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# Converting clinical risks into economic value: The role of expectations and institutions in health technology development

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## ABSTRACT

The ability to handle clinical and business risks is critical to an academic spin-off that seeks to develop a new medical technology. The milestones it has to meet to materialize its innovation are objects of speculation for those who finance its operations, and also for stakeholders who comment publicly on its progress. Such future-oriented expectations are not, however, mere hype since they operate within a set of practices that are highly institutionalized. Building on insights from sociology of expectations and institutions, this paper elicits how specific institutional requirements provide potency to the expectations that pave the health technology development pathway. Nested within five years of qualitative fieldwork, our study relies on a media coverage analysis to examine, over a decade, technology development in five Canadian spin-offs. Our findings illustrate a three-step process that involves: 1) measuring clinical risks that are convertible into business opportunities; 2) structuring technological entrepreneurship for growth; and 3) mitigating commercial risks to protect the spin-offs' economic value. Over time, expectations and institutions redefine where risks and opportunities lie, converting clinical risks into economic value. While the spin-offs support speculative economic value extraction, the technologies they materialize may fall short of fulfilling their clinical promises.

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## 1. “What if” expectations in innovation policy

Technological innovation in a knowledge-based economy is “an intensely future-oriented business with an emphasis on the creation of new opportunities and capabilities” (Borup et al., 2006: 285). As a result, future-oriented expectations pervade innovation policy. For instance, in their report to the Canadian Government, the members of the Independent Panel on Federal Support to Research and Development took care to provide an explanation for their cover page, which featured a geographical representation of the country lifted up by a glowing light bulb. The explanation goes as follows:

While the great American inventor Thomas Edison is given credit for “inventing” the light bulb, the story is really one of incremental innovation. In 1810, British chemist Humphry Davy invented the “electric arc,” a precursor to the light bulb. A series of innovations followed and, by the 1860s, the race was on to develop a commercially viable light bulb. Joining this race were two Canadians, Henry Woodward, a medical student in Toronto, and Mathew Evans, a hotel keeper. In 1874, they patented a nitrogen-filled light bulb that

lasted longer than others of the era. But they could not get financing for their work, and in 1878 were eclipsed by British inventor Joseph Swan and then in 1879 by Thomas Edison. Realizing the commercial viability of the light bulb, Edison was successful in obtaining major financial backers. He used these funds to continue his experiments, but also to buy out many patents, including those of Swan and of Woodward and Evans.

As we reflected on our consultations held across Canada, during which we heard first-hand of the struggles and successes of Canadian entrepreneurs, we wondered: What if Woodward and Evans had been able to interest investors? What if they had been able to obtain financing to carry on their work and beat out Swan and Edison to be the first to commercialize the light bulb? (Jenkins, 2011).

This story resonates well with the idea of a knowledge-based economy in which commercial entities “seek capital, in the form of speculative investment, to transform [research-based] discoveries into commercial products and services” (Morrison and Cornips, 2011: 264). The story also illustrates two key observations from the sociology of expectations (Borup et al., 2006; Brown and Kraft, 2006; Brown and

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Michael, 2003). First, by foregrounding a likely rivalry between inventors located in different countries, the story casts Canada as racing against the United States and Britain. Albeit it does so implicitly, the story designates winners and losers, thereby setting the stage for a particular past political economy to be understood (Brown, 2003). Second, the “what if” questions encourage readers to envisage a more desirable future. The speculations about Canadian inventors’ ability to attract investments and surpass their British and American counterparts capture the main thrust of the Report, which posits securing access to capital as the key turning point in the light bulb development story. Contemplating such “what if” questions opens up a straightforward path of action to the Government of Canada, eager to see a wealthier future unfold.

Future-oriented expectations highlight the mustering power of imagination in the innovation landscape. Yet, in the capital-intensive and highly institutionalized world of health technology development, which involves clinical trials, regulatory approvals and eventually stock exchange transactions, one should ponder not only how expectations function in scientific, policy and media discourse (Nerlich and Halliday, 2007), but also how they operate in practice (Pollock and Williams, 2010). For how long does a promising new technology remain promising? What counts as concrete progress? And what happens if expectations are not met?

The goal of this paper is to empirically elicit how specific institutional requirements provide potency to expectations. To do so, we rely on a qualitative media coverage analysis that was nested within five years of fieldwork in which we examined how, over an eleven-year period, five Canadian spin-offs developed and commercialized new health technologies. As a young company emerging from a public research setting, an academic spin-off faces soaring expectations that have to do with its future (Vohora et al., 2004). Its ability to handle clinical and business risks is critical. The milestones it has to meet to materialize a new technology are objects of speculation not only for those who finance its operations, but also for those who comment publicly on its clinical, commercial and financial progress (Morrison and Cornips, 2011). Over time though, concrete achievements and shortcomings become matters of scrutiny and the gap between expectations and the material world becomes more problematic.

By explicitly considering how institutions both constrain and enable certain forms of action in technology development, this paper endeavours to fill a key research gap: the role of institutions is largely missing from sociological analyses of expectations in innovation development (see, for instance, the special 2006 issue of *Technology Analysis & Strategic Management*). Adopting a sociological perspective, an important contribution of this paper is to provide empirical observations that clarify the process by which future-oriented expectations support speculative economic value extraction even if the technologies being materialized fall short of fulfilling their clinical promises. Process-oriented research like that reported in this paper involves constructing an in-depth narrative of actions that unfold over time in order to generate “concepts, understanding, and theory closely linked to data” (Ferlie et al., 2005: 119). Such research can help enrich theoretical models and revisit the empirical basis upon which policy frameworks rely.

This paper is comprised of four sections. Firstly, we define what expectations are from a sociological perspective and how they provide direction to action within institutionalized practices. We then describe our qualitative data set, emphasizing how we analyzed the media coverage ( $n = 814$ ) of five spin-offs located in Quebec (the second largest health R&D region in Canada) between 1998 and 2009. Thirdly, we empirically illustrate a three-step process that shapes the technology development pathway and involves: 1) measuring clinical risks that are convertible into business opportunities; 2) structuring technological entrepreneurship for growth; and 3) mitigating commercial risks to protect the spin-offs’ economic value. Fourthly, we summarize why research on future-oriented expectations proves insightful when institutional requirements are factored in the analysis and discuss the policy implications of our findings.

### 1.1. What expectations are and how they provide direction to action

In their simplest form, expectations have to do with imaginings, visions and other kinds of future-oriented abstractions (Berkhout, 2006; Brown and Kraft, 2006; Brown and Michael, 2003). In the case of health technology-based spin-offs, this future may easily span a 10-year period. The term future-oriented expectation thus underscores the long temporal frame within which innovation stakeholders reason and operate. Nerlich and Halliday (2007) suggest that one may distinguish expectations that are understood as *negative* and need to be prevented from occurring (risks, threats, damages, etc.), from expectations that are *positive* and have to “come into being” (scientific breakthroughs, leaps forward, etc.). Notwithstanding the fact that safety issues are rarely if ever settled once and for all (Faulkner, 2008; Jasanoff, 2005), health innovations generally fall into the latter category; the most pervasive wish is to make them come into being. Actors who foster health innovation development usually call upon two categories of positive expectations: social and economic. Morrison and Cornips refer to a “double promise” where the “value of intangible scientific knowledge in the present is closely intertwined with both the projected social benefits arising from new technologies and the concomitant promise of future economic growth” (2011: 264).

Establishing a set of shared expectations is particularly important in commercially oriented R&D. The necessity to bridge different worlds and coordinate actions across venture capital, business and scientific communities is indeed salient (Borup et al., 2006). Innovation developers generate and build on hopeful narratives through which the complex potentials of R&D activities can be translated into promising stories of opportunities for investors and other stakeholders (Fortun, 2001; Petkova et al., 2013; Pollock and Williams, 2010).

Future-oriented expectations may be framed more or less persuasively in order to increase actors’ ability to secure financial resources (6 Perri, 2005), but are always narratives of a particular kind. Expectations have a “pragmatic force” in that they “orientate” groups and individuals to “particular possibilities for action” (Nerlich and Halliday, 2007: 50). Early warnings like early promises are forged by actors to shape visions of the future, but with the intent to affect social and political actions in the present (Berkhout, 2006; Horst, 2007; Rosengarten and Michael, 2009). What provides direction to actors involved in the technology development pathway is the “hoped for end point”: the launch of a successful, revenue-generating technology (Morrison and Cornips, 2011: 271).

Future-oriented claims are located within a broad temporal frame, which may remain implicit but which has to resonate with those one wishes to take action. Morrison and Cornips (2011) call this frame a metanarrative since it tacitly organizes a credible “actionable” path from the present to the expected future. One particularly effective metanarrative in R&D activities is that of a linear, stepwise scientific model:

If extrapolations create a link between the present and future, the already established, recognizable metanarrative of *how* scientific progress is understood to occur serves as an implicit explanation of how the transition will be made from one state to the other (Morrison and Cornips, 2011: 271).

While remaining in the background, the metanarrative articulates a common path—made of a series of successive milestones—for actors to relate to and coordinate their actions around (Pollock and Williams, 2010).

### 1.2. Locating expectations within institutionalized practices

When expectations around agreed upon milestones capture the interest of necessary allies and help build “mutually binding obligations and agendas” (Borup et al., 2006: 285), sociologists of expectations

consider them performative (Brown and Kraft, 2006; Rosengarten and Michael, 2009). Expectations define roles, clarify duties and offer “some shared shape of what to expect and how to prepare for opportunities and risks” (Borup et al., 2006: 285). But, in what ways may expectations shape the material world of technology development? This begs the question of the relationship between discourse and action, and between imagination and materiality (Brown and Kraft, 2006).

In their extensive and enlightening review of the constructivist literature on technology and organizations, Leonardi and Barley argue that transcending the enduring dualisms that have haunted the study of technology will require “a pragmatic vision of sociomaterial reality, a concern for the dynamics of power” and “attention to the role that institutions play in shaping technological trajectories” (2010: 3). They underscore that science and technology scholars have aptly shown how technology can shape and be shaped by society. But there are turning points where materialistic forces dominate. What Leonardi and Barley compellingly bring to our attention is the relationship between such materialistic forces and institutions, which represent “social mechanisms by which one group’s volition can be translated into another group’s constraint” (2010: 37).

Despite the fact that several institutions structure the health technology development pathway and are likely to affect the performativity of expectations (Abraham and Davis, 2007), they are largely missing from sociological analyses of expectations. Table 1 lists institutions that regulate key aspects of medical technology development, including public policies (ranging from R&D tax credits to healthcare reimbursement criteria), capital investment, regulatory approval, financial markets, legal frameworks, corporate governance and the media (Petkova et al., 2013; Vohora et al., 2004). These institutions both constrain and enable action in technology development by defining the “rules of the game,” that is, when and how actors have to comply with specific requirements (Geels, 2004). More precisely, each milestone a given spin-off may reach over its lifecycle is conditioned by specific rules that may be set, for instance, by legal, clinical or financial institutions (Lehoux et al., 2015) (see Table 1). Through these rules, institutions contribute to the stability and functioning of innovation systems by providing incentives for innovation, supplying information, reducing uncertainty, fostering cooperation and making available mechanisms to handle conflicts (Edquist and Johnson, 1997). Institutions thus support the coordination of the work of many innovation stakeholders, including technology developers, investors, lawyers, clinical investigators, regulators, financial analysts and business reporters.

Hence, to further current understanding of how future-oriented expectations shape, in practice, the development of new health technology, one must locate these expectations within the set of highly institutionalized practices that structure the technology development pathway and its key milestones. One must also acknowledge that

**Table 1**

The institutions and key milestones shaping the evolution of academic spin-offs.

Institutions that structure the technology development pathway	Key milestones in the lifecycle of academic spin-offs
<ul style="list-style-type: none"> <li>• Innovation policy (R&amp;D tax credits, etc.)</li> <li>• Health policy (coverage, reimbursement, etc.)</li> <li>• Early (venture capital) and late stage capital investment</li> <li>• Regulation of medical devices (market access and post-market surveillance)</li> <li>• Regulation of financial markets</li> <li>• Regulation of corporate governance</li> <li>• Legal frameworks</li> <li>• The media (ranging from the business-oriented to the health-oriented press)</li> </ul>	<ul style="list-style-type: none"> <li>• Obtain intellectual property protection (IP)</li> <li>• Secure public and private investments, which may involve multiple rounds</li> <li>• Perform pre-clinical and clinical studies</li> <li>• File and obtain regulatory approvals to market one’s products in different countries</li> <li>• Decide whether and when to make an initial public offering (IPO), which implies entering the stock exchange and selling shares to the public</li> <li>• Prepare the potential acquisition of the spin-off by another company</li> </ul>

**Table 2**

The concepts guiding our analysis of how future-oriented expectations shape technology development in practice.

Future-oriented expectations	What institutions do
<ul style="list-style-type: none"> <li>• Can be negative (risks) or positive (opportunities)</li> <li>• Orientate institutions, groups or individuals to particular possibilities for action</li> <li>• Are anchored in a shared timeframe that helps organize R&amp;D activities (metanarrative)</li> </ul>	<ul style="list-style-type: none"> <li>• Define and apply the rules and requirements that constrain and enable certain actions</li> <li>• Support and prolong power relations among actors</li> <li>• Impose binding, long-term obligations</li> </ul>

institutional requirements have binding, long-term effects. For instance, regulatory agencies such as the American Food and Drug Agency (FDA) exert power over market access, but once technology developers have reached this milestone they remain accountable for fulfilling the safety requirements set to protect patients (Faulkner, 2008; Jasanoff, 2005). Likewise, financial market authorities set rules that condition the governance and accountability of the spin-offs listed on the stock exchange, transforming their structure and obligations (i.e., board composition, financial and legal accountability, information disclosure) (Aspara, 2009; Buchanan et al., 2009; Zider, 1998). Hence, the promissory claims made by innovation stakeholders regarding health technology spin-offs need to be analyzed in relation to their institutionally regulated progression along the development pathway if one wishes to clarify how expectations operate in practice (see Table 2).

## 2. Methods

### 2.1. A media coverage analysis nested within five years of fieldwork

The current study was nested within five years of fieldwork that began in 2008 and involved a phased approach wherein we gathered a multifaceted corpus of qualitative data to examine retrospectively the evolution of five health technology spin-offs (Gibbert and Ruigrok, 2010). These Montreal-based spin-offs developed a diversified set of innovations: 1) an optical molecular imaging device for diagnosing and characterising breast cancer; 2) a line of cryoablation catheters for the treatment of arrhythmia disorders; 3) a decision-support software to monitor prolonged labour and abnormal foetal heart rates and help detect birth-related injuries; 4) a home telehealth solution comprising remote patient monitoring and a set of coordination tools to promote continuity of care for chronically ill patients; and 5) a computer-assisted navigation system to support minimally invasive orthopaedic surgery.

Consistent with a theoretically informed yet inductive analytical strategy (Creswell, 2012), the analyses presented in this paper were guided by the concepts summarised in Table 2 and informed by the other data sources we gathered and analysed throughout our fieldwork (interviews, annual reports, press releases, media articles).<sup>1</sup> We primarily draw on the media coverage of the five spin-offs between 1998 and 2009 because performing an in-depth, qualitative analysis of this empirical material was particularly important to fulfill the goal of the paper. First, the media provides a rich empirical window for examining the

<sup>1</sup> We conducted interviews ( $n = 11$ ) with technology transfer and regulatory experts and with the CEOs of five Montreal-based spin-offs that had started their R&D operations in the mid 1990s and whose core products were in the early stage of commercialization when our study began. We analysed their annual reports ( $n = 21$ ) and press releases ( $n = 568$ ). Then, additional interviews ( $n = 23$ ) were conducted with technology developers, capital investors, regulators and policymakers, as well as three mixed focus groups with clinicians, technology developers and patient representatives ( $n = 19$ ). All face-to-face interviews and focus groups were recorded and transcribed verbatim. Both the documents and the interview transcripts were integrated within QDA Miner data analysis software. This large qualitative data set enabled our team to develop an in-depth understanding of how innovation stakeholders interact and contribute to technology development.

interplay between scientific and commercial progress, which “is central to understanding the way in which the promissory” operates (Morrison and Cornips, 2011: 271). Second, this material saliently reflects the empirical richness of expectations; it contains explicit predictions, newsworthy events, economic estimates and various experts' appraisals as to whether or not future-oriented claims are sound. Third, the media are regularly fed either reactively or proactively by the actors involved in the technology development pathway (Petkova et al., 2013). For example, journalists regularly quote official correspondence by regulatory authorities and expert sources such as clinical investigators, investors and financial market analysts. Hence, our analytical goal was to build a longitudinal understanding of how institutional requirements and future-oriented claims made by technology developers and by actors who comment publicly on their progress operate along the technology development pathway.

Fig. 1 shows the distribution of the media documents retrieved for each spin-off between 1998 and 2009. Using a combination of databases to cover both French and English Canadian media content (*Eureka Bibliobranche*, Canadian Business & Current Affairs, Canadian Newstand), we gathered all the documents that mentioned the spin-offs since their inception. This corpus includes printed media (i.e., newspapers, magazines) and electronic media (i.e., TV and radio transcripts) directed either at the general public or at a specific audience (i.e., business magazine, healthcare industry bulletins). The majority (85%) of these 814 documents addressed business issues (as opposed to health issues).

All media documents were electronically available and thus retrieved, indexed and analysed. Our analysis was chronologically ordered and paid attention to the way news stories apply a certain frame of understanding to events (6 Perri, 2005). The interviews supplemented the media analysis and were used to develop a detailed understanding of when and how institutional requirements come into play. The spin-offs' annual reports and press releases enabled us to identify the milestones these spin-offs reached and their corresponding concrete, material achievements. Only one of the spin-offs did not enter the stock exchange and another one financed a large part of its R&D activities through an early revenue-generating licensing agreement. These specificities were precious from an analytical standpoint since we were able to contrast the way these spin-offs managed “critical junctures” along the pathway (Vohora et al., 2004). Our longitudinal observations were iteratively condensed into a three-step process that elicits how over an eleven-year period specific institutional requirements provide potency to future-oriented expectations. Rather than describing each spin-off's progression, our findings illustrate the overarching dynamics of this three-step process.

Formal ethical approval was obtained by the Health Research Ethics Review Board at University of Montreal. As agreed upon with our participants, we conceal the names of the spin-offs, their products, CEOs and employees when quoting empirical material.<sup>2</sup> Excerpts were translated from French to English when necessary.

### 3. Converting clinical risks into economic value: a three-step process

Business news reports share a strikingly similar narrative structure: the future is where everything happens, as explained in a large Canadian daily:

<sup>2</sup> Our participants were cognizant of the fact that *preventing* a breach of confidentiality was beyond our power. Someone who would be interested in searching for additional information –i.e., more details than those made available in our publications– would be likely to find information about the spin-offs, their former CEOs and/or high-level executives between the early 1990s and 2008 and make “guesses” about who we might have interviewed. It should be underscored that our interviewees are not particularly vulnerable participants and did not report on sensitive issues. We shared findings with them before and/or after publication. Our findings are neither detrimental to, nor supportive of their commercial, financial, policy or clinical past achievements. We do not disclose product names because we do not wish to engage in advertisement.

Now the Internet balloon has developed a serious leak—many stocks are down 50 per cent or more from their peaks—and the mad money from the venture capitalists is drying up. It's probably too late for Canadians to make a big splash in the Internet market, but it's not too late for them to do so in the next hot industry—health care. That boat is about to dock. Health care is one those nebulous terms that encompasses pharmaceuticals, biotechnology (also known as life sciences) and medical devices. It is in the latter two categories that Canadian companies are making headway and it's all happening very quickly. Canada stands a good chance of building health care “clusters”—groupings of like-minded companies that both compete with, and feed off, each other—in Vancouver, Toronto and Montreal. So far, the Montreal area is leading the pack (PGB-13).<sup>3</sup>

The gist of this excerpt is the same as that of the light bulb story: a race is on and a foreseeable (bright) future will erase the (disappointing) past. But there is more than a seemingly anodyne narrative at play. Our findings describe below how expectations acquire potency through institutional requirements that involve: 1) measuring clinical risks that can be converted into business opportunities; 2) structuring technological entrepreneurship for growth; and 3) mitigating economic risks when facing material challenges. Fig. 2 illustrates this three-step process, which begins with estimates of the clinical risks the innovations promise to address and ends when economic value can be extracted from the spin-offs. The vertical arrows depict the gap between expectations and achievements, which increases over time.

#### 3.1. Step n°1: Measuring clinical risks that are convertible into business opportunities

The first step emphasizes the clinical risks (negative expectations) associated with existing technologies that a spin-off must measure and make explicit in its business plan (an institutional requirement). For instance, before introducing cryoablation, an innovation that uses extremely cold temperatures in the treatment of cardiac arrhythmia, the clinical shortcomings of the “rival” heat-based catheter procedures using radiofrequency (RF) are carefully described:

Doctors perform 800,000 RF ablations annually in the US alone. But with a hot chunk of metal snaking around inside the heart, there are bound to be risks. «Although RF is a very useful and safe technique in general, it has some downsides that are begging for improvement,» says Dr. George Klein, an arrhythmia specialist at the London Health Sciences Centre (LHSC) in London, Ont. «RF can be very unstable.» Klein, who performs a couple of RF procedures every day, says it can be extremely difficult to hold the flexible catheter steady. And once the tip burns into the tissue, the damage is irreversible. So if a doctor hits the wrong spot, too bad. There's also the risk of poking a hole right through the heart wall, which could cause a life-threatening hemorrhage. Or of forming a clot, which could lead to a stroke. «RF essentially fries the tissue,» says Klein. «It's like dropping an egg on a hotplate» (PSB-2).

In such accounts, significant attention is devoted to the medical explanations regarding the nature and magnitude of the risks associated with current treatments. Claims reported by physicians, including the founders of the spin-offs, contain precise data.

Because of badly located screws, traditional operations to the spine cause in 2% of patients neurological damages that may include paralysis, says [name], President and founder of [spin-off]. The [technology] eliminates this risk and reduces almost to zero alignment

<sup>3</sup> Throughout the paper, we use the following system of indexation of our media sources: PGB: Printed General Business; PSB: Printed Specialised Business; PGNB: Printed General Non-Business; PSNB: Printed Specialised Non-Business; EGNB: Electronic General Non-Business; EGB: Electronic General Business; and ESB: Electronic Specialised Business.

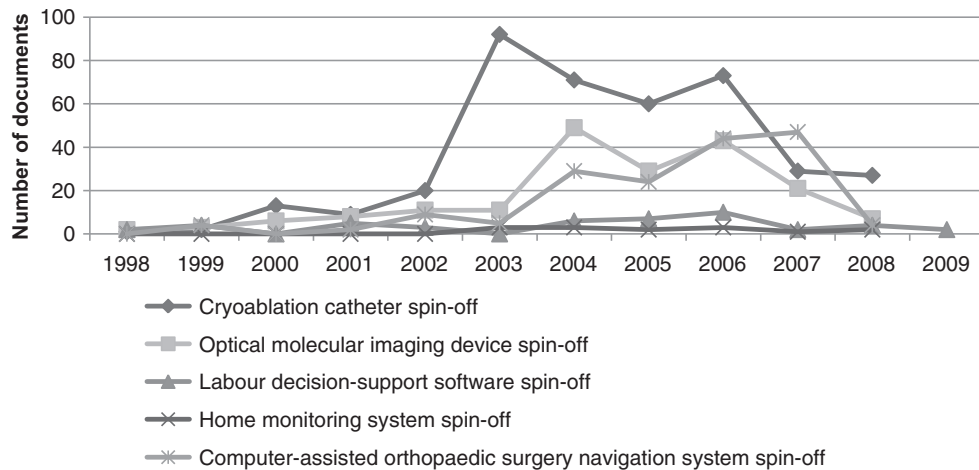


Fig. 1. Distribution of the media documents that mentioned the five spin-offs between 1998 and 2009 (n = 814).

problems in hip or knee surgeries. Healing is also faster and implants last longer. Thus the risk of imprecise alignment of a knee prosthesis, which was 10 to 15% in the past, is decreased at less than 1%. Moreover, a difference of one centimeter found normal in the length of a leg, after hip replacement, is reduced to two millimeters or less (PGNB-1).

Although potentially alarming, shortcomings observed in the present are not called into question. Rather than being of interest in themselves these carefully mapped and measured risks convey the business plan focal point through which the “need” for a new technology must be justified. As Morrison and Cornips (2011) observe, the “start” of the pathway is anchored in the present, but its role is to suggest that breakthroughs will soon occur. For example, after the completion of Phase II clinical trials, the prospects of the molecular optical imaging device that “can detect cancer tumors in the breast” are presented favourably:

Instead of exposing patients to radioactivity of X-rays, as is the case with traditional mammography, the device emits a beam of infrared

light without side effects. The screening device, unlike other methods, moreover, does not compress the breast of the patient. [...] According to Nathalie Duchesne, radiologist and principal investigator of the study, [technology] «is a very promising new method for detecting breast cancer» (PSB-1).

In the transcript of a television news program, the putative women-friendly benefits of the breast imaging device are compared to traditional mammography:

JENNIFER TRYON (Reporter): This technology could revolutionize the search and destroy mission Canadian women are on with breast cancer. UNIDENTIFIED WOMAN: You can fall asleep during the procedure very easily. TRYON: That's a far cry from this, the painful breast compression of a mammogram, recommended every two years after the age of 50 in an effort to catch breast cancer easily. DR. DAVID FLEISZER (McGill University Hospital Centre Surgeon): We have even had some people pass out during the mammograms. That's a really extreme example, but for women who are on the

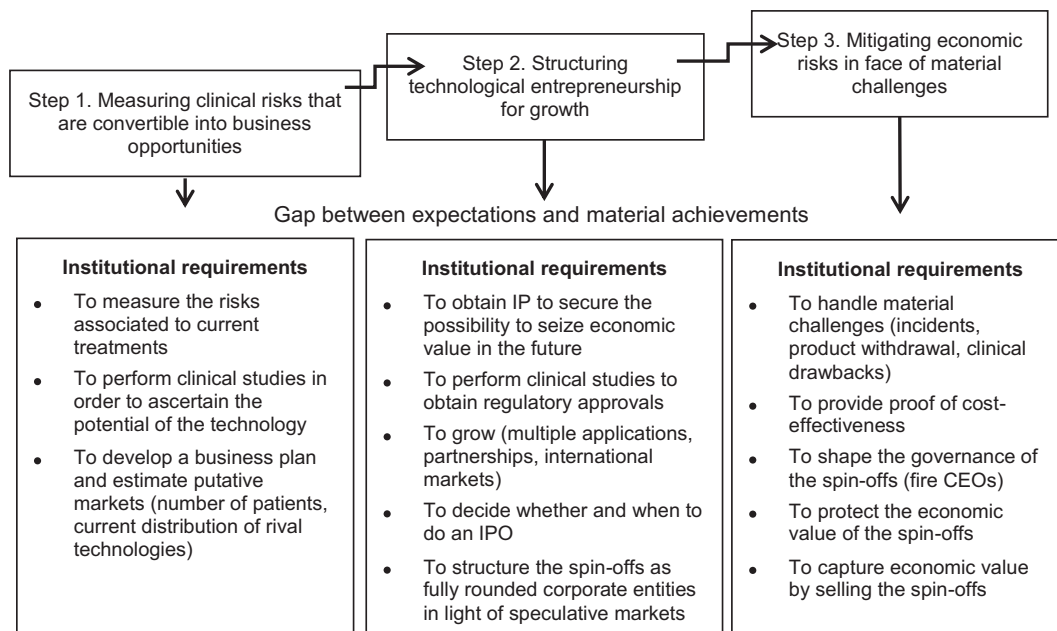


Fig. 2. A schematic summary of the three-step process

sensitive end of the scale, I think this is going to be a tremendous boon (EGNB-2).

More dramatic, the value of the obstetrical risk assessment computerised tool is illustrated in a television news report by pointing out irreversible dangers: the loss of a newborn.<sup>4</sup> Clinical risks (shoulder dystocia) are described by a physician as “absolutely the scariest complication an obstetrician could face in the birthing room” and the new tool as “a major leap in terms of our ability to predict and to prevent this injury” by the technology developer (EGNB-1). The report starts with a devastating event for patients and clinicians and ends with the happy wonders a new medical technology could deliver: a safe and healthy child. A woman who is said to have been “resisting advice to have a C-section” was revisiting the decision made 8 months before, “a healthy Noah now safely in her lap” (EGNB-1). What patients are said to want makes the demand for a new technology more concrete: “With the aging of the population, [telehomecare] technologies will be doomed to grow. [...] «People increasingly want to be cared for at home, said [technology developer]. By 2015, we will see an explosion of health care at home»” (PSNB-2). Narratives around clinical risks thus situate the prospects of a new technology by aligning its future with clinicians' and patients' expectations.

As we will see below, the size of putative markets is not taken for granted by those who support and finance the spin-offs and who rely on institutional processes to formally scrutinize business plans (Lehoux et al., 2015). But the media systematically report these numbers, conflating clinical risks and business opportunities. For instance, the market for the breast cancer imaging device “was an obvious one” because it “strikes one in nine women, making it the most common cancer in females” (PSB-4). Without further ado, these at-risk women are relocated within a market analysis metric:

The device at your local clinic undoubtedly uses X-rays, as do the other 1000 units across the country. According to a 1999 study by Frost & Sullivan, 30,000 of them worldwide must be replaced over the next decade. The market for mammography equipment is worth an estimated US\$250 million a year. These devices save lives—but they're hardly state-of-the-art (PSB-4).

Overall, Step 1 emphasizes measurements of where current risks lie, which enables a formal, market-oriented appraisal of the “promissory value” of the spin-offs, thereby opening up the key path of action of Step 2 (Morrison and Cornips, 2011).

### 3.2. Step n°2: Structuring technological entrepreneurship for growth

Step 2 is characterized by soaring expectations around clinical and business opportunities (positive expectations) and by institutional requirements that transform the spin-offs into corporate entities able to thrive on financial markets. Key requirements have to do with intellectual protection, regulatory strategies, management and reporting (see Fig. 2). To begin with, technology developers are presented as ambitious, highly capable and action-driven:

«We are going to change the world,» says with forceful conviction the engineer [name], President and Chief Executive Officer of [spin-off] since September 2002. «This is very ambitious to say so, but we have developed the right technology at the right time, while the market for molecular imaging is at our doorstep. We also have the right partner, GE Medical Systems, the world leader in healthcare

equipment. Not forgetting that we have the right team!» (PSNB-3)

Patents are described as crucial components of the business arsenal of a dogged technology entrepreneur:

In an otherwise unremarkable lobby at [spin-off's] headquarters in a desolate industrial area near Montreal's Dorval Airport hang seven US patents, engraved on brushed steel and mounted on wooden plaques. The various patents are for such futuristic-sounding things as «cryoablation catheter and method for performing cryoablation» and «cryogenic mapping,» and include complicated diagrams that look like something you'd find in an alien spacecraft. Each time the medical devices company lands another precious patent, [name]—a chemist with a few cryo patents of his very own hanging on the wall of his otherwise bare office—has it engraved in steel and unveils it to his 80 employees at an office party. «We're trying to create a minefield of intellectual property that will make it virtually impossible for somebody to reverse-engineer a 'me-too' version,» he says. «Anyone who wants to do this would have to come to us for a license—which, of course, we wouldn't give them.» (PSB-2)

While patents may serve many purposes, a formal intellectual protection strategy is part of capital investors' immediate institutional requirements (Ackerly et al., 2008). Otherwise, their ability to capture economic value in the future would be compromised. Once such a future-oriented expectation is formalized through a patent, the spin-off can seek to earn the confidence of investors. In this process, those responsible for raising capital need to share the financial risks with other investors: «There are a lot of people who are willing to put like 2, 3 or 4 million, provided we find an institution ready to go with a principal investment of \$15 million» said Mr. LaSalle” (PGNB-3). Such partnerships are part of established rules and the endorsement by more than one investor sends a powerful message within the investment community: capital backed ventures are considered as more opportune targets for speculative transactions (Petkova et al., 2013; Pollock and Williams, 2010).

Once spin-offs have secured investment (or revenues), a large part of their actions are geared at showing others their ability to grow.<sup>5</sup> This may entail engaging in the development of multiple applications for the same technology and for which market prognoses can be made.

That's exactly what potential investors should be looking for these days in the risky biotech sector: companies with more than one product in the works. «If you're developing one product and it hits the wall, you're finished,» says [technology developer]. «But if you're developing multiple products for multiple markets, there's less risk and more downstream potential» (PSB-2).

A significant milestone in a spin-off lifecycle consists in choosing whether and when to make an Initial Public Offering (IPO), which is the first sale of shares to the public by entering the stock exchange. While making an IPO is not an institutional requirement, the principal investors are those who set the conditions in which IPOs happen since this is when returns on their investments materialize (Buchanan et al., 2009; Zider, 1998). Financial market analysts regularly comment on IPOs:

<sup>5</sup> While market prognoses may take various forms, they always evoke growth prospects. Growth may be estimated in terms of dollars per year—the current market and its expected progression—or in terms of an annual percentage—the increase in sales of the current year compared to those of the preceding year. For instance:

Computer-assisted surgery is widely used in cardiac and many other areas, but for now [spin-off] will stay in the hip and knee replacement segment. It is growing at an annual rate of 30% as people live longer and technology improves, Feilders said. «Our navigation system has been used in more than 25,000 hip, knee and spinal operations and we see a big opportunity ahead. In the U.S. alone, one million orthopedic operations of this type are completed each year» (PGB-20).

<sup>4</sup> As explained by one of the technology developers we interviewed, current risks justify the need for the computerised tool since it would have picked up that a pregnant woman “had many, many bad things happened through her labour” because “a lot of it has to do with trends and what you see over time, and our brains are picking up, snip it, snip it, snip it, and trying to put it all together is tough!” (Developer 2). In other words, the risks mothers face would be dependent upon the limited “brain power” of the obstetricians and this is the gap the new technology intends to fill.

Claude Camiré, an analyst at Dundee Securities Inc., gives [spin-off] and [CEO's] management team high marks for developing the cryocatheter technology during the past five years. «It would be very easy to sell this IPO because it's a simple story,» he said. «It's a tube with freezing at the end that treats heart disease. Heart disease is a very sexy sector these days» (PGB-8).

When technology developers prepare for an IPO, business prospects that are concrete, alluring and enticing for a range of (non-specialized) shareholders are emphasized:

A company that intends to multiply its sales next year and which accumulates honors thanks to a unique technology in the world, we do not see that often. Especially when it is a SME in a niche area like orthopedic surgery and it is about to make its IPO. [Spin-off] is attracting more and more interest in the stock community. [...] The company track record is rather attractive for an investor. In addition to being a leader in its domain, [spin-off] is already a financial success, another rarity for a young company. [...] [Name of CEO] will not reveal the amount of the profits of the company for the moment, but his predictions have something to covet for. «Our plan is to deliver within 18 months 10 times more systems that we delivered in the past year [...]» says the CEO. [Name of CEO] does not say how these additional sales will affect the turnover of the company, but the twinkle in his eyes betrays his great enthusiasm (PGB-7).

Over the years following an IPO, the value of the stock as well as the spin-off's financial statements form objects of intense scrutiny. Fortun describes stocks whose value “is contingent upon the kind of narrative that can be spun around them” as “story stocks” (2001: 143). Stock narratives are not, however, told haphazardly; all articles reporting stock-related information use a similar, repetitive set of metrics. Once turned into a public company, a health technology spin-off must comply with the institutional requirements of financial market authorities. It must conform to established communicational rules, including the duty to disclose to shareholders information that may affect the value of the share. When doing so, technology entrepreneurs not only seek to build a consistent narrative around their business operations, but they must also report publicly on their progress.

Obtaining market approval is by far the milestone around which expectations generate the most performative effects since it launches the marketing phase that may generate revenues in the present. To this end, clinical studies are institutional requirements that technology ventures usually plan ahead. Because of the sheer size of the American market, obtaining US market approval has particular significance (Faulkner, 2008). But seeking approval in Europe first enables spin-offs to benefit from revenues while continuing to gather the clinical trial data required by the U.S. FDA. This explains why more than one regulatory milestone can be communicated altogether, providing a certain momentum to the planned chain of events.<sup>6</sup> Regulatory approvals are like highways to markets and their immediate effect on the stock value is systematically reported.

[Spin-off] shares rose more than 21 per cent Thursday after the company said it had received a Health Canada license to commercialize its breast cancer optical imaging device. Stock [...] jumped seven cents to 39.5 cents on the Toronto Stock Exchange, with more than

950,000 shares changing hands. [...] «We are very pleased by Health Canada's licensing of [technology] which constitutes a major milestone and a first step in our strategy to penetrate a global market of US\$1.8 billion; it is a testimony to the fact that our product is safe, effective and of high quality and ready for commercialization,» [spin-off's] president and CEO [name] said in a release. «Health Canada's green light will give Canadian hospitals, clinics and research centres the opportunity to deliver the benefits of [spin-off's] optical imaging technology to their patients and thus offer the prospect of better diagnosis for Canadian women affected by breast cancer and, eventually, this technology will help clinicians around the world improve breast care for women» (PGB-5).

The narrative emphasises positive opportunities—for the spin-off, clinicians, patients and shareholders—that seem to all converge in the promise that the marketing, distribution and implementation of the new technology will happen as fast as the blink of an eye. The practicalities of technology adoption by healthcare settings are, however, rarely if ever discussed. Rather, commercial achievements are examined. Financial market analysts may offer contextualized narratives explaining why past expectations have not been fully met as well as a new set of predictions:

[Spin-off] has yet to declare a profit and revenues have been slower than expected, said analyst Claude Camire. But Camire, who follows the company for Paradigm Capital, calls [spin-off] «a good story.» He expects shares to reach \$4.50 during the next 12 months, compared with about \$1.80 now. Camire points to an endorsement this year by McKesson Corp., the largest health-care software provider in the United States, which added the [technology] to its suite of software. [...] Other clients include medical malpractice insurance providers Aon Risk Services and TriState. Camire said revenues from annual licensing fees have been much lower than he expected because of delays in completing software and internal marketing shuffles. «It sounds like these problems are behind them.» He is calling for revenues in the current fiscal year, which ends in March, of \$8 million, with a loss of 29 cents a share. In fiscal 2008, he predicts a first profit of 25 cents a share and revenues of \$20.7 million as hospitals equip themselves with the newer technology (PGB-15).

The above detailed predictions are both enabled and constrained by institutional rules; as the fiscal year is formally broken down into quarters, financial market analysts examine the quarterly reports of the spin-offs whose progress they monitor. They thus regularly reassess their financial forecasts, providing often optimistic yet rationalized and nuanced statements:

We are optimistic about the future of the company, writes Mr. Piccioni of BMO. «We believe that good news on the side of medical imaging will continue to push the stock on the rise.» The analyst believes that the stock will provide above market returns. His target is \$11.75 in the 12 coming months. He warns, however, that [spin-off] remains a speculative investment. Only investors with a higher level of tolerance should venture (PSB-1).

Overall, Step 2 implies that spin-offs, once embedded in speculative financial markets, actively respond to growth expectations through their management, regulatory strategies and financial reporting.

### 3.3. Step n°3: Mitigating economic risks in face of material challenges

As the gap between expectations and concrete achievements becomes more tangible and problematic, Step 3 is characterized by institutional risk mitigation practices (see Fig. 2). After several years of activities, the spin-offs are not “emerging” companies anymore and their innovations are not as “promising” as they were thought to be:

<sup>6</sup> The excerpt below illustrates the phased-logic at play:

[Spin-off] got the green light from the European Community in July 2005 to launch his catheter on the Old Continent, and 10 centers are participating in the study. The progress of [technology] push Douglas Loe, an analyst with investment bank Versant Partners, to say that investors can be optimistic. «We are very encouraged by the impressive results of these studies, and it makes us believe that the product will generate similar results in trials in the United States, which should begin later this year,» writes Mr. Loe in a note sent Monday. «We are still confident about the medical usefulness of [technology] and a likely approval from the Food and Drug Administration of the United States,» says the analyst. Douglas Loe maintains its buy recommendation on the title of [spin-off], and set a target of over \$6.50 over 12 months (EGB-2).

clinical, marketing and business challenges accumulate (Lehoux et al., 2014b). Such material obduracies prove particularly troublesome for investors since they threaten the clinical value of the technologies and the economic value of the spin-offs. Maximizing one's return on investment represents, at this stage, an overriding institutional requirement.

While the institutional requirement of conducting clinical studies has contributed so far to build hopeful expectations, the cumulative effect of diverse clinical trials is that clinical investigators are now in a better position to critically appraise what these technologies actually deliver and fail to deliver. For example, after “nearly a decade” of research, clinical expectations about the breast imaging device are reassessed:

The new machine will not replace mammograms, which will continue to be the standard tool for pinpointing breast cancers for the foreseeable future, said Dr. Nathalie Duchesne, a professor of radiology at Quebec City's Laval University. «There are no side effects to this technology», said Duchesne, who has worked in clinical trials with [technology] for nearly a decade and is a paid consultant for [spin-off], which makes the machines. But it still needs to be extensively tested to determine its usefulness in detecting cancer, a top breast radiologist at Toronto's Princess Margaret Hospital said. Dr. Pavel Crystal, who is involved with a trial of the machine, said [technology] is not ready for clinical use and women cannot trust its results. «The idea is nice, but behind the idea you need performance», Crystal said. «Currently, there is not any data on performance. While previous trials determined its safety, it has yet to prove itself as a cancer-fighting technology», Crystal said (PGB-4).

In face of criticisms, technology developers have to clarify the implications of the drawbacks clinical studies reveal while persuasively maintaining shareholders' confidence. Technology dissemination challenges, including healthcare institutional requirements such as for proof of cost-effectiveness, appears commercially risky:

The commercial risk of [spin-off] is related to the willingness of the health system to develop telecare services at home. «We need to change attitudes, believes the President of the SME [name]. It is up to us to justify the benefits against the costs.» That is why he gathers for its clients data and studies. Because to innovate, it is not enough to invent a new product; one must be able to demonstrate to the client its innovative qualities (PSB-9).

When the ability of the spin-offs to hit the mark on financial markets is unimpressive, experts' expectations become less abstractly optimistic, more concretely pragmatic. Because corporate governance rules entail the provision of specific data, they enable financial market analysts to develop a “thicker” understanding of how spin-offs cope with business challenges.

But [spin-off] will have had to pay its dues before the windfall arrives, says Laurence Terrisse-Rulleau, analyst in biotechnology and medical technology at Orion Securities. «In the short term, it is difficult and quarterly revenues of [spin-off] have ups and downs in addition to remaining fairly low, she said. During the last quarter, it returned \$9.2 million, a record quarter, which is still not huge.» [...] She also notes that [spin-off], even after placing devices in 515 hospitals, still has weak sales. «The business model of this industry is to give away, or sell the device substantially under the cost price, while making up on sales of disposable accessories which must be replaced after each surgery, she says. Yet here, we see that surgeons are slow to adopt the device and the cold technology even if there is a [technology] unit in the hospital» (PGB-1).

In the above quote, the analyst criticises the venture as a whole, seeking to provide an assessment of where the spin-off is heading. In contrast to Step 1 where the spin-offs had no track record, their

achievements are straightforwardly assessed in Step 3, making their value in the future less certain. Within this perspective, the duty to disclose bad news —news that bears heavy consequences such as a clinical incident or a product recall— may be one of the most delicate institutional requirements. For technology developers, it does not only imply knowing when and how to share the news, but also how to mitigate the effects of such news on one's company survival:

[Spin-off] is voluntarily replacing some of its catheters, used by doctors to treat heart disease, after one of the medical devices broke and adversely affected a patient in Italy. The Montreal-based company, which announced the move after markets had closed Tuesday, said it expects its earnings will be reduced by \$1.5 million and sales will be down \$3 million in the current quarter due to the precautionary move. [...] [Spin-off] reassessed the situation after receiving e-mail on July 31 from a doctor in Milan, Italy, whose patient had trouble breathing and whose heart rate slowed during a procedure using [spin-off's technology]. [...] because of the event, [spin-off] decided late Monday to withdraw all of the products with the older design from the market and from inventory. [...] [Spin-off] expects to lose about \$3 million in sales in the fourth quarter as a result of prioritizing manufacturing capacity to replace the catheters and related measures (PGB-2).

In another article, underscoring that “no lawsuit has been filed,” the CEO stresses that “it is the first such incident in 4000 interventions” and that the source of the problem had already been corrected by releasing a modified version of the catheter.<sup>7</sup> Yet, the journalist pushes his query further:

When asked why [spin-off] had not initiated a recall immediately instead of waiting for an incident, [CEO] argued that the company «had no reason to believe that there was a security issue in this defect. The problem had been reported as a source of annoyance by customers (physicians who operate), nothing more.» [CEO] said that yesterday's transactions involved mainly small detail lots and «very few» institutional investors. «This means that strategic investors consider this incident as a minor glitch, and that they see beyond this episode» (PGB-3).

Invoking the need to see “beyond this episode” is not anodyne since such “glitches” influence the appraisals of financial market analysts. Below, the value of the spin-off is promptly reassessed, having both the present and the future in mind:

A recall mandated by the U.S. Food and Drug Administration would have had an «even greater negative impact on the company» [said Philippa Murphy, an analyst with RBC Capital Markets]. Ms. Murphy, who has an \$8.50 target price on the stock and rates it «outperform with speculative risk,» also warned that the company could suffer in the longer term if competitors attack «the perception of the reliability of the product» (PGB-11).

Another challenge spin-offs face has to do with the price and uptake of their technologies:

«Funding for new technologies in Canada is fairly limited, in terms of the health care system's ability to purchase new equipment,» Laberge says. Private hospitals and clinics in the US —which compete on service offerings— will likely be more receptive. [Technology's] US\$450,000 price tag could slow uptake; it's comparable to digital X-ray gear, but much more expensive than traditional analog equipment that runs US\$75,000 to US\$150,000. «It's a long shot,» Piccioni concludes, «but wouldn't it be great if it worked out?» (PSB-4).

<sup>7</sup> The CEO of the spin-off explains that the gas that has leaked inside the patient's right atrium during the procedure “is nitric oxide, the laughing gas that dentists sometimes use, and it is easily and quickly absorbed by the body” (PGB-3). A point emphasized in the article by the use of the subheading: “laughing gas.”



Like other governance-related changes, the departure of a CEO constitutes a newsworthy event. Entitled “surprising departures,” one article announces a “hard blow to the Quebec health technologies” since “two of the leading companies in the sector have lost their boss during last week.” The article quotes a financial expert for whom: “The departure of [CEO] is not entirely surprising given the poor performance of the title in recent months” (PSB-5). By holding a seat at the Board of Directors, investors have the power to transform how a spin-off is governed. All five spin-offs went through restructuring,<sup>8</sup> which facilitated acquisitions by established firms. For those who invested in the spin-offs, such acquisitions may qualify as “good deeds” (EGB-3):

Among the successful achievements in the past year, it should be noted the sale of shares in the company [spin-off]. The Montreal-based company, specialized in software and instruments for orthopedic computer-assisted surgery, was sold to the U.S. Zimmer Holdings for \$ 50 million. The [Société Générale de Financement] held 19% of [spin-off] actions (EGB-3).

While the story of a technology does not end at this point, the gap between expectations and material achievements becomes problematic in Step 3, when economic value capture is about to take place.

#### 4. Expectations and institutions in technology development

We began this paper by highlighting the need to locate future-oriented expectations about new health technologies in the context of the capital-intensive and highly institutionalized practices that characterize this sector. We suggested pondering for how long a new technology is considered promising, what achievements count as progress and what kinds of action are taken if expectations are not met. Then, our findings illustrated how the pragmatic force of expectations lies in specific institutional requirements that structure the technology development pathway.

##### 4.1. Contribution of our study

We believe the theoretical contribution of our study to current knowledge is three-fold. First, our study complements previous research in the sociology of expectations since we factored in our analyses the institutional requirements that provide potency to expectations. The sociological literature that has developed the concept of expectations has used it to characterize a situation in which innovative technologies are ascribed a set of desirable features while seeking to clarify why speculations often fail to materialize (Abraham and Davis, 2007; Berkhout, 2006). Our study pursued another goal and laid bare the institutional requirements that structure such desirable futures. Like Pollock and Williams (2010), we contend that expectations are not simple hype—that is an unstructured set of “unwarranted and exaggerated claims” that “make an emotional appeal to the audience” (Guice, 1999: 84). Expectations do not operate in a vacuum: what sociologists of expectations observe is not only the result of the mustering power of imagination in innovation development, but also the product of institutional forces that structure the technology development pathway (Leonardi and Barley, 2010).

Second, our findings clarified the dynamics by which spin-offs support speculative economic value extraction even when the technologies they materialize fall short of fulfilling their clinical promises. This reflects the dominant role capital investment and financial markets play in today’s knowledge-based economy (Lazonick and Tulum, 2011).

Albeit they do so involuntarily, even health-oriented institutions like the FDA provide economic worth to these ventures (e.g., augmenting the value of their share). The three-step process we presented makes more explicit why future-oriented expectations provide impetus for technology development and speculative investment activities to begin in Step 1 and expand in Step 2. Only in Step 3, does the gap between expectations and achievements become problematic. Nevertheless, one can hardly treat patients without the material world “behaving” as it should, that is, the technology has to accomplish in practice what it pretends to do (Abraham and Davis, 2007; Robert et al., 2010). Hence, innovation scholars should examine more critically the impact of capital investment and financial markets on technology development in healthcare (Lehoux et al., 2014b, 2015).

Third, our study provides empirical ground to mull over the way certain economic theories become self-fulfilling prophecies by modifying reality through institutional arrangements, social norms and language.<sup>9</sup> For Ferraro et al. (2005), neoclassic economic theories can play this role “when their language is widely and mindlessly used and their assumptions become accepted and normatively valued, regardless of their empirical validity” (2005: 21). Similarly, Nightingale and Coad (2014) have argued that current innovation policies are firmly based on the premise that technology-based ventures stimulate economic growth even though the body of evidence on the relationship between economic growth and small, entrepreneurial firms is inconclusive. Our media coverage analysis shows that expectations towards health technology-based spin-offs are indeed imbued with a neoclassic economics language, which is prolonged by institutional requirements that impose clear material constraints along a path that is reified as the “normal” cycle of entrepreneurship.

##### 4.2. Policy implications

Our process-oriented research was articulated by explicitly acknowledging, on the one hand, the pervasiveness of future-oriented expectations in innovation policy and, on the other hand, the institutions that coordinate the work of technology developers, investors, clinical investigators, regulators and business analysts. Such findings can help revisit the presumptions upon which policy frameworks rely and reconsider the institutional requirements that support their operationalization. When it comes to fostering innovation in health, North American and European policies often share the presumption that the two policy agendas of “health” and “wealth” can be reconciled (Lehoux et al., 2014a). For instance, the Canadian Advisory Panel on Healthcare Innovation recommended that Health Canada in collaboration with Industry Canada develop “a whole-of-government federal strategy to support the growth of Canadian commercial enterprises in the healthcare field” (Naylor, 2015: 107). This strategy should include “approaches to encourage greater availability of capital for innovative start-ups,” “support for commercialization and export of successful products” and “value-based procurement practices to encourage adoption of high impact innovations” (Naylor, 2015: 107). Such policy frameworks tend to ignore the extent to which health and wealth policy goals are unequally supported by the institutional requirements that structure the health technology development pathway.

As summarized in Table 3, Step 1 frames where certain clinical needs lie and their importance as putative markets; there are no institutional requirements for ascertaining the relevance of addressing such needs within the broader universe of healthcare needs. This is worrisome considering that new costly medical technologies threaten the

<sup>8</sup> The restructuring plan of one spin-off was complex enough to require a “100-page long circular” (PGB-21) that had to be approved by the Superior Court of Quebec (EGB-5). Another spin-off requested “a 30-day court order under the Bankruptcy and Insolvency Act to prevent its creditors from seizing assets” (PGB-22).

<sup>9</sup> For Ferraro et al. (2005), three mechanisms are at play. First, institutional arrangements create conditions that favor the predictions made in the theory. Second, actors integrate as accepted truths what the theory predicts, which once turned into social norms govern how actors behave. Third, the language couched in the theory reifies certain associations, motives and norms that become the natural way of talking about, and engaging in the world.

**Table 3**  
Policy implications of the three-step process by which clinical risks get converted into economic value.

Key findings	Policy implications
Step 1. Clinical risks that can be converted into business opportunities constitute the “promissory value” of the spin-offs	Lack of institutional requirements to examine the importance of addressing such clinical risks within the broader universe of healthcare needs
Step 2. Once embedded in speculative financial markets the spin-offs have to actively respond to growth expectations (management, regulatory strategies, financial reporting)	Lack of institutional requirements for carefully appraising whether and how the uptake of a new medical technology is warranted
Step 3. Risk mitigation practices take precedence at the point where the gap between expectations and clinical, marketing and business achievements becomes problematic, that is, when the innovations are not as “promising” as initially anticipated	From a speculative economic standpoint, health technologies do not have to entirely fulfill their healthcare promises From a health policy standpoint, key institutional requirements (e.g., proofs of relevance, safety, cost-effectiveness) come into play when it is too late to realign the innovation process

sustainability of publicly and privately funded healthcare systems. Then, Step 2 emphasises opportunities for investors, clinicians and patients that all converge in the promise that the uptake of the new technology will happen swiftly and smoothly. Such an idealistic endpoint is, nonetheless, more the exception than the rule, as confirmed by health technology implementation research (Robert et al., 2010). Carefully appraising whether and how the uptake of a new medical technology is warranted would better inform the spin-offs' organizational development strategy. What makes Step 3 challenging for technology developers and investors is the fact that institutional requirements enable business analysts to assess more fully the achievements and shortcomings of a spin-off, including the technology's impact on health. At this point, clinical trials support a concrete appraisal of what the technology actually delivers (and fails to deliver) and the regular reporting of sales brings forward healthcare third-party payers' response to quality, price or cost-effectiveness. Health policy requirements thus come more forcefully into play when it is too late to realign the innovation process; technologies that fall short of fulfilling entirely their clinical promises can still enable speculative economic value extraction, but their ability to support health policy goals remains compromised.

As Martin (2015: 9) underscores, innovation policymakers need to “keep pace with a fast changing world” and one of today's challenges implies knowing how to move “from innovation for economic growth” to innovation for sustainable economic development. Since the late 1980s, healthcare third-party payers have generally been supportive of technology-based innovation, thereby creating significant opportunities for economic growth in this industrial sector. Yet, the sustainability of healthcare systems is at stake in many industrialised countries, including the United States where the “era” of the largely cost-unconscious demand that characterized the country's healthcare system is fading away (Robinson, 2015). For Garber and colleagues, innovation policymakers should “offer greater financial rewards for inventing low-cost technologies” and “less reward for inventing high-cost ones” (Garber et al., 2014: 2). Acknowledging that the challenges of healthcare systems are not limited to costs, there is clearly a need to develop the “conceptual, methodological and analytical tools” that can support economically viable technology-based innovation in health (Martin, 2015: 10). Countries that spend an ever-increasing portion of their Gross Domestic Product (GDP) on healthcare services may see their capacity to stimulate other economic sectors diminish. We thus believe that a proper system of incentives and rewards for health innovation should seek to create technologies that protect the sustainability

of health care systems, thereby contributing to sustainable economic development.

#### 4.3. Limitations and further research

The key strength of our study lies in the theoretical and empirical insights that five years of fieldwork enables distilling and consolidating over time (Gibbert and Ruigrok, 2010). The empirical material we analyzed represents a solid dataset since the innovations produced by the five spin-offs necessitated overcoming a large range of business and clinical challenges. Nevertheless, our analyses are necessarily reflective of the particular challenges spin-offs in Quebec faced in the period preceding the American 2008 economic crisis. One of these spin-offs did not enter the stock exchange and, as a result, its media coverage was less abundant.

Further research could examine in greater depth the kinds of expectations experienced by spin-offs that remain “off the radar” of speculative investments. As Abraham and Davis suggest, “much greater perspective on the relationships between expectations, values and knowledge about the risks and benefits of new technologies” could be gained through international comparative research (2007: 403). Likewise, shedding light on the contexts in which expectations may fail to prove performative would be useful (Pollock and Williams, 2010), something our empirical material did not allow us to do. Our analytical framework and three-step process could certainly be used to articulate a new set of research questions for innovation scholars. For instance, examining the ways and means by which information, knowledge and expectations about new technologies circulate across various categories of actors (entrepreneurs, journalists, investors, market analysts, shareholders, clinical experts, patients, etc.) and the extent to which the institutional requirements in different countries are associated to certain types of entrepreneurial successes and failures would prove enlightening. Such comparative research would have tremendous value for policy, finance, governance and public accountability purposes.

#### 4.4. Conclusion

Studying the way risks and expectations function in the scientific, political or media discourse is important because it has implications for the allocation or misallocation of resources (Nerlich and Halliday, 2007). Given the public and private financial support health technology spin-offs receive, this paper sought to generate a better understanding of how future-oriented expectations shape technology development in practice. Our findings showed that expectations acquire potency through specific institutional requirements. The spin-offs that meet these expectations and comply with these rules conflate clinical risks and business opportunities, pursue fast-growing corporate ambitions and seek to compete in a globalised knowledge-based economy. Our findings suggest that capital investment and financial markets largely structure the spin-offs' fate (Lehoux et al., 2014b). While these spin-offs make speculative economic value extraction possible, the technologies they materialize do not have to entirely fulfill their healthcare promises. Because there is a need to foster the sustainability of healthcare systems, innovation policies should integrate health policy concerns into their institutional requirements so as to support entrepreneurial activities that respond adequately to important healthcare system challenges.

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## References

- 6, Perri, 2005. What's in a frame? Social organization, risk perception and the sociology of knowledge. *J. Risk Res.* 8 (2), 91–118.
- Abraham, J., Davis, C., 2007. Deficits, expectations and paradigms in British and American drug safety assessments prising open the black box of regulatory science. *Sci. Technol. Hum. Values* 32 (4), 399–431.
- Ackerly, D.C., Valvered, A.M., Diener, L.W., Dossary, K.L., Schulman, K.A., 2008. Fueling innovation in medical devices (and beyond): venture capital in health care. *Health Aff.* 68–75 (Web Exclusive).
- Aspara, J., 2009. How do institutional actors in the financial market assess companies' product design? The quasi-rational evaluative schemes. *Knowl. Technol. Policy* 22, 241–258.
- Berkhout, F., 2006. Normative expectations in systems innovation. *Tech. Anal. Strat. Manag.* 18 (3–4), 299–311.
- Borup, M., Brown, N., Konrad, K., van Lente, H., 2006. The sociology of expectations in science and technology. *Tech. Anal. Strat. Manag.* 18 (3/4), 285–298.
- Brown, N., 2003. Hope against hype – accountability in biopasts, presents and futures. *Sci. Stud.* 162, 3–21.
- Brown, N., Kraft, A., 2006. Blood ties: banking the stem cell promise. *Tech. Anal. Strat. Manag.* 18 (3–4), 313–327.
- Brown, N., Michael, M., 2003. A sociology of expectations: retrospectively prospecting and prospecting retrospects. *Tech. Anal. Strat. Manag.* 15 (1), 3–18.
- Buchanan, L.W., Stavropoulos, S.W., Resnick, J.B., Solomon, J., 2009. *Endovascular Repair of Aortic Disease: A Venture Capital Perspective*. Seminars in Interventional Radiology Vol. 26, No. 1. Thieme Medical Publishers, p. 56.
- Creswell, J.W., 2012. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*. Sage.
- Edquist, C., Johnson, B., 1997. Institutions and organisations in systems of innovation. In: Edquist, C. (Ed.), *Systems of Innovation-Technologies, Institutions and Organizations*. Pinter, London.
- Faulkner, A., 2008. *Medical Technology into Healthcare and Society: A Sociology of Devices, Innovation and Governance*. Palgrave Macmillan, Hampshire, UK.
- Ferlie, E., Fitzgerald, L., Wood, M., Hawkins, C., 2005. The nonspread of innovations: the mediating role of professionals. *Acad. Manag. J.* 48 (1), 117–134.
- Ferraro, F., Pfeffer, J., Sutton, R.I., 2005. Economics language and assumptions: how theories can become self-fulfilling. *Acad. Manag. Rev.* 30 (1), 8–24.
- Fortun, M., 2001. Mediated speculations in the genomics futures markets. *New Genet. Soc.* 20 (2), 139–156.
- Garber, S., Gates, S.M., Keeler, E.B., Vaiana, M.E., Mulcahy, A.W., 2014. *Redirecting Innovation in US Health Care: Options to Decrease Spending and Increase Value*. Rand Corporation.
- Geels, F.W., 2004. From sectoral systems of innovation to socio-technical systems. Insights about dynamics and change from sociology and institutional theory. *Res. Policy* 33, 897–920.
- Gibbert, M., Ruigrok, W., 2010. The “What” and “How” of case study rigor: three strategies based on published work. *Organ. Res. Methods* 13 (4), 710–737.
- Guice, J., 1999. Designing the future: the culture of new trends in science and technology. *Res. Policy* 28, 81–98.
- Horst, M., 2007. Public expectations of gene therapy scientific futures and their performative effects on scientific citizenship. *Sci. Technol. Hum. Values* 32 (2), 150–171.
- Jasanoff, S., 2005. *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton University Press.
- Jenkins, T. (Chair). (2011). *Innovation Canada: a call to action: review of federal support to research and development: expert panel report*. Government of Canada, Industry Canada.
- Lazonick, W., Tulum, O., 2011. US biopharmaceutical finance and the sustainability of the biotech business model. *Res. Policy* <http://dx.doi.org/10.1016/j.respol.2011.05.021>.
- Lehoux, P., Daudelin, G., Hivon, M., Miller, F.A., Denis, J.-L., 2014a. How do values shape technology design? An exploration of what makes the pursuit of health and wealth legitimate in academic spin-offs. *Sociol. Health Illn.* 36 (5), 738–755.
- Lehoux, P., Daudelin, G., Williams-Jones, B., Denis, J.-L., Longo, C., 2014b. How do business models and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Res. Policy* 43 (6), 1025–1038.
- Lehoux, P., Miller, F.A., Daudelin, G., Urbach, D.R., 2015. How venture capitalists decide which new medical technologies come to exist. *Sci. Public Policy* <http://dx.doi.org/10.1093/scipol/scv051>.
- Leonardi, P.M., Barley, S.R., 2010. What's under construction here? Social action, materiality, and power in constructivist studies of technology and organizing. *Acad. Manag. Ann.* 4 (1), 1–51.
- Martin, B.R., 2015. Twenty challenges for innovation studies. *Science Policy Research Unit (SPRU), SPRU Working Paper Series, SWPS 2015-30* (November).
- Morrison, M., Cornips, L., 2011. Exploring the role of dedicated online biotechnology news providers in the innovation economy. *Sci. Technol. Hum. Values* 37 (3), 262–285.
- Naylor, D. (Chair) (2015). *Unleashing innovation: excellent healthcare for Canada*. Report of the Advisory Panel on Healthcare Innovation. Government of Canada, Health Canada; Ottawa: ISBN: 978-0-660-02680-0.
- Nerlich, B., Halliday, C., 2007. Avian flu: the creation of expectations in the interplay between science and the media. *Sociol. Health Illn.* 29 (1), 46–65.
- Nightingale, P., Coad, A., 2014. Muppets and gazelles: political and methodological biases in entrepreneurship research. *Ind. Corp. Chang.* 23 (1), 113–143.
- Petkova, A.P., Rindova, V.P., Gupta, A.K., 2013. No news is bad news: sensegiving activities, media attention, and venture capital funding of new technology organizations. *Organ. Sci.* 24 (3), 865–888.
- Pollock, N., Williams, R., 2010. The business of expectations: how promissory organizations shape technology and innovation. *Soc. Stud. Sci.* 40 (4), 525–548.
- Robert, G., Greenhalgh, T., MacFarlane, F., Peacock, R., 2010. Adopting and assimilating new non-pharmaceutical technologies into health care: a systematic review. *J. Health Serv. Res. Policy* 15 (4), 243–250.
- Robinson, J.C., 2015. Biomedical innovation in the era of health care spending constraints. *Health Affairs* 34, 203–209.
- Rosengarten, M., Michael, M., 2009. The performative function of expectations in translating treatment to prevention: the case of HIV pre-exposure prophylaxis, or PrEP. *Soc. Sci. Med.* 69 (7), 1049–1055.
- Vohora, A., Wright, M., Lockett, A., 2004. Critical junctures in the development of university high-tech spinout companies. *Res. Policy* 33 (1), 147–175.
- Zider, B., 1998. How venture capital works. *Harv. Bus. Rev.* 76 (6), 131–139.

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