) that is more aligned to an academic identity rather than a commercialization-focused entrepreneurial identity.

We also witnessed preferences toward the vehicle for translational activities across the three UCEEs. Specifically, UCEE US favored spinout ventures, UCEE UK emphasized licensing, while UCEE Russia was more flexible and had no preference between spinout or licensing. These variances suggest varied UCEE priorities and/or limited commercialization options, which placed pressure on individual scientists who sought commercial pathways that differed from the intuitional norms.

In sum, our study found several contradictions across the research settings. While all UCEEs had formal mechanisms to promote science commercialization, UCEE agents' perceptions of the legitimacy of these mechanisms differed greatly for each UCEE, which had important influences on agent commercialization behavior and commercialization pathway choices. In part, commercialization activities require academic scientists to first identify any individual-institutional conflicts toward science commercialization and then be adept at overcoming them.

4.2. UCEE science venturing

Our findings across the UCEEs revealed the uncertainties inherent to science venturing. UCEE agents consistently spoke of the ethical uncertainties and challenges surrounding regenerative medicine, which created tension with the University's TTO mission. Others spoke of regulatory uncertainties associated with regenerative medicine venturing – see Table 3, example A. At the same time, many spoke, more generally, of the institutional challenges to commercializing regenerative medicine innovations and science commercialization. The guidance provided by the university and TTO to these institutional challenges helps to form the UCEE agent-institution dynamics and commercialization pathway.

A critical element of the commercialization pathway was the regenerative medicine venture's business model. Across the UCEEs, our findings illustrate informants discussing both current and future business models. Legitimizing these business models was an important factor of the commercialization pathway within our dataset across the UCEEs. Yet, the commercialization pathway was constrained by the availability of resources. All UCEEs faced significant financial capital constraints because they operated in capital deficient institutional environments. However, resource munificence is not solely about financial capital; UCEE Russia, much like new ventures, faced significant human capital constraints, which required UCEE agents to look beyond the immediate UCEE and attract international human capital to enable science commercialization activities – see Table 3, example B. Such activities emphasize the requirement of UCEEs to have porous boundaries, where people and knowledge can ebb and flow. For science commercialization, this is imperative since life science venturing, especially in nascent markets, requires ventures to leverage knowledge capabilities within and across the UCEE. As such, and encouragingly, our findings revealed the importance of planned collaborations and partnerships as a necessary requirement and strategy for science commercialization activities. Similarly, our findings also revealed the importance of networks in fostering science commercialization within the UCEE. While some of these networks were formal and as a result of established science commercialization mandates, others were more informal, as shown in Table 3, example C. Again, in Table 3, example C, we witness a scientist-turned-entrepreneur struggling with a commercialization-focused entrepreneurial identity.

4.3. UCEE agent-institution dynamics

The idiosyncratic nature of science commercialization influenced how UCEE agents responded to institutional mandates. While we know that entrepreneurial action is driven by individual agents'

Table 3. UCEE science venturing: UCEE agent quotes

Example	UCEE agent quote
A	'*…it's broke, you have got a broken regulatory system strapped onto a broken venture capital system…*' (Informant #10 – UCEE UK ENT)
B	'*To have good results in our organization we need people…we tried to find leading people in different countries and ask if they have the possibility to come work here in Russia. We go to States, to Germany, to Holland…we need these guys to have advantage in this technology.*' (Informant #39 – UCEE Russia ENT)
C	'*I've been going to as many of the informal local entrepreneurial network meetings. You know, trying to meet people…to kind of get some insight as to what it takes. It's still a foreign world to me 'cause' none of my training to this point has been in this area (entrepreneurship).*' (Informant #26 – UCEE US ENT)

assessment of relative institutional support, our findings build on this. Across the three UCEEs, our findings reveal agent behavior (i.e., entrepreneurial action) toward science commercialization manifests in various ways. In particular, we see distinct agent behavioral responses toward science commercialization as a consequence of differences in institutional mandates (or lack thereof) and institutional support (or lack thereof) across the three UCEEs. Specifically, we observe *adhering*, *sidestepping*, or *violating* behaviors to progress science commercialization.

4.3.1. Adhering (UCEE US)

Within UCEE US, we report both a well-developed and perceived supportive institution toward science commercialization:

…She really urged me to talk to [The TTO] and file an IDR…I talked with them…they were so supportive…they're like, 'Yes, file something. You know, this is really cool.' And so, I put it in, and they said, 'we want to move this forward,' and I feel like all of a sudden, I have this opportunity that is not likely going to happen elsewhere. (Informant #25 – UCEE US ENT)

Thus, we witness entrepreneurs partaking in science commercialization activities within the current prevailing institutional mandates:

…it was a very dynamic and diverse environment and institution to develop a perspective about entrepreneurship and regenerative medicine…we developed a business plan…I was in contact with the TTO…there was some complementary between the two technologies, business plans…And the TTO suggested putting these together and launching a startup, which is what we did. We worked closely with them (the TTO) on the startup and when the company launched, with their support, we immediately began a fundraising effort…And not long after we ended up raising Series A venture financing and we were off and running… we've raised the Series B round and the company is continuing to develop products…now we're exploring interactions with strategic partners, large medical device companies, that have shown an interest in acquiring the technology…that's where our interactions with the university, local university community, and the wider local surrounding community becomes very important. (Informant #33 – UCEE US ENT)

This reflects UCEE agents *adhering* to the existing supportive institutional science commercialization frameworks in place to drive commercialization activities, as further emphasized in the following example:

That's where my entrepreneurial days started in those formative years, here in [this research institution]… my lab develops translational model systems… people in this industry talk to me about the use of our system and when it would be clinically ready for human use…there was one company that wanted to acquire our technology, so we went through the TTO procedures to achieve this. (Informant #26 – UCEE US ENT)

Specifically, adhering reflects the translation of scientific innovations within existing technology transfer and commercialization structures and policies.

4.3.2. Sidestepping (UCEE UK)

Within UCEE UK, despite institutional mandates being in place to support science commercialization activities, UCEE agents repeatedly spoke about challenges and conflicts in their efforts to commercialize their regenerative medicine innovations. For example, some spoke of the institutional challenges toward science commercialization and their fear of agents leaving the UCEE, prior to even commercialization their innovations, due to these challenges:

…if I look at the colleagues that I work with, they're kind of young, and they're very keen [to commercialize] to get it out there and really wanting to make a difference. But they're being stifled -- so many boulders are being put in their way…I fear they will leave sooner rather than later because they feel that they can't do anything. And that is because the university is standing in their way…It's extremely frustrating! (Informant #22 – UCEE UK AS)

Others focused on the misalignment of academic and commercial goals and outcomes:

Part of the funding for that was on the basis that there was a commercial aspect to the activities in this building. That's slightly at odds with what the university interests are…So, you have a bit of a disconnect between the university who wanted this fantastic research facility and some of the funders who say, 'well hang on a minute, we want to commercialize it, we want to see this thing exploited. (Informant #8 – UCEE UK SEA)

As a consequence, within UCEE UK, we observed agents acting upon the institution and *sidestepping* science commercialization institutional mandates to drive forwards commercial activity. Specifically, sidestepping reflects the translation of scientific innovations through political means and lobbying to change/adapt/shape existing technology transfer and commercialization structures and policies:

…we fortunately had an extremely good and influential backer…he heads up the [name of Centre], he's also Chief Executive of [name of organization], plus he's a clinician…he was keen and supportive of the idea…he was our main sponsor within

the university…he said, 'if you wait for them [the University TTO] you'll never do it,' he said 'just do it.' So, we did it, we created the company, and we did it on the basis that the university would, hopefully at due course, join the party once the venture was established…we managed to persuade them…and this was the key I guess, we persuaded them that it was in their interest or the UK's interest in developing this regenerative medicine capability. (Informant #7 – UCEE UK SEA)

4.3.3. Violating (UCEE Russia)

UCEE Russia highlighted strong institutional support to science commercialization activities. However, UCEE agents revealed a perceived challenging institutional environment toward entrepreneurship:

Some three and a half years ago, the [university collaboration] initiative began… Eventually, he got made Director of [role withheld to preserve anonymity of individual]…and he said that he doesn't want to commercialize anymore! (Informant #38 – UCEE Russia AS)

As such, within UCEE Russia, we witnessed UCEE agents acting upon the institution and *violating* science commercialization institutional mandates to drive forward science commercialization pathways. Here, agents were translating scientific innovations by operating and engaging in science commercialization activities outside the existing technology transfer and commercialization structures and policies:

…concerning the translational part, we just have to do it ourselves in Russia…the greatest challenge for us is to overcome this instability and know the rules, and to elaborate our own strategy and to find reliable industrial partners…so I have some fundamental research and that's why I have to commercialize with abroad laboratories and companies in Sweden, in US, and in the UK. (Informant #41 – UCEE Russia AS)

More specifically, within UCEE Russia, we witnessed UCEE agents driving science commercialization activities through reliance on institutions external to the immediate UCEE. In essence, the UCEE was serving as a proxy:

…we started to develop a collaboration with Germans and invest money…Also, we have some collaborations with a lipoxin company on the AIM in UK…we developed this drug together, with our collaborator company in the US…and together with another collaborator in Germany, developed this drug. (Informant #37 – UCEE Russia ENT)

At the same time, we witnessed a strong reliance on expertise and support from outside of UCEE Russia (particularly overseas expertise and support) since this was not available within the proximate UCEE:

…It's especially important inside Russia because what we realize is that people who are doing innovations here, they feel quite alone, they still don't have strong networks…We're trying to invite people from outside…so now we have a community of mentors from US, and other countries… (Informant #40 – UCEE Russia SEA)

Furthermore, there was a heavy reliance on a transplanted-in operating business model:

We are working very closely with [external US institution]…this is the mother of our model…it's a really important factor for us 'cause' we've learned most of what we've learned from [external US institution]… Every week we have a call with a Manager from [external US institution], who is a good friend of ours by now, and we discuss cases, approaches, their practices, how would they go around this case or that case, even policy development…we implement their principles and models here. (Informant #42 – UCEE Russia SEA)

Ultimately, across the different stages of UCEE development within our dataset, we observe a range of agent-institution dynamic interactions distinct to each UCEE. These findings have important implications for science commercialization pathways. We now discuss these implications and offer possible avenues for future research.

5. Discussion

Taking a systems view, we extend earlier work that proposed frameworks and empirically tested conditions when entrepreneurial scientists carved out commercialization pathways under conditions of misaligned and/or limited institutional mandates (Criscuolo et al. 2014; Markman, 2015; Drivas et al., 2018; Klingbeil et al., 2019). Specifically, we discuss the idiosyncrasies of science commercialization within a UCEE, reflecting on the institutional mandates that support (or hinder) UCEE agents advancing science by undertaking commercialization activities. Since this reflects only one part of the dynamic – institutions acting on agents – we continue our discussion to consider the second part of the dynamic – how agents act on institutions during science commercialization, which is an equally important element in determining commercial pathways since this has important implications for how UCEEs evolve.

5.1. Science commercialization within a UCEE

Our findings highlight factors that influence (i.e., positively or negatively) science commercialization

at the individual, organizational, and institutional levels of analysis. At the individual agent level, our findings recognize the importance of UCEE agent behavior. We reveal tensions between how individuals interpret institutional mandates that balance teaching and research with translational activities. In doing so, we recognize the potential role-identity conflicts (Jain et al., 2009) during science commercialization, especially when the commercial path does not follow institutional norms. In some instances, we observe some entrepreneurs struggling with identity, using language more aligned to their prior role as an academic (e.g., publication process and outcomes) rather than commercialization-focused entrepreneurial language. While these scientist-turned-entrepreneurs identify themselves as 'entrepreneurs,' they may still be transitioning from a scientific identity to a commercialization-focused entrepreneurial identity (Hayter et al., 2021). In some instances, they may have not completely transitioned and retain a hybrid academic-entrepreneur identity (Jain et al., 2009), which has been shown to complement science commercialization (Wang et al., 2021).

In translating regenerative medicine innovations from laboratory to the clinic (and even the market), our findings revealed multiple discussions from UCEE agents relating to navigating business model formation and structure within the prevailing institutional mandates. The configuration of the structural elements of the venture's business model will determine how ventures pursue the entrepreneurial opportunity (George and Bock, 2011). Legitimization of the regenerative medicine venture's business model is important too (Jain and George, 2007; Bock and Johnson, 2018).

Additionally, our findings reveal the importance of individual agents in the form of human capital availability, which differed greatly across the UCEEs. Findings revealed the exodus of promising scientists and entrepreneurs in UCEE Russia. While human capital deficiencies are not a new phenomenon, such deficiencies casts doubt on innovation (Michailova et al., 2013), which is problematic for science commercialization and the development of UCEEs. Yet, agents in UCEE Russia were addressing this concern by expanding the boundaries of the UCEE; they actively recruited individuals external to the immediate UCEE, particularly returnee Russian nationals who had spent time in more developed economies, to assist in the development of knowledge capabilities, international knowledge spillovers, and social capital (Liu et al., 2010). This activity is especially important during the early stages of entrepreneurial ecosystem evolution (Schaefer, 2018).

Organizationally, prior research has highlighted how TTOs with clearer policies are better placed to support commercialization activities (Lockett et al., 2003). At the same time, those that incentivize commercialization activities foster venturing (Macho-Stadler and Pérez-Castrillo, 2010). In some instances, our findings revealed that translational activities were driven by the TTO rather than driven by market opportunities. Training for UCEE agents was one norming process TTOs employed. Recent studies have emphasized the importance of TTOs as providers of science and technology entrepreneurship education (Bolzani et al., 2021). Additionally, our findings reveal the importance of dedicated, purpose-built science commercializing centers, as well as incubators and accelerators, and their role in translational activities, emphasizing the importance of organizational infrastructure to science commercialization and UCEE evolution (Kolympiris and Klein, 2017; Clayton et al., 2018; Breznitz and Zhang, 2019; Johnson et al., 2019).

At the institutional-level, institutions can support or hinder science commercialization activity (Huyghe and Knockaert, 2015; Escobar et al., 2017). Our findings revealed that when institutional mandates supported knowledge exchange activities within and across the UCEE, increased collaborations and partnerships were observed. Our observations revealed these collaborations and partnerships to be planned strategic activities (c.f. Mintzberg and Waters, 1985). More specifically, across the UCEEs, there were differences between the emphasis placed by the institution toward encouraging and supporting knowledge exchange activities. This is important to science commercialization since knowledge exchange activities enable the development of knowledge capabilities and absorptive capacity, which are essential for venturing activities and entrepreneurial ecosystems (Alnuaimi and George, 2016; Miller et al., 2016). Yet, while institutions and institutional mandates are important to UCEE science venturing, we also recognize the importance of UCEE agent behavior in driving science commercialization. This agent-institution bi-directional relationship is important and speaks to the wider literature on institutional work (Lawrence et al., 2011), specifically the role of collective agent behaviors in institutional creation work (Farny et al., 2019). Therefore, we now turn our attention to this agent-institution bi-directional relationship.

5.2. *UCEE agents and institutions: a bi-directional relationship*

Our findings provide credence to the belief that UCEE agents act on institutions through *adhering* to, *sidestepping*, or *violating* rules and norms, which enables them to pursue an established or create a new

path toward commercialization. UCEE agents select one of these modes after assessing the prevailing institutional environment and determining if (or to what extent) institutional conditions could support or align to their individual goals. More specifically, within UCEEs at different stages of development, our findings reveal differing agent science commercialization behaviors. First, in established UCEEs (i.e., UCEE US) with perceived supportive institutional mandates toward entrepreneurship, we observe UCEE agents acting upon institutions and adhering to these institutional mandates to drive science commercial activities.

Second, within UCEEs that are still evolving (i.e., UCEE UK), and with perceived challenging institutional mandates toward entrepreneurship, we witness UCEE agents acting upon institutions and adapting and sidestepping institutional mandates to drive science commercialization. For the most part, this behavior is incremental in nature and does not fundamentally challenge the rules of the game. Recent research has highlighted that academics within the life sciences are more likely to bypass formal university commercialization structures (Goel and Goktepe-Hulten, 2018). While confirming individual motivation remains an empirical challenge, (i.e., bypassing formal university commercialization structures may be as a result of ignorance to these structures), in the life sciences, bypassing cannot be explained solely by a lack of knowledge toward university commercialization structures (Huyghe et al., 2016).

Third, in UCEEs at the early stages of development (i.e., UCEE Russia), we observe a fast-evolving UCEE but one with perceived institutional challenges toward science commercialization. As a consequence, we witness UCEE agents acting upon the institution by violating rules/norms and purposely avoiding the immediate UCEE to drive science commercialization activities. More specifically, agents placed a strong emphasis on both external institutions and external expertise, as well as a transplanted-in operating business model during science commercialization. Such activity reflects an attempt to create a parallel commercialization system outside of the existing UCEE, at least in the immediate term, while the UCEE further evolves. This *parallel UCEE* is externally legitimized and resourced and does not engage with the proximate UCEE (other than the UCEE serving as a proxy to receive and distribute financial capital). It also facilitates entrepreneurial behavior akin to bypassing (c.f. Gianiodis et al., 2016) and bootlegging (c.f. Criscuolo et al., 2014), but goes further in an attempt to completely avoid the proximate UCEE in order to successfully drive science commercialization pathways.

Further, our findings of agent behavior, and subsequent science commercialization pathways developed by influencing existing UCEE institutions, suggest important implications for the evolution of UCEEs. Enhancing our understanding of ecosystem evolution is especially timely (Dedehayir et al., 2018; Cho et al., 2021) and best observed by investigating the behaviors of multiple ecosystem agents across several ecosystems (Hakala et al., 2020; Wurth et al., 2021). Accordingly, our findings suggest that when UCEE agents align and adhere to institutional rules, norms, and mandates, this reflects an ecosystem that evolves through an engineered process (Ritala and Almpanopoulou, 2017). Yet, when ecosystems are at the early stages of evolution, it is important not to overlook the importance of ecosystem agents. For example, despite planned institutional mandates designed to engineer ecosystems in a particular way, ecosystem agents can (and do) play a critical role in shaping the direction and evolutionary pathway of the ecosystem (Lowe and Feldman, 2017; Feldman and Lowe, 2018). In particular, the entrepreneurial ecosystem co-evolves (Ritala and Almpanopoulou, 2017) as a consequence of agent behavior. Specifically, when institutional science commercialization mandates challenge venturing activity, UCEE agents can still act entrepreneurially to drive commercial activity (Lucas and Fuller, 2017).

How entrepreneurial processes influence ecosystem emergence and development remains a significant limitation to entrepreneurial ecosystem research (Spigel and Harrison, 2018). At the formative stages of the entrepreneurial process – opportunity development – ecosystem agents have been shown to engage in three distinct opportunity co-evolution phases: co-intuiting, co-interpreting, and co-integrating (O'Shea et al., 2021). In our study, we build upon O'Shea et al.'s (2021) work by exploring the latter stages of the entrepreneurial process – opportunity commercialization. While O'Shea et al. (2021) considers potential commercialization pathways during opportunity co-evolution within entrepreneurial ecosystems, we reveal how UCEE agents enact science commercialization pathways based on their behavioral responses to science commercialization mandates (i.e., adhering, sidestepping, violating). In doing so, we highlight how UCEEs evolve based on distinct behavioral responses to science commercialization mandates. As such, we contribute to the limited research connecting (phases of) the entrepreneurial process (e.g., opportunity commercialization) to entrepreneurial ecosystems emergence (Spigel and Harrison, 2018; O'Shea et al., 2021).

5.3. *Limitations and future research*

As with all research, there are certain limitations to our study, which future research should address. First, the complex legal, regulatory, ethical, funding, technological, and operational uncertainties inherent to regenerative medicine commercialization (Bock and Johnson, 2018) may have unique consequences for science commercialization activities, which may be otherwise absent/different for less controversial and complex technologies. Further studies could explore other scientific fields, such as nanotechnology or synthetic biology, to observe whether we see the same behavioral responses to science commercialization mandates and UCEEs evolution. Further, our findings may not be generalizable to wider entrepreneurial ecosystems. For example, within UCEEs, entrepreneurial activities are not the sole/predominant role of universities, unlike more traditional entrepreneurial ecosystems (Canter et al., 2021). Within UCEEs, commercialization success may come at the expense of academic success (George and Bock, 2008). Future research should examine entrepreneurial ecosystems with a limited university presence to observe if our research findings hold true.

Second, ecosystems are dynamic in time and space (Canter et al., 2021). Yet, we rely on a static, cross-sectional dataset. However, during the interviews, UCEE informants did recall historic information regarding science commercialization activities within the UCEE. Related, this static focus prevents us from examining how UCEE agent behavior changes over time. Therefore, researchers should employ longitudinal methodologies that capture changes in agent behavior and organizational and institutional arrangements. This may shed light onto whether we see shifts in UCEE agent-institution dynamics. For example, future research could investigate whether we see shifts from sidestepping or violating behaviors to adhering behaviors if/when the UCEE has better science commercialization support mechanisms in place. This will build upon recent work exploring the role of agency and institutional creation work (Farny et al., 2019).

Third, given that, ultimately, the end goal for the different actors was the commercialization of a stem cell innovation, we dealt with the three different groups of UCEE agents in our study as a collective since all had the same end goal in sight. Therefore, we should be mindful that our findings are not specific to each distinct agent role. At the same time, we should be mindful that our dataset includes some scientist-turned-entrepreneurs. Our findings hint toward these agents taking a hybrid scientist-entrepreneur identity (Jain et al., 2009; Hayter et al., 2021), which warrants further investigation prior to generalizing our findings more broadly to entrepreneurial agency. Further research should explore these different UCEE agents in further detail, perhaps developing psycho-social models of individual behavior.

6. Conclusion

Our study examined agent-institutional dynamics during science commercialization activities and represents an important step forward in our understanding of entrepreneurial behavior within UCEEs. We reveal the idiosyncrasies of science commercialization activities across three UCEEs at differing stages of development. First, by investigating science commercialization within a UCEE, as well as exploring agent-institution dynamics, we address both the limitations of uni-level studies and studies that fail to consider the bi-directional relationship between agents and institutions. In our study, by adopting a multi-level approach and investigating how institutions act on agents *and* how agents act on institutions, we close this gap in the literature. In doing so, we reveal important implications for UCEE evolution. From a policy perspective, this is important since it reveals the need to align institutional science commercialization mandates to agent entrepreneurial behaviors, motivations, and intentions. Doing so may prevent the unintended outcome of bypassing (Gianiodis et al., 2016) or bootlegging (Criscuolo et al., 2014).

Second, by taking a microfoundations approach, we demonstrate the behavioral responses of UCEE agents to institutional expectations and pressures. Specifically, we capture the nuances of the science commercial mode choice – how UCEE agents seek possible commercial pathways given perceived benefits and limits in their institutional environment. This finding has policy implications; crafting strong yet flexible institutions that better align individual interests are likely to prevent UCEE agents from enacting extraordinary quasi-institutions.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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APPENDIX A Additional information relating to the selection of UCEEs and UCEE agents

We chose our research settings based on three criteria: first, given that the formation of UCEEs is a global phenomenon, we wanted a sample of UCEEs across multiple countries. Second, we wanted different types of universities – that is, driven by both explicit and implicit missions and strategies. Third, we required UCEEs to span different stages of regenerative medicine commercialization activity.

We began our search of appropriate research contexts by investigating UCEEs with dedicated stem cell research centers/institutes. Complementing this search, we studied stem cell/regenerative medicine patent data, and journal and news articles, to catalog UCEEs that were active in regenerative medicine commercialization. Our search surfaced many suitable UCEEs from across the globe. From this sample frame, we selected three institutions where the authors had current relationships, which could contribute to a secured access to the different agents operating in the UCEEs.

Each of the UCEEs under investigation have sufficient similarities (e.g., a dedicated stem cell center/institute, world renown scientists, etc.) and differences (e.g., at different stages of regenerative medicine commercialization, level of endowed resources, etc.), in addition to being geographically dispersed. Of the three locations, the UCEE US has the longest history of regenerative medicine commercialization. The UCEE UK reflects a UCEE that has a less established history of regenerative medicine commercialization in comparison to UCEE US. Finally, UCEE Russia, while less established than the other two UCEEs, was created with a key strategic focus to foster an entrepreneurial ecosystem.

Within our dataset, the entrepreneurs were founders of regenerative medicine spinouts from the respective university but also included more established ventures that were connected to the UCEE in some way. For example, some of the more established ventures were operating from the university science park, while others had technologies through research collaborations with the university. Some of the entrepreneur informants were prior academic scientists, as indicated in Table 1. All the academic scientists were Principal Investigators operating out of the stem cell labs of the university. Support entities were either directly linked to the university (i.e., the university TTO) or operated closely with the university (i.e., provided regional support for stem cell scientists and entrepreneurs). This support ranged from grants for research and/or venturing activities, business training, assistance with industry collaborations, and/or assistance in connecting the scientists and ventures with investors. Additionally, support entities included venture capitalist firms and angel investor networks. We interviewed senior executives from these support entities.

APPENDIX B Illustrative examples from UCEE agents across each UCEE

Theoretical dimensions	Second-order categories	Illustrative examples from UCEE agents
Institutional science commercialization support mechanisms	Academic entrepreneurs	*'And so, in our Group, we are working hard to develop our science so that it can be commercialized…This is where I see the commercial opportunities emerging for us'*. (Informant #32 – UCEE US AS) *I think we do find it difficult [to commercialize science] here…The two communities [academic and industry] are different aren't they, I mean, we speak a different jargon, speak a different language…The academic needs to be interested in commercializing their work and some, probably most, of my colleagues are not… The system will recognize commercial development in one way or another, but by the time they get to a stage of making any significant development, it's too far down the line and too late in their careers*. (Informant #5 – UCEE UK AS) *'Indeed, we could commercialize in my lab a lot of different things…I do not think that we will introduce them to the market…I personally would not like to be involved in commercialization because I can see that I would better stay in my place, in my lab and my bench…I need to work towards my KPIs, which does not involve commercialization!'* (Informant #44 – UCEE Russia AS)
	Technology transfer	*'We believe that investing in start-up companies based on the University's licensed technology is good business…We've had a number of very successful companies that have been formed with our support and have cashed out, have exited and made a nice profit for us, which we can use to support the university and wider ecosystem'*. (Informant #31 – UCEE US SEA) *'So, in terms of regenerative medicine, that's where I would come in and work at getting translational funding for them… the idea would be to get funding to move it to a stage where we can license it or spin out…Also, my role would be to look at the patentability of the product/the research and decide, if it's suitable, we would want to file a patent. And then, I'd be looking at the commercial exit strategy; talking to commercial partners'*. (Informant #8 – UCEE UK SEA) *'…Trying to provide a kind of a comfortable area where people can register their start up, get certain benefits, and feel more protected from various risks that appear…Run a so-called translational research and innovation program…Our task is to identify which research teams inside the Institute have gotten to the level where they would like to make an impact, to bring their development to the use of society…and then we select these and help them commercialize'*. (Informant #40 – UCEE Russia SEA)
	Institutional supporting infrastructure	*'I manage the Accelerator…We look for commercially promising technology at the University from investigators who have an interest in commercializing their research…We work with the investigator to understand how we can help advance that research, move it forward to commercialization…So, one component is funding but we have wide latitude in terms of what can we do to help move the innovation along…We will even continue to help investigators after they have formed a company'*. (Informant #24– UCEE US SEA) *'…It's the Science Triangle…these Science Parks were launched to connect the science community, not just life sciences, but tech companies as well, and the research institutes, try and bring them all together…Partnering activity to generate a community where business-to-business activity happens, research-to-business happens, and generates commercial companies…The Science Parks have about 120 plus companies all wanting to, you know, benefit the economy and that's what our remit is basically…To help the regional economy develop in terms of business growth and to trap inward investment into the region across the Parks'*. (Informant #6 – UCEE UK SEA) *'So, this facility itself is responsible to find new projects, which need some support in terms of translation or commercialization. So, if I take as the example, let us say pharmaceutical projects, I mean, drug development/drug discovery projects. We are picking up the project somewhere in the stage of late preclinical studies and we can support it up to the phase of clinical studies. Later it's already industry role there, earlier it's more like scientific part, classical science. What I'm saying about support: that means we first evaluate the project, expertise it, we use internal expertise of the Cluster on the first stages of the evaluation. Later on, we evaluate it with the support of external blind expert panel. And when the project gets through the expertise, the project can get the status of the resident in the Science Park, enjoy the tax benefits and that's very high level of tax benefits we provide here. Also, access to machinery, lab equipment etc…'* (Informant #43 – UCEE Russia SEA)

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APPENDIX B (Continued)

Theoretical dimensions	Second-order categories	Illustrative examples from UCEE agents
UCEE science venturing	Uncertain venturing landscape	*'I just think there's still a lot of uncertainty about the regulatory path, the commercial viability, the cost and the reimbursement… But if you have a high degree of uncertainty about whether it will be reimbursed and at what rate and the likelihood even if the best case scenario gets reimbursed, it's going to give you fairly low margins because it's such an expensive process…I'm not sure anyone is going to invest a lot of money…So I'm not saying they will not but to me that's a risk, that's a huge uncertainty'.* (Informant #36 – UCEE US SEA) *'If you can imagine taking a drug to market, only large pharmaceutical companies can really afford to do that…and it is absolutely no different with cellular therapeutics…the commercialization landscape is so uncertain at the moment'.* (Informant #13 – UCEE UK ENT) *'So, prior to commercialisation we had many challenges…the main challenge was the uncertainty…how do you commercialize something here? It's hugely stressful'.* (Informant #37 – UCEE Russia ENT)
	Tangible and intangible resources	*'We've still done a lot of great deals recently, with Midwest VC syndicates or a blend of Midwest and coastal syndicates [Boston and Palo Alto VC/private equity firms]'* (Informant #36 – UCEE US SEA) *We work across the life sciences…We work in knowledge transfer…We're funded by the UK Government…We're all about community building, providing access to funding, and access to partners for collaboration…Ultimately, our stap line is 'knowledge transfer,' which is key to help these companies commercialize their technologies…'* (Informant #12 – UCEE UK SEA) *'So, the team is very important…We need to ensure that we carefully select the right people for our business…It's really important but a challenge here in Russia…'* (Informant #47 – UCEE Russia ENT)
	Venture legitimacy	*'…The business, was there a viable business plan here? Convincing investors that there was one, finding talented people to get us off the ground who are willing to take a risk…From the standpoint of credibility, you have to be published in peer reviewed journals. You need to speak at all the meetings. And we have now been published three times and we speak at meetings all the time. And when we were at Society of Toxicology meeting week before last, everyone stops by the booth, they all know us. And it just took time to build that…'* (Informant #30 – UCEE US ENT) *'So, in effect, if you can convince the hospital that you have got enough data…So, if we just turned up at the Hospital across the road and said, 'we have done three patients, it looks really good, would you pay for some?' you know what the answer would be. But if you partner with them, build their trust, it then becomes achievable, this commercialization piece is achievable'.* (Informant #2 – UCEE UK ENT) *'So, they published the results of our commercialized products in two scientific journals, in two Russian journals. It really adds to our credibility. We did not find anything matching globally, it was quite a premier application in the world…We went deeper in publications, in Pubmed, about what's happening in this field in the world…So, at the end of 2014, another important milestone is this publication – a highly respectable publication…'* (Informant #47 – UCEE Russia ENT)
	Science commercialization activities	*'So, this has been important, I think, to getting us where we are as a new venture, and continue to be…We've been able to test our technology and collect evidence of safety for regulatory purposes…And we are now at the place where we can validate and test in Europe…It's critical for our business model* (Informant #30 – UCEE US ENT) '*I do see it changing, but the commercialization timescales are not clear…We're driven by money and if money is flowing into the industry, if there are more companies taking drugs or products through into clinical trials, then our business we will continue to develop the solutions they need for production technologies…'* (Informant #19 – UCEE UK ENT) *'We have a dream to treat kidney, it's our dream because we understand that it's one of the biggest problems…We did not think about pharmaceutical market, we did not think about some test systems, we think about human organ itself. It's our main driver and goal. This way we start to invest in this company…We're building our business model around this vision…'* (Informant #39 – UCEE Russia ENT)

(Continues)

APPENDIX B (Continued)

Theoretical dimensions	Second-order categories	Illustrative examples from UCEE agents
	Knowledge capabilities	*'Our network is designed to connect entrepreneurs with high profile individuals, or companies, through a variety of programs in and around the State…Those individuals, or companies, have a high profile within their community, they help make it possible to spur that process of innovation in tech transfer'*. (Informant #28 – UCEE US SEA) *'So, essentially, I had a long-term connection with them and then I established this business. In the early days, I learnt a lot from them. What it adds to us now is that they are a pathway both to manufacture and distribution. For someone like us, a very small company, this would take a huge amount of time to establish that. As a large company, they are very good at production and very good at getting products to people. It also gives us a pathway into the cellular therapeutic aspect of things…We have a very, very close relationship with them, they are very, very supportive of my endeavor. Potentially, in the long term, there may be a potential purchaser of my business'*. (Informant #13 – UCEE UK ENT) *'…We will provide these embryos for research to obtain stem cells and to make initial publications, and then, we'll utilize these stem cells and start our commercial company…But, we need to find a partner in England or in Europe…We are a very, very big clinic in Russia but we need to unite together with British or European scientists to progress this'*. (Informant #46 – UCEE Russia ENT)
UCEE agent-institution dynamics	Adhering	*'I started this company and ended up being probably the only person in the world who licensed that technology, you had to take a license from the University to get this started. And we did end up taking a license and forming the company. The tech transfer office here was super supportive in helping us do this. And at that time, the State Governor also had an initiative here to start stem cell companies. It was sort of his match to California's Prop 71, which was the 3-billion-dollar initiative, he had 5 million dollars for companies to start here. And that was kind of the impetus for the jumping off at that time. I was intrigued by entrepreneurship and because there were the systems in place and money available to get started, I went all in. And so that's how we ended up starting the company. That was the concept'*. (Informant #30 – UCEE US ENT) *'And so, for us, the technology that has really changed our research lives is induced pluripotent stem cells…And then the other direction that I think is moving towards commercialization much more rapidly is using these cells for drug testing. And so, we are working hard to make a way that these cells can be used for commercialization…You know, many academics were raised thinking industry was bad. But this has changed, it's a change of culture and that's helpful for commercialization…And then the university, the transfer office here, they are driving this change and supporting us in our commercialization endeavors, it's all exciting, exciting times!'* (Informant #32 – UCEE US AS) *'So, what my organization has been doing is shifting the focus from being primarily teaching and research institution to having the culture to accept and engage those people, and give them the ability to commercialize their innovations…there's been quite a bit of work around the here in the Institution and the State to build up the base of activity that's going on in each of the institutions and to provide support and funding. So, we receive funding through the Institution system and the State. We identify research activities that have potential for commercialization, and we are able to then provide various support, such as grant funds, to different professors in different ways in order to kind of help them advance the work that they are doing. They would assign the intellectual property to us, and then we can market those invention disclosures and file for patents, create a portfolio, market them, create new companies, and kind of advance the activity in the State. So that's in a nutshell what we are doing'*. (Informant #34 – UCEE US SEA)

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APPENDIX B (Continued)

Theoretical dimensions	Second-order categories	Illustrative examples from UCEE agents
	Sidestepping	*'The whole commercialization system is broken…,you can imagine some new system coming out – I do not know what it is yet – but there are systems out there; we are working hard to try and sort this out now, because I think that's the critical bit, that's what it will take to see these technologies or therapies in the market, and we are trying to influence that system, I'm in a good position to try and influence that'*. (Informant #10 – UCEE UK ENT) *'…We were talking about delivering [commercializing] regenerative medicine and the scientific community were talking about stem cell biology/stem cell research, there was a huge chasm between the two, so how are you ever going to bridge that gap between stem cell research and regenerative medicine commercialization? I think [senior University staff member – name withheld to preserve anonymity] recognized this was important to drive forwards, but when we tried to do that we actually found that, in theory, that was a great idea but, in reality, it was a huge challenge…I think the problem with – now let me think carefully how to word this – I do not think the technology transfer departments are well set up to try to exploit regenerative medicine technology that emanates from the universities…If we are going to be leaders in this field and not lose out to other areas, we need to be creative and work around these challenges…'* (Informant #1 – UCEE UK SEA) *'I mean, there is a real sense of disappointment among some of us that we are not achieving anymore. It does then make you think, I mean, there's a tendency to, as it were, cruise along, to keep going in your own little research path unless there's either some encouragement or some money. I guess it must mean that you have got to change your perspective, you know, have a mindset that says, despite the challenges of commercializing our science here, we can do this, we can work around this University system…I know people in California who are doing this in our area, so what cannot we? I've said enough times that we need to change our mindset and adapt to working with what we have got here, we should not let it stop us from commercializing, that would be a real shame…we have to align to the system to some extent here but also navigate around it as well'*. (Informant #5 – UCEE UK AS)
	Violating	*'Well, I would say that in Russia, the biggest uncertainty is the law…I'm not going to discuss this Federal law that was prepared by the Minister of Health because it's really disgusting [laugh]…But, that's what we have…Unfortunately, as I told you, we have change in rules every day and funds are restricted…So, we still have permanent changes in the game, the rules, and it's rather complicated to adapt to the game [laugh] frankly speaking!…We have different rules here inside Russia…So, we have to be creative around these rules if you know what I mean. I'm not saying that we break them, but we cannot really work with them if we are to commercialize here. So, we need to be creative, I would say that it is very helpful to have international expertise, expertise outside Russia for this…We cannot really commercialize here without having this international support…This is essential to us…'* (Informant #44 – UCEE Russia AS) *'So, I think this is very valuable for our future, but unfortunately now in our country, commercialization is challenging, not possible for us…Currently, we are not involved in commercialisation of the stem cells but we are desperately trying to navigate the system despite the difficulties, for example, the difficult regulatory, political, and commercialization environment… So, this field is very risky…I'm not sure when I'll be able to commercialize anything here as things currently stand…I really need partners, companies, scientists, in Europe, the US, to be able to commercialize this, can you help me with these (laugh)'* (Informant #46 – UCEE Russia ENT) *'So, we are trying to get this money. We keep working on this and doing research to help commercialization…So, basically, commercialization is really suppressed in Russia right now, maybe due to sanctions but also the research market is bleak. Some companies are trying to do something here but there's just not really a big market here and a lot of bureaucracy, a hell of a lot of bureaucracy! So, for us, I mean, we are doing what we need to do to push forwards with this…There's some procedures we have to follow here, but others we are not (laugh)! So, maybe I'm in trouble, really big trouble with the Institute for that! But, I do what I need to do to survive (laugh)!'* (Informant #38 – UCEE Russia AS)