The Implications of Organizational Learning Types for Technological Innovation

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ABSTRACT

Organizations engage in a number of activities designed to foster effective learning. Three forms of learning with important implications for the innovation process are experiential (whereby firms gain relevant insights through direct experience with routines and patterns of action), vicarious (the observation of external activities, with inference and other attributions being employed to reconstruct the underlying processes), and inter-organizational (direct contact with outside entities or formal partnering initiatives). The papers in this thesis examine the relative influence of these forms of learning throughout the process of technological innovation.

The first empirical paper ("Sequences of Learning in Technological Innovation – Towards a Process Model") employs interview and archival data from eleven innovation projects in the biopharmaceutical and medical device sectors. I find evidence of three distinct learning sequences operating throughout the innovation process: 1) intensive-externalizing; 2) intensive-internalizing; and 3) expansive-internalizing. The sequences vary both in the breadth of learning forms utilized early in the innovation project and in the degree to which the resultant knowledge is internalized as subsequent innovations are pursued. These findings offer useful insights into the locus and sources of learning related to innovation processes in technologically complex settings.

In my second paper ("Learning and Innovative Performance – A Longitudinal Study of U.S. Medical Device Approvals"), I analyze a panel dataset of new product approvals for U.S.-based publicly traded companies in the medical

device industry. There is evidence for the independent effect of geographically proximate vicarious learning on innovation outcomes (number of approved medical devices) as well as for the interactive effect of experiential and geographically proximate vicarious learning on innovation outcomes.

The thesis contributes to current organizational research on learning sequences associated with technological innovation (Bingham & Davis, 2012) and to the literature on the role of vicarious learning within the innovation process by examining vicarious and other forms of learning in new product development (Srinivasan, Haunschild & Grewal, 2007).

RÉSUMÉ

Les organisations se livrent à diverses activités visant à favoriser un apprentissage efficace. Trois formes d'apprentissage avec des implications importantes pour le processus d'innovation sont expérientiel (où les entreprises acquièrent des solutions pertinentes à travers l'expérience directe avec les routines et les habitudes de l'action), vicariant (l'observation des activités extérieures, avec inférence et les autres attributions étant employées pour reconstituer les processus sous-jacents) et inter-organisationnel (contact direct avec des entités extérieures ou des initiatives de partenariat officielles). Les études dans cette thèse examinent l'influence relative de ces formes d'apprentissage tout au long du processus d'innovation technologique.

La première étude («Séquences d'apprentissage dans l'innovation technologique - Vers un modèle de processus»; traduction de "Sequences of Learning in Technological Innovation – Towards a Process Model") emploie les entrevues et les données d'archives reliés à onze projets d'innovation dans les secteurs des dispositifs médicaux et produits biopharmaceutiques. Je trouve preuves de trois séquences d'apprentissage distinctes opérant à travers le processus d'innovation: 1) intensive-externalizing; 2) intensive-internalizing; et 3) expansive-internalizing. Les séquences varient à la fois dans l'ampleur des formulaires utilisés au début du projet d'innovation dans l'apprentissage et le degré dans lequel la connaissance qui en résulte est intériorisée lorsque les innovations subséquents sont poursuivis. Ces résultats offrent des indications

utiles sur le lieu et les sources d'apprentissage liées aux processus d'innovation dans les milieux technologiques complexes.

Dans ma deuxième étude («Apprentissage et la performance innovatrice - une étude longitudinale de l'approbation des appareils médicaux aux États-Unis»; traduction de "Learning and Innovative Performance – A Longitudinal Study of U.S. Medical Device Approvals"), j'analyse un ensemble de données reliés aux approbations de nouveaux produits pour les entreprises publics américaines dans l'industrie des dispositifs médicaux. Il existe des preuves de l'effet indépendant de l'apprentissage vicariant géographiquement axé sur les résultats d'innovation (nombre de dispositifs médicaux approuvés) ainsi que de l'effet interactif de l'apprentissage expérientiel et vicariant géographiquement axé pour la réussite innovante.

La thèse contribue à la recherche organisationnelle actuelle sur l'élaboration détaillée des séquences d'apprentissage associées à l'innovation technologique (Bingham & Davis, 2012), et à la littérature sur le rôle de l'apprentissage vicariant dans le processus d'innovation par l'examen de l'apprentissage vicariant et d'autres formes d'apprentissage dans le développement de nouveaux produits (Srinivasan, Haunschild & Grewal, 2007).

ACKNOWLEDGMENTS

This thesis is the culmination of my years of study into the process of technological innovation in two fascinating sectors – biopharmaceuticals and medical devices. Perhaps more importantly, though, it is also the endpoint of my studies at McGill University. When I first arrived in Montreal, it was to pursue my MBA with a vague notion of some desired change after a demanding early career in corporate finance. Little did I know then how profoundly my time at McGill would influence my professional life – and how many outstanding individuals I would have the rare privilege to interact with in the interim.

First and foremost, I have to offer my sincerest thanks and appreciation to my thesis advisors, Margaret Graham and Jan Jorgensen. Both have been great sources of support and feedback during my studies, and they have patiently read through and commented on numerous drafts of this document. They continuously challenged me to clarify my thinking, to consider the implications (both theoretical and practical) of my research, and to ponder the directions in which I plan to extend these studies in the future. The effort to meet their exacting standards has been rewarded with what I believe to be the creative and original piece of scholarship that follows. My work is immeasurably improved as a result of their thoroughness and insight.

Peter Younkin, who joined my research proposal committee after his arrival at the Desautels Faculty of Management, has likewise been a great source of ideas and encouragement during this last (and undoubtedly most challenging) phase of the doctoral program. I would especially like to thank Peter for his

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McGill students are lucky to have access to some of the best researchers in the world, and I have eagerly availed myself of this valuable resource. The four-school joint program in Montreal further extends this opportunity. Ann Langley has willingly given of her time and insight, and her thoughtful feedback at key stages of my research is greatly appreciated. At several points throughout the PhD, Jeroen Struben, Paola Perez-Aleman, Greg Vit, Mary Dean Lee, and Thomas Dotzel were key sources of knowledge with regards to relevant literature, data collection, and methodological approaches.

As any PhD student can attest, financial support during the many years of focused research demanded by the program is critical, and I am fortunate to have benefited from many generous grants during my time at McGill. Doctoral fellowships from the Social Sciences and Humanities Research Council of Canada (SSHRC), the Fonds québécois de la recherche sur la société et la culture (FQRSC), and the McGill Doctoral Program in Management were hugely important at the outset of my doctorate. I also gratefully acknowledge the Centre for Strategy Studies in Organizations (CSSO) and its Academic Director Robert David, for the Dissertation Grant that facilitated the data collection for my thesis and for continued support of my conference travel expenses. Finally, I have been the beneficiary of several one-time awards that further defrayed my expenses during the dissertation phase; the Rathlyn Foundation PhD Fellowship, Walter John Stenason Fellowship, and Administrative Sciences Association of Canada /

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To the many company executives, researchers, and industry association members who gave so freely of their time during my data collection, I offer a heartfelt thank you. I hope that my thesis does justice to the dedication and passion that you bring to your own professional work.

Finally, and most importantly, I owe a huge debt of gratitude to my wife Dena for her patience, indulgence, and unconditional love. Dena's unwavering support throughout the PhD – and in all parts of my life beyond academia – has been the single biggest reason for any of the successes that I have enjoyed in the program. As we await the arrival of our first baby (due any day now) I'm again cognizant of the fact that my career should always serve the needs of my family, rather than the other way around. Dena, this thesis would not have been possible without your support; I dedicate this work to you.

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CHAPTER 1: INTRODUCTION

1.1 Overview

The papers in this thesis examine the relationship between diverse forms of organizational learning and the phenomenon of technological innovation. The notion that firms continuously engage in the generation and assimilation of new knowledge is one of the cornerstones of research into learning processes (Crossan, Lane & White, 1999). The adaptive behaviour implicated in learning helps organizations to produce new patterns of action as well as to improve existing activities. While direct first-hand experience has long been recognized as a fundamental means of firm-level knowledge creation, alternate forms of learning have more recently come under the purview of management scholars. These additional mechanisms include vicarious learning, which involves the observation of processes being undertaken within other organizations and the inference of lessons applicable to the observing firm's own operations (Haunschild & Miner, 1997; Terlaak & Gong, 2008; Bresman, 2013), and inter-organizational learning, in which partnerships function as vehicles for the creation and transmission of key insights (Holmqvist, 2004; Larsson, Bengtsson, Henriksson & Sparks, 1998).

My research is motivated by both theoretical and practical considerations. From a theoretical perspective, the idea that firms learn both experientially and vicariously has long been recognized by management researchers (Huber, 1991; Levitt & March, 1988). However, scholars have only recently turned their attention to the ways by which these distinct modes of learning interact through complex organizational processes such as the decision to expand into new

countries (Bingham & Davis, 2012) or the in-licensing of drugs by pharmaceutical companies (Bresman, 2013). The process of technological innovation, which involves a number of inter-related steps and specialized contributions by diverse organizational functions for its successful completion, would benefit from a similar learning-centric study. Determining how organizations make use of internal and external sources of knowledge to move forward with innovation projects characterized by uncertainty and emergent insights promises to improve our understanding of such fundamental activities as new product development, knowledge management, and organizational change and renewal.

The value of examining types of learning as they relate to innovation processes is further exemplified by the changing industry structures and knowledge strategies in real-world settings. In sectors such as biopharmaceuticals, medical products, and container shipping, trends towards inter-firm alliances and outright acquisitions (Baum, Calabrese & Silverman, 2000; Karim & Mitchell, 2000; Mitsuhashi & Greve, 2009) have expanded the locus of knowledge relevant to continuing operations. In a broader sense, the shift from largely self-contained industrial research departments characteristic of large firms in the post-World War II era towards external sources of R&D and collaborative initiatives (Graham, 1985) has significant – and currently underexplored – implications for organizational learning and innovation. An 'external turn' is evident in the dynamics of knowledge search and acquisition, lending added impetus to the need for study of the interdependencies among experiential, vicarious, and inter-organizational learning in company activities.

The role of these learning dynamics in facilitating new innovations remains a key question in organizational studies, and one that I seek to address in greater detail through this research. To this end, the chapters collected in this thesis focus on different (though ultimately related) aspects of the learning-innovation relationship. Three forms of organizational learning form the core of my theoretical approach to this topic: experiential, vicarious, and inter-organizational learning. My main research questions can be stated as follows:

> 1) How are experiential, vicarious, and inter-organizational learning involved in the development of technologically innovative products?
>
> 2) Does the overarching learning process differ materially across innovation projects within the same industry sector?
>
> 3) What characteristics of the underlying innovations account for differences in the types of learning used and the interactions between these types as the development process unfolds?

Chapter 2 of the present document surveys the extensive literature related to learning and innovation. My aim is to identify primary themes, contradictions, and unresolved issues that have needed further study. Having thus examined the many theoretical and empirical studies germane to this area, I have focused my research on the roles of these forms of learning as they relate to organizational ability to conceive, develop, and commercialize technologically innovative offerings.

In Chapter 3 ("Sequences of Learning in Technological Innovation – Towards a Process Model"), I report the results of an inductive study undertaken to better understand the dynamics of learning throughout the innovation process.

This project entailed the collection of qualitative interview data on eleven new product development projects led by small biopharmaceutical and medical device companies in the UK and Canada. The research identified three specific learning sequences – each involving differential emphases on experiential, vicarious, and inter-organizational learning at particular stages in the new product development process.

A key finding from this first paper is the joint importance of forms of learning in the innovation process. Firms rarely rely on a single means of learning as they strive to advance their nascent products towards commercialization. Instead, they employ a combination of learning types, each of which offers benefits that might not be realized by a narrower approach to knowledge generation. This conclusion motivates my second paper, described in Chapter 4 ("Learning and Innovative Performance – A Longitudinal Study of U.S. Medical Device Approvals"). For this project I assemble a multi-year dataset of U.S.-based publicly traded firms in the medical device industry, with the goal of examining the relationship between the three forms of learning and successful ongoing new product approvals. The main conclusion from this paper is the joint importance of experiential and vicarious learning for technological innovation. New product innovation is associated with organizations that have both recent innovation experience in the industry and access to vicarious learning from geographically proximate innovative firms.

As described in the conclusion, I make a number of contributions with this research. The detailed elaboration of learning sequences associated with

technological innovation has recently attracted the attention of organizational researchers (Bingham & Davis, 2012), and my thesis extends this work by seeking to enrich our understanding of change and innovation. My thesis contributes to ongoing explorations of the interactions between experiential and vicarious learning, and sheds light on the question of whether these learning types are complementary or substitutive in nature (Posen & Chen, 2013; Schwab, 2007; Simon & Lieberman, 2010). Given the shifting knowledge boundaries of organizations, wherein "the use and creation of knowledge for innovation and production […] do not necessarily correspond to the legal boundaries of the firm" (Adams, Brusoni & Malerba, 2013: 94), better understanding of the ways through which internally- and externally-focused forms of learning are mobilized to support creative activity offers benefits for academics and practitioners. The specific role of vicarious learning in the development of technological innovations also constitutes a promising area of inquiry in and of itself. By focusing on the innovation process as a broad phenomenon of interest, I aim to fill a lacuna in the learning literature: scholars "know little about the nature of vicarious learning in NPD [new product development]" (Srinivasan, Haunschild & Grewal, 2007: 25). Finally, from a methodological perspective, my use of inductive research to develop theoretical propositions amenable to subsequent testing via large-sample quantitative approaches aims to achieve better contextualized empirical studies in this domain and in the management literature as a whole.

1.2 Research Context

This thesis examines the process of technological innovation in two sectors: biopharmaceuticals and medical devices. These domains fall into the broader category of medical technologies designed to maintain human health and/or treat disease. Both are characterized by the distribution of specialized technical knowledge across a range of actors in a variety of organizational settings, and both have experienced recent trends towards consolidation and partnership that necessitate more effective internal learning mechanisms to make use of these disparate sources of expertise. However, there are some important differences – specifically with regards to underlying patterns of product development and regulatory oversight – that distinguish one from the other. In this section I provide an overview of each sector in turn.

1.2.1 The Biopharmaceutical Sector

The large pharmaceutical firms – familiar names such as Merck and Pfizer – responsible for many of the early drugs used in the treatment of disease made large investments in internal research and development labs in order to foster new product development. The overarching approach was to screen a wide variety of organic compounds in the search for a useful disease-fighting agent that would also be safe and free of severe side effects (Robbins-Roth, 2001). While this strategy was responsible for the discovery of numerous life-saving therapies, its largely random nature presented challenges for the therapeutic efficacy of a given product and, at a deeper level, the generation of insights into the nature of disease:

> The problem with this [big pharma drug discovery] approach was that scientists didn't really know enough about the

> details of how the body worked and what caused many diseases. And they didn't have ways to ensure that their drug candidates would act only on the desired target. As a consequence, most drugs treated only the symptoms of disease […] without stopping the cause of the disease. (Robbins-Roth, 2001: 7)

In contrast, the more recently established field of biotechnology is premised upon a more thorough understanding of human biology and the characteristics of disease progression. Building upon basic scientific research conducted primarily in university settings[1], biotechnology firms have parlayed new advances in molecular biology into the design of more targeted and effective treatments of human ailments. The technologies derived from this new field of study "have given great impetus to the possibility of understanding the 'causes' of diseases and the action of drugs" (Arora & Gambardella, 1995: 189). The term 'biopharmaceuticals' generally refers to products based on biological processes, and targeted at human diagnostics and therapeutics (Arora & Gambardella, 1995).

As described above, the underlying discovery and development process diverges substantially from the earlier pharmaceutical model. In addition, the pattern of interaction and collaboration has undergone important changes in the biopharmaceutical era. Beginning in the 1970s, a transition occurred from the large, vertically integrated drug companies that were the sources of innovation for much of the twentieth century towards smaller, more specialized biotechnology

[1] The importance of university research to biotechnology is exemplified by Herbert Boyer, whose work in biochemistry at the University of California San Francisco during the early 1970s – conducted in collaboration with Stanley Cohen of Stanford – led to the development of recombinant DNA technologies that would underpin many new biotechnology products introduced in the following years. In 1976 Boyer and venture capitalist Robert Swanson founded Genentech, a company that would serve as a vehicle to develop new therapies emerging from this basic research.

firms (Galambos & Sturchio, 1998). The abiding ties to academia – specifically, university research labs – enjoyed by these biotechnology organizations gives them a comparative advantage in basic research (Arora & Gambardella, 1995), while the financial resources and marketing expertise of pharmaceutical companies makes them adept at commercialization of new compounds. The large drug companies do still maintain internal expertise in early-stage drug development, and so have not ceded discovery activities completely over to biotechnology firms. However, the era in which a pharmaceutical organization could singlehandedly shepherd a drug candidate from initial feasibility through to market introduction has drawn to a close. Given the complementary strengths of the primary participants in this industry, the creation of formal alliances between biotechnology and pharmaceutical firms is an ongoing characteristic of the sector (Baum, Calabrese & Silverman, 2000; Powell, Koput & Smith-Doerr, 1996; Rothaermel & Boeker, 2008; Rothaermel & Deeds, 2004).

The pace of scientific progress in biopharmaceuticals and the problems evident in overreliance on exploitation of existing competencies have made active exploration key for ongoing technological innovation. As such, the biopharmaceutical sector is a particularly relevant setting within which to examine forms of learning as they relate to innovation. Table 1 lists several key events in the modern history of the biopharmaceutical sector.

TABLE 1: KEY MILESTONES IN DEVELOPMENT OF THE BIOPHARMACEUTICAL SECTOR

1953	Building upon previous work conducted by Rosalind Franklin, James Watson and Francis Crick publish their research into the double-helical structure of deoxyribonucleic acid (DNA), the basic building block of living cells.
1973	Herbert Boyer and Stanley Cohen successfully produce the first recombinant DNA organism.
1976	Genentech, the first major biotechnology company specializing in the use of recombinant DNA technology for drug development purposes, is founded by Herbert Boyer and Robert Swanson.
1978	Recombinant human insulin is synthesized for the first time (by Genentech), using transgenic genetically modified bacteria.
1980	In *Diamond v. Chakrabarty*, the U.S. Supreme Court upholds the first patent on a 'man-made' living organism.
1980	U.S. Congress passes The Bayh-Dole Act into law. The Act permits universities, small businesses, and non-profit institutions to pursue ownership of an invention developed with federal government funding.
1980	Interferons – proteins that help to trigger immune system response to viruses and other pathogens – are inserted into bacteria using recombinant DNA technology for the first time.
1982	The first biotechnology drug (human insulin produced in genetically modified bacteria) is approved by the U.S. Food and Drug Administration. The product is co-developed by Genentech and Eli Lilly.
1994	One of the genes associated with breast cancer is discovered.
1996	A gene associated with Parkinson's disease is discovered.
1998	The U.S. Food and Drug Administration approves Herceptin (trastuzumab), a monoclonal antibody drug that interferes with the HER2 receptor in cancer patients. The product is co-developed by Genentech and UCLA.

2001	The U.S. Food and Drug Administration approves Gleevec (imatinib), a gene-targeted drug for patients with chronic myeloid leukemia. Researchers at Novartis and the Oregon Health & Science University contribute to the discovery.
2003	Sequencing of the human genome is completed by the Human Genome Project.
2007	Researchers at two companies (454 and The J. Craig Venter Institute) announce that the first individual genomes – those of James Watson and genomics pioneer Craig Venter, respectively – have been sequenced.
2009	Swiss healthcare company Roche purchases Genentech for $45.7 billion U.S., in the largest-ever acquisition of a biotechnology company.
2009	U.S. President Barack Obama issues Executive Order 13505 rescinding the previous ban on research using stem cells from human embryos.
2011	The French pharmaceutical maker Sanofi-Aventis acquires Boston-based biotechnology firm Genzyme for $20.1 billion U.S.

Sources: "History of Biotechnology" (http://www.bio.org/articles/history-biotechnology), Accessed June 4th, 2013; "History of Biotechnology" (http://www2.dupont.com/Biotechnology/en_US/intro/history.html), Accessed June 4th, 2013; "First individual person's genome decoded" (http://www.cosmosmagazine.com/news/first-individual-persons-genome-decoded/), Accessed June 21st, 2013; Singer (2007); "Timelines" (http://lifesciencesfoundation.org/timeline.html), Accessed June 21st, 2013.

1.2.2 The Medical Device Sector

If patterns of collaboration and cross-firm learning have established themselves fairly recently in the biopharmaceutical sector, they are enduring traits of the medical device sector. However, in contrast to the link to universities required to access basic knowledge for therapeutic drug development, medical device innovation "relies heavily on the transfer of technological capabilities already generated outside of the medical sector – and indeed more commonly generated in the industrial world rather than the academic world" (Gelijns & Rosenberg, 1995: 7). An example of such broad technical outreach activities in

the medical device sector is the lithotripter, which brought urologists at the University of Munich into contact with the German aircraft maker Dornier on a collaborative endeavour to treat kidney stones with the use of shock waves (Gelijns, 1991).

Medical devices run the gamut from simple tools such as scalpels used in the performance of surgeries, to monitoring devices including stethoscopes, and on to more complex interventional technologies represented by heart pacemakers and computed tomography (CT) scanners. Reflecting this breadth, the U.S. Federal Food, Drug, and Cosmetic Act defines a medical device as

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" that is intended for use in "the diagnosis of disease or other conditions [or the] cure, mitigation, treatment, or prevention of disease [or] intended to affect the structure or any function of the body of man, which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal purposes". (quoted in Foote, 1992: 9)

Table 2 lists notable milestones in the ongoing development of the medical device sector.

TABLE 2: KEY MILESTONES IN DEVELOPMENT OF THE MEDICAL DEVICE SECTOR

1949	Wilfred Bigelow and John Callaghan use hypothermia to reduce metabolism and produce bradycardia (slow heart rhythm), thereby permitting the performance of cardiac surgery.
1953	Dr. John Gibbon performs the first successful open-heart surgical procedure using his heart-lung machine.

1957	Earl E. Bakken (co-founder of Medtronic Inc.) produces the first battery-operated wearable pacemaker.
1973	Introduction of computed tomography (CT) scanning, which brings developments in computing technologies into the domain of medical imaging.
1977	The first examination of a human subject using magnetic resonance imaging (MRI) technology is undertaken.
1982	The first permanent artificial heart transplant (Jarvik-7) is completed.
1989	A U.S. patent is granted for a method of modifying the corneal curvature of the eye via surgical procedure, forming the basis for the newly emerging laser-assisted in situ keratomileusis (LASIK) process.
1994	The U.S. Food and Drug Administration approves the Palmaz-Schatz stent for use in the United States.
1999	LASIK is approved by the U.S. Food and Drug Administration.
2003	The first drug-eluting stent, the Cypher (manufactured by Johnson & Johnson and Cordis), is approved by the U.S. Food and Drug Administration.
2011	The U.S. Food and Drug Administration proposes the Innovation Pathway, a priority review program for breakthrough medical devices.
2012	Autodesk, the industry leader in computer-aided design (CAD) software, announces a partnership with biological printer manufacturer Organovo to create software for the designing and printing of living tissue.
2013	Researchers from Harvard's School of Engineering and Applied Science and the University of Illinois at Urbana-Champaign demonstrate the feasibility of 3D-printed lithium-ion microbatteries (the size of a grain of sand) for the next generation of miniaturized medical devices.

Sources: Aquilina (2006); Bradley (2008); "A Look at LASIK Past, Present and Future" (http://www.aao.org/publications/eyenet/200906/feature.cfm), Accessed June 4th, 2013; "A Short History of the Magnetic Resonance Imaging (MRI)" (http://www.teslasociety.com/mri.htm), Accessed June 4th, 2013; "FDA launches Medical Device Innovation Initiative" (http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm242629.htm.), Accessed June 21st, 2013; Flaherty (2012); Hicks (2013).

1.2.3 Regulating Innovation in Medical Technology: U.S., Canada, and UK

Biopharmaceutical and medical device innovations are increasingly global phenomena. Research and distribution facilities are located around the world, while clinical trials of promising new therapeutic compounds are managed in multiple geographic locations by their organizational sponsors. In addition, the basic technologies underlying these offerings – particularly in the case of medical devices – are accessible only through knowledge transfer across institutions dispersed throughout numerous countries. Yet despite this trend towards multinational development, an important component of the innovation process – regulation – retains a state-level character. In this section I identify the key regulators in three countries (the United States, Canada, and the United Kingdom) represented in the data for my thesis. I also describe the regulatory process that underpins the development of drugs and medical devices as their originating firms guide them from early concept identification to possible commercial introduction.

1.2.3.1 National Regulators for Biopharmaceutical Products

In the United States, the Food and Drug Administration (FDA) within the U.S. Department of Health & Human Services is responsible for oversight of products in the biopharmaceutical sector. Specifically, two FDA departments regulate the review and approval of these offerings. The first is the Center for Drug Evaluation and Research (CDER), whose mandate is to ensure the safety and efficacy of all prescription and non-prescription or over-the-counter drugs marketed in the United States. Complementing the work of this first group is the

Center for Biologics Evaluation and Research (CBER). The CBER has jurisdiction over biological products, which include blood and blood components, certain medical devices used in blood banks, gene therapy products, human tissues for transplantation, and vaccines. All such biological goods are approved for marketing under provisions of the Public Health Service (PHS) Act.

In Canada, the Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate of Health Canada are the agencies charged with regulating therapeutic and diagnostic offerings for sale on the Canadian market. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK-based government body that fulfills the same oversight functions as the FDA and the TPD. The MHRA was established in 2003 to merge the previously separate tasks of drug and medical device regulation performed by the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA), respectively (The Medicines and Healthcare products Regulatory Agency, 2012).

1.2.3.2 Stages of Regulatory Review for New Drugs

While each national regulator requires a newly developed biopharmaceutical product to follow the steps detailed in its particular guidelines, the overall review process contains many of the same elements regardless of jurisdiction.

Pre-clinical trials. Pre-clinical testing is first undertaken in laboratory animals to observe the overall properties of the drug. If positive outcomes follow from this first stage, the drug sponsor can file an Investigational New Drug (IND) Application demonstrating to the regulator the results of these studies and

describing their proposed plans for clinical testing in humans. At this point the agency will make an assessment as to whether it is prudent from a health benefits standpoint for the company to move forward with further development of the offering.

Next comes review of the IND application by both the regulator and a local institutional review board. The board is tasked with deciding whether to approve the clinical study protocols, "which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details" ('The FDA's Drug Review Process': U.S. Food and Drug Administration, 2012).

Phase I clinical studies. The first set of clinical trials is undertaken with healthy volunteers as subjects. Phase I testing is intended to uncover any frequently occurring side effects associated with the drug, as well as to determine how the drug is metabolized and excreted by the body. In general between 20 and 80 subjects are recruited for these tests.

Phase II clinical studies. Provided that the previous stage of clinical testing does not show excessive levels of toxicity of the drug, Phase II studies emphasizing effectiveness are started. These trials generate data regarding whether the drug works in people with a specific disease indicated for treatment by the compound. Anywhere from a few dozen to about 300 subjects form the sample for this round of studies.

Phase III clinical studies. As in the previous stage, the launch of Phase III trials is contingent on evidence of effectiveness from Phase II. The goal is to

collect additional safety and effectiveness data through the study of different populations of patients (often in numerous sites around the world) and the administration of different dosage regimes. Testing of the focal drug in combination with other drugs is also undertaken in order to reveal potential contraindications. Several hundred individuals (up to about 3,000 subjects) could be recruited for this stage of clinical testing. Phase III trials are typically the most expensive and lengthy part of the approval process, spanning many years and costing millions of dollars. The FDA and other national regulators require positive results from at least two Phase III trials if a market approval submission is to be made (Long & Works, 2013).

Post-market surveillance. Once the drug has been approved for marketing by the regulatory agency in question, post-market studies are agreed upon in order to ensure the ongoing collection of information concerning safety and efficacy.

New Drug Application (NDA). An NDA is the formal request on the part of a drug sponsor for FDA approval to market the product in the United States. The NDA "includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured" ('The FDA's Drug Review Process': U.S. Food and Drug Administration, 2012). The equivalent request in Canada is filed with the Therapeutic Products Directorate, and is known as a New Drug Submission (Health Canada, 2001). In the UK, approval of a new drug is granted in the form of a marketing authorization or product license. The majority of new medicines approved by the UK regulator are ultimately licensed by the European Medicines Agency, so as to ensure equal availability and consistency of usage across all member states of the

European Union (The Medicines and Healthcare products Regulatory Agency, 2012).

1.2.3.3 National Regulators for Medical Device Products

As is the case for biopharmaceuticals, the U.S. FDA exercises oversight of medical device products in the American context. In this sector it is the Center for Devices and Radiological Health (CDRH) which "assure[s] that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products" ('About the Center for Devices and Radiological Health': U.S. Food and Drug Administration, 2012). The corresponding Canadian regulator is the Medical Devices Bureau of the aforementioned Therapeutic Products Directorate in Health Canada, while the MHRA performs this role for products targeted to the UK market.

1.2.3.4 Stages of Regulatory Review for New Medical Devices

The regulatory review process for newly developed medical devices begins with a classification of the product based on its potential risk to patients. The CDRH uses a three-part classification scheme for this purpose, with required controls increasing from Class I to Class III:

> [D]evices are to be classified into class I (general controls) if there is information showing that the general controls of the [Federal Food, Drug, and Cosmetic] act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to

> support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. (Government Printing Office, 1998)

In Canada a similar format prevails, though the Medical Devices Bureau adheres to a four-fold classification program (Class I through Class IV).

The specific class into which the device falls then determines the form of regulation that applies. Regardless of the risk profile of the product, in the United States manufacturers and distributors of medical devices are required to register their establishments with the FDA, while manufacturers must also list their devices with the agency. Manufacturers of Class I (low-risk) devices in Canada are monitored through the granting of analogous Establishment Licences, which enable the TPD to keep track of producers and sellers of devices in the Canadian marketplace.

Class I devices are generally exempt from specific testing procedures, and need only meet the general provisions of federal legislation that aim at ensuring the safety and effectiveness of the approved device. Enema kits and elastic bandages are two examples of relatively uncomplicated product offerings falling under the FDA's Class I designation. The majority of Class II devices, in contrast, require the filing of a Premarket Notification or 510(k); this is "a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device […] that is not subject to PMA [Premarket Approval, the more stringent control applicable to Class III devices]" ('Premarket Notification (510k)': U.S. Food and

Drug Administration, 2010). Powered wheelchairs and certain pregnancy test kits are included in the Class II category. For higher-risk Class III devices that pose greater risks to patients – and for which no previously approved product is found to be equivalent – a Premarket Approval is obligatory. This includes the submission of clinical data in support of manufacturer claims. Examples of Class III devices are implantable cardiac pacemakers and breast implants.

The next step in the regulatory process entails an Investigational Device Exemption, which allows the device in question to be used in clinical trials designed to collect data related to safety and effectiveness. The Quality System regulations stage "includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices" ('Overview of Device Regulation': U.S. Food and Drug Administration, 2013). In the UK (and Europe more generally), medical devices must also carry a CE marking, which "is applied by the manufacturer and means that the device meets the relevant regulatory requirements and, when used as intended, works properly and is acceptably safe" (The Medicines and Healthcare products Regulatory Agency, 2012: 7). Finally, a reporting stage is included to capture data related to devices that have caused death or serious injuries, as well as to account for product malfunctions.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In this chapter I appraise and synthesize the relevant academic literature that underpins my thesis work, and to which I intend to contribute with this research. Three particular types of learning – experiential, vicarious, and inter-organizational – as well as antecedent factors for each are discussed in sequence. I cover the role of knowledge and routines in detail before I turn to a discussion of technological innovation. Acknowledging the diversity of definitions of innovation prevalent in organizational studies, I describe some of the important characterizations of this phenomenon that researchers have addressed. I then bring together the broad approaches examined in the preceding paragraphs. The chapter concludes with observations on the ways in which scholars have studied each of the three forms of organizational learning for their impact on innovation; this overview leads to the Research Questions around which my subsequent empirical papers are oriented.

2.2 Organizational Learning

2.2.1 Early Theories and Definition

In early work that laid the foundation for future research into organizational learning, Cyert & March (1963) conceived of the firm as an adaptive system that responds to external shocks by mobilizing selected operating procedures to resolve difficulties. This approach presumed that procedures that generated preferred outcomes would be retained and used more frequently in the

future. A hierarchy of procedures, whereby "SOPs [standard operating procedures] guided change in organizational behavior in response to short-run feedback, while more slowly changing higher-level procedures guided change in lower-level SOPs in response to long-run feedback" (Schulz, 2002: 416), facilitated organizational adaptation. The fit between a firm and its broader environment as well as the assessment of ongoing performance versus aspiration levels emerged as key aspects of early theories of organizational learning (Cyert & March, 1963; Levinthal & March, 1981).

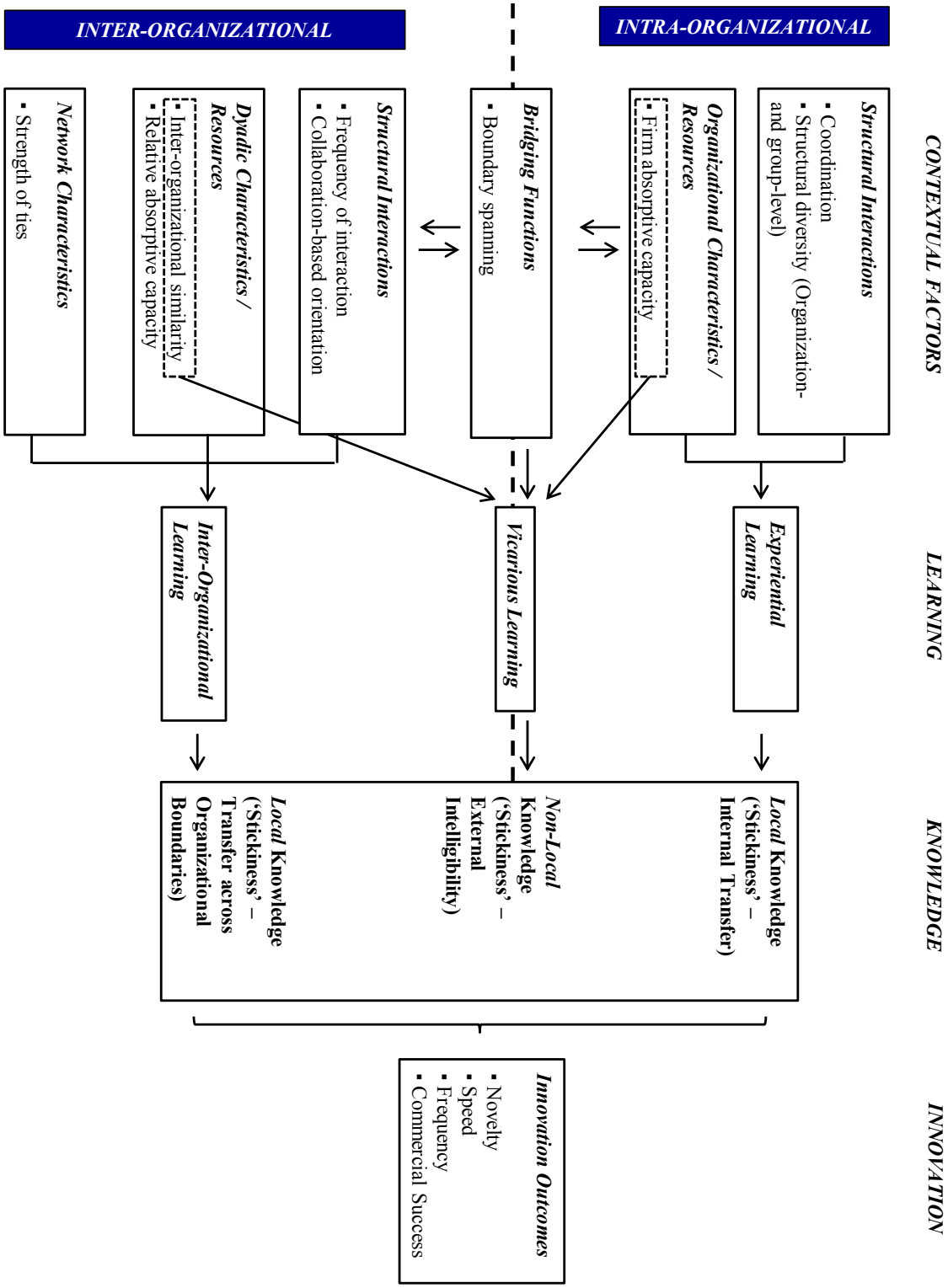
A number of formal definitions of organizational learning can be found in the literature. Learning refers to "the process of improving actions through better knowledge and understanding" (Fiol & Lyles, 1985: 803) and as "a principal means of achieving the strategic renewal of an enterprise" (Crossan, Lane & White, 1999: 522). In addition, an organization learns "if, through its processing of information, the range of its potential behaviors is changed" (Huber, 1991: 89). Extrapolating from these conceptualizations, in this thesis I define organizational learning as *the generation of new knowledge or insight that facilitates either new behaviours (actual or potential) or the improvement of existing ones*. In this work I am especially concerned with new behaviours that lead to the successful development of technological innovations.

In the discussion that follows I focus on three specific forms of organizational learning. *Experiential learning* occurs when organizations obtain new knowledge through direct experience with a given practice or technology. Processes of trial-and-error and experimentation are common routes by which firms learn experientially. *Vicarious learning*, by contrast, comes into use when

organizations lack first-hand familiarity with an activity that takes place in some external entity. In this case, learning is realized through indirect means of observation and inference. The object of observation may be an organizational routine itself or the documented trace of that activity (for example, the recounting of a technical procedure in a patent filing or an academic paper). In either case, vicarious learning involves an attempt to understand external processes via partial data. Inferential thinking is thus an important complement to observation for filling in unseen details. Finally, *inter-organizational learning* takes place when formal collaborations with other firms – strategic alliances, joint ventures, and other contractual partnerships – draw new knowledge into firm boundaries.

In the framework developed below, I list contextual factors identified by past research as precursors to the forms of learning (experiential, vicarious, and inter-organizational) considered in my research. I distinguish between the internal organizational setting, on the one hand, and the external setting that encompasses dyadic and network arrangements between firms, on the other. These are labeled 'Intra-Organizational' and 'Inter-Organizational', respectively, in Figure 1. After describing the three types of learning in detail, I specify characteristics of the resulting knowledge, as well as the link between knowledge and innovation outcomes. The conceptual framework is displayed in Figure 1 and discussed in detail below.

FIGURE 1: LEARNING, KNOWLEDGE AND INNOVATION – CONCEPTUAL FRAMEWORK



2.3 Antecedents to Learning: Contextual Factors

Past studies have identified specific factors facilitating the development of organizational learning. Fiol & Lyles (1985) discuss four such contextual aspects: corporate culture, strategy, organizational structure, and the environment. Dodgson (1993) argues that environmental changes and internal factors reciprocally influence organizational learning, with firm-level strategy and resources in an intervening role. Scholars have advanced typologies of antecedents to knowledge transfer and knowledge management. Argote, McEvily & Reagans (2003) describe three aspects of context – properties of units (whether the organization, an individual inside the firm, or a population of organizations), properties of the relationships between units, and properties of knowledge – that determine effective knowledge management. In a meta-analytic review of the knowledge transfer literature, van Wijk, Jansen & Lyles (2008) posit three categories of antecedents to the transfer process: knowledge characteristics, organizational characteristics, and network-level characteristics (cf. Adler & Kwon, 2002; Inkpen & Tsang, 2005). Aspects of strategy, structure, and resources – at both the organizational and the inter-organizational levels – are common themes across these works, and I discuss these in turn below.

2.3.1 Intra-Organizational

2.3.1.1 Structural Interactions

Coordination. In one of the first papers in the approach that has become known as the knowledge-based view, Grant (1996a) argued that the primary role of the firm is the integration of knowledge. The proper design of organization

structures should therefore "reduce the extent and intensity of communication needed to achieve knowledge integration" (Grant, 1996a: 381). Coordination and communication efficiencies were paramount concerns, as they would foster the effective use of knowledge internally, and would lead to better overall learning. The importance of coordination is especially relevant to multi-unit organizations, as it facilitates the knowledge sharing that drives capability development (Kogut & Zander, 1996). Tsai (2002) examines both formal and informal means of coordination and their implications for knowledge flows in large firms. His study concludes that decentralization and inter-unit social interaction are two mechanisms that allow for knowledge sharing within the firm.

Structural diversity. A second firm-level antecedent to organizational learning is structural diversity. Much of the work in this vein is influenced by March's (1991) seminal article on the trade-off between exploration and exploitation. Due to the immediate and tangible returns to exploitation, organizations tend to pursue this type of competence-building activity to the relative exclusion of more experimental, uncertain exploratory initiatives. As a result, a substantial literature dealing with 'structural isolation' (Fang, Lee & Schilling, 2010), or the maintenance of separate organizational subgroups keyed in to different strategies and driven by separate cultures, has developed (Benner & Tushman, 2003; O'Reilly & Tushman, 2004; Siggelkow & Levinthal, 2003). The maintenance of structural diversity fosters heterogeneity of ideas, thus enhancing learning outcomes (Fang, Lee & Schilling, 2010). In the case of so-called 'ambidextrous' organizations (Tushman, Anderson & O'Reilly, 1996; He &

Wong, 2004), executives implement separate reporting structures for units tasked with incremental (exploitation-centered) modifications to current technologies and products, on the one hand, and those seeking to develop radically new (exploration-centered) offerings, on the other. To the extent that the same corporate hierarchy houses these dissimilar groups, the organization benefits by profiting from closely related technological advances while simultaneously preparing for discontinuous competitive shifts. This separation also protects the nascent entrepreneurial unit from the encroachments of its well-entrenched organizational counterpart.

In addition to this organization-level treatment, researchers have studied diversity at the team- or work group-level for its effects on knowledge and learning. Cummings (2004) describes the potential of heterogeneous work groups to uncover different sources of information over the course of their operations. The author associates four types of diversity – geographic locations, functional assignments, reporting managers, and business units – with performance-enhancing external knowledge sharing. Bunderson & Sutcliffe (2002) also conclude that functional diversity is positively associated with information sharing; teams comprised of individuals with broad functional expertise are more inclined to exchange information within their groups.

2.3.1.2 Organizational Characteristics / Resources

Firm absorptive capacity. Diversity fosters learning by exposing individuals (and their organizations) to sources of knowledge that might otherwise be overlooked (Cummings, 2004). However, such diversity is a necessary but

insufficient condition for learning. In order to make use of the qualities produced by a diverse work group, companies require mechanisms allowing for the utilization of prior knowledge and for building upon past insights. This is the now well-established characteristic of firm-level absorptive capacity (Cohen & Levinthal, 1989; 1990), according to which a greater stock of accumulated knowledge enables an organization to identify and value other relevant knowledge residing outside firm boundaries. The organization that nurtures such capacity strengthens its ability to make use of both proprietary and public knowledge in refreshing its portfolio of offerings.

Recent studies have added nuance to the prevailing view that this organizational property is positively linked to future learning irrespective of the setting in question. Posen & Chen (2013) argue that absorptive capacity plays two roles in learning, by both fostering the ability to absorb new knowledge from outside and reducing the need for this knowledge in the search for solutions. "The net effect of prior knowledge on external knowledge acquisition depends on which of these roles is more important in a given context" (Posen & Chen, 2013: 13).

2.3.2 Inter-Organizational

2.3.2.1 Structural Interactions

Frequency of interaction. In strategic alliances and other collaborative ventures between organizations, an increased frequency of interaction between partners precedes learning. Doz (1996) observes a sequence of learning-reevaluation-readjustment in the evolution of alliances, whereby ongoing

interaction builds trust, flexibility, and the willingness to make greater subsequent commitments to the venture. Dyer & Singh (1998) argue that the combination of complementary resources created as a result of frequent partner interactions creates difficult-to-imitate dyadic competencies. In their study of a large sample of biotechnology alliances, Zollo, Reuer & Singh (2002) uncover a positive relationship between the number of previous alliances and the performance of a focal alliance; familiarity in this case generates productive coordination patterns that lead in turn to greater learning effects.

Collaboration-based orientation. Many scholars have studied the question of why firms choose to pursue inter-organizational partnerships, with issues such as beneficial complementarity between partners (Chung, Singh & Lee, 2000; Mitsuhashi & Greve, 2009; Rothaermel & Boeker, 2008) and the attempt to develop new products (Rothaermel & Deeds, 2004) key among these. Orientation towards the collaborative activity is an important such consideration for future learning. Hamel, Doz & Prahalad (1989) argue that parties to a strategic alliance who adopt a proactive learning strategy are better able to capitalize upon the opportunity to gain technical resources and knowledge from the relationship on an ongoing basis. In a more prescriptive vein, Inkpen (1998) develops a framework of collaborative learning to guide practicing managers through the process of alliance-based knowledge acquisition. Grant & Baden-Fuller (2004) take issue with what they see as simplistic learning-based explanations of alliance formation, arguing instead that collaboration of this form provides benefits in accessing the

knowledge stock of partners rather than acquiring such external knowledge outright.

2.3.2.2 Dyadic Characteristics / Resources

Inter-organizational similarity. Organizations possess limited resources and their constituent members have imperfect cognitive capabilities. Even when examples from the full set of peer organizations are available as a basis for learning, imperfect causal reasoning can lead to bias in the resulting attributions (Denrell, 2003; Levinthal & March, 1993). Given the prohibitive costs of obtaining information from all members of an organizational population, firms look for similar others to emulate. The presumption is that organizations with some degree of relevant similarity will face the same challenges and respond in ways both appropriate and possible for the focal firm.

In past research, similarity based on organizational size has been studied in the context of market entry decisions of U.S. savings and loan associations (Haveman, 1993), curricular changes in American colleges (Kraatz, 1998), Ontario nursing home chain acquisition location decisions (Baum, Li & Usher, 2000), and new product development activities within the U.S. digital camera market (Srinivasan, Haunschild & Grewal, 2007). Other bases of similarity represented in the academic literature are market position (Kraatz, 1998) and common membership in an industry sector (Baum & Dahlin, 2007). In fast-moving, technologically complex settings, organizations may benefit from observing and internalizing the lessons of companies with closely related technical bases. Referent firms of this type provide guidance for how to make use

of specific organizational capabilities to navigate changing competitive environments.

Relative absorptive capacity. Taking their cue from the firm-level absorptive capacity concept, Lane & Lubatkin (1998) argue that the ability of firms to learn from each other is a function of similarities in knowledge bases, organizational structures, and dominant logics – that is, of relative absorptive capacity. Some degree of overlap or commonality in these key respects is thus an important facilitator of inter-organizational learning. In a further test of the concept, Lane, Salk & Lyles (2001) find that relative absorptive capacity between an international joint venture and its foreign parent determines the ability of the venture firm to understand new knowledge held by the parent.

2.3.2.3 Network Characteristics

Strength of ties. The role of tie strength in organizational networks for the transfer of knowledge and eventual learning is another recurring theme in the literature. Hansen (1999) finds empirical support for the differential effect of strong and weak ties on either search or transfer of information: weak ties provide search benefits by fostering access to nonredundant information, while the existence of strong ties facilitates the actual transfer process. Levin & Cross (2004) posit that trust acts as a mediator between ties and knowledge usefulness, such that weak ties are associated with acquisition of more useful knowledge than strong ties, after controlling for levels of trust. In a study of the interactive effect of strong ties and sparse networks on knowledge creation, McFadyen, Semadeni

& Cannella (2009) conclude that "while strong ties do not provide diverse knowledge resources per se, they are efficient for capturing and utilizing the diverse knowledge made available through sparse ego networks" (McFadyen, Semadeni & Cannella (2009: 560).

2.3.3 Bridging Functions

'Bridging functions' is the final set of antecedents to learning considered in this review. These roles and structures are distinct from external factors in that bridging functions exist inside a given firm, as opposed to within broader inter-organizational entities such as alliances or formal networks. Recent literature has turned attention to the importance of domains beyond the organization as sources of learning and innovation. As one example of these functions, firms gain new knowledge through brokerage (Hargadon, 2002) and boundary-spanning, especially in product development teams, which represent an important locus for the contextual learning preceding commercialization of new innovations (Bresman, 2010). Boundary spanners engage in activities that include scanning beyond organizational boundaries for information about competitors and customers, as well as collecting data on general technical trends emerging in the environment (Ancona & Caldwell, 1992).

2.4 Forms of Organizational Learning

2.4.1 Experiential Learning

Learning at the organizational level occurs when firms generate new knowledge that facilitates either new behaviours or the improvement of existing

ones (Fiol & Lyles, 1985; Huber, 1991; Crossan, Lane & White, 1999). Direct experience with a new organizational routine or type of knowledge yields a number of positive effects over time. Some of the earliest research in this area relates to the so-called 'learning curve' effect (Wright, 1936; Rapping, 1965; Yelle, 1979), wherein ongoing experience with a process leads to steadily decreasing unit costs. Recent research on the knowledge-based view of the firm (Grant, 1996b; Argote & Ingram, 2000) ascribes a more central role to learning, arguing that knowledge is the basis for sustained competitive advantage at the organizational level. In contrast to experience curves that foresee learning as occurring via repetition and improvement of specific activities, the knowledge perspective treats learning as arising from interactions among individuals, routines, and tools; these dynamics create benefits for the firm beyond the setting of immediate use.

However, it has long been recognized that organizational learning can also have negative results. Competency traps (Levitt & March, 1988; Leonard-Barton, 1992) arise as the continued elaboration of expertise along familiar lines makes it difficult to justify reorientation towards emerging technologies. Levinthal & March (1993) make a similar point, arguing that myopia leads organizations to privilege short-run considerations and lessons from success, to the exclusion of more distant – yet potentially more informative – data sources. As firms work within domains associated with their current products, a reification of knowledge architectures results (Ahuja & Lampert, 2001; Henderson & Clark, 1990) and organizational routines become ossified (Leonard-Barton, 1992). Positive short-term returns to experience, if not balanced by attention to longer-term

implications, reduce the motivation (Laursen & Salter, 2006) and ability (Cohen & Levinthal, 1990) to seek out and internalize external knowledge for more 'distant' innovative efforts. Dougherty & Heller (1994) go so far as to argue that proposed innovations take on an air of illegitimacy in established organizations:

> [W]e suggest that the constituent activities of effective product innovation either violate established practice or fall into a vacuum where no shared understandings exist to make them meaningful. (Dougherty & Heller, 1994: 200)

The speed of learning can also present unforeseen problems for firms. Rapid adaptation favours reliability over uncertainty, such that fast learning biases an organization against initially unfavourable alternatives that may still have positive long-term consequences (Denrell & March, 2001). Yet considering the fact that the utility of knowledge gained from learning decays rapidly in the absence of continuous use (Argote, Beckman & Epple, 1990), the dilemma for the firm is to find both an optimal learning speed and an appropriate locus for learning. Finally, the possibility of inappropriate attributions between causes and effects (an incorrect belief that process 'x' invariably leads to outcome 'y') creates the possibility of dysfunctional superstitious learning (Schwab, 2007) in the organization.

2.4.2 Vicarious Learning

A form of learning that may become more necessary as the amount of available information grows, and as the ability of firms to gain experience in all the relevant areas they need to consult is stretched, is *vicarious learning*. Here organizations "faced with insufficient information to learn from their own

experience, attempt to reduce uncertainty by attending to visible and comparable organizations' actions for clues about how to interpret their own situation and act" (Baum, Li & Usher, 2000: 767). That is, organizations also learn by making inferences or attributions related to activities observed in other firms. While early research in this domain conceives of vicarious learning as the mere finding and copying of practices (Darr, Argote & Epple, 1995; Haunschild & Miner, 1997), later work argues for a greater degree of tailoring or modification of externally sourced practices to the realities of the firm in question. In some cases – particularly where learning takes place between independent units within the same company – vicarious learning can even entail collaboration "that may require as much commitment from the experienced group as from the group attempting to learn from that experience" (Bresman, 2013: 36). The outcome of this learning process is a change in the collective cognition or behaviour of an organization due to observation of an external actor (Bingham & Davis, 2012; Kim & Miner, 2007). As noted above, however, this observation can take many forms, ranging from wholesale copying of outside activities to an active engagement with external initiatives designed to ascertain the value of these practices for the would-be adopter. The inferential nature of vicarious learning characterized by recent work also helps to distinguish this phenomenon from more narrowly targeted activities such as reverse engineering (Samuelson & Scotchmer, 2002), which focuses on the replication of competing products or services but is less useful as a source of broader organizational learning.

Conceived of in this way, vicarious learning functions to some degree as a surrogate for direct experience. Vicarious learning has long been recognized as an

important phenomenon at the individual level (Bandura & Walters, 1963; Bandura, 1977), while recent work describes its role within organizational teams (Bresman, 2010), firms (Baum & Dahlin, 2007; Bingham & Davis, 2012; Srinivasan, Haunschild & Grewal, 2007), and industries (Kim & Miner, 2007).

Taking the organizational level of analysis first, the roots of vicarious learning can be traced back to studies of diffusion (cf. Rogers, 1995). Both social and technical aspects are involved in diffusion processes, wherein a new practice or technology becomes more widely adopted by a set of users. As Rogers (1995: 34) states,

> the heart of the diffusion process consists of interpersonal network exchanges and social modeling between those individuals who have already adopted an innovation and those who are then influenced to do so. Diffusion is fundamentally a social process.

Diffusion in this sense can be understood as a process of contact transmission, where the acquisition of a particular routine results from direct contact with another firm (Miner & Haunschild, 1995).

Neoinstitutional theory also emphasizes the role of social factors in organizational decisions. Miner & Haunschild (1995: 143) classify such institutional explanations as cases of broadcast transmission, which occurs "when a single source, such as an organization or a governmental agency, is responsible for diffusing a new routine, practice, or structure across a population of organizations". Early work in this tradition (DiMaggio & Powell, 1983) highlights the role of isomorphic pressure in driving firms to become more similar in key respects as they strive to demonstrate their legitimacy to key audiences. Adoption

of new practices in many cases serves ceremonial or non-technical purposes (Meyer & Rowan, 1977; Tolbert & Zucker, 1983). While the isomorphism claimed by institutional theorists may be one plausible explanation for organizational action, it ignores learning that takes place within the firm. Indeed, it treats learning merely as a means of achieving greater understanding of how legitimacy may be secured for the company in the outside world rather than examining its implications for internal organizational operations.

How, in fact, do organizations learn vicariously from the experiences of others? In the absence of direct experience, firms make inferences by which they attribute observed outcomes to unobserved processes. Such outcome-based imitation can lead an organization to modify internal structures and strategies in an attempt to attain a desired result. In their study of the choice of which investment banker to consult as adviser on an acquisition decision, Haunschild & Miner (1997) identify three mechanisms of vicarious learning: the collection of relevant data through public data sources, the dissemination of information via contacts in inter-organizational forums (business associations or social clubs), and the direct provision of information from an investment banking firm to the potential acquirer. Additional procedures associated with this learning type include reflecting with knowledgeable others on what has worked (and what has failed) in the past, extracting lessons about specific tasks by observing the work of others, and discussing possible ways to improve work processes with others (Ancona & Bresman, 2005). While the means of information acquisition can be more proximate – as in the case of direct discussions – or more distant – as with

the analysis of secondary data sources – the common denominator is an attempt to reconstruct underlying processes with the benefit of partial data. The use of inference then serves to round out these incomplete details for the vicarious learner.

The centrality of intellectual property to the technical expertise of organizations in many sectors also represents an opportunity for potential learning. Researchers have used patent citations as a measure of the flow of ideas and knowledge production (Huang & Murray, 2009), as well as patent cross-citation rates as an indicator of technological overlap (Mowery, Oxley & Silverman, 1998); however, patent data have not yet been mobilized for the purpose of measuring vicarious learning. Scholars have likewise studied licensing as an empirical context within which learning occurs (Bresman, 2013), but have not addressed the specific role of licensing information as a source of learning. Given the value of patents as a source of competitive intelligence (Saluja & Rawat, 2007) and the widespread availability of searchable public databases containing these details, scholarly work that examines the extent to which organizations consult a firm's portfolio of intellectual property assets for the purposes of learning is overdue.

Like experiential learning, vicarious learning has its drawbacks as well. The possibility of superstitious learning, which occurs "when the subjective experience of learning is compelling, but the connections between actions and outcomes are misspecified" (Levitt & March, 1988: 325), can be particularly problematic in vicarious learning. This is especially so when organizational decision-makers focus their observational lenses solely on successful cases,

thereby undersampling from the true population of interest (Denrell, 2003; however, cf. Terlaak & Gong (2008) for an argument stressing the conceivable benefits of learning from incomplete samples of referent organizations).

2.4.3 Inter-Organizational Learning

From an initial focus on learning processes as they unfold within firm boundaries (Fiol & Lyles, 1985; Huber, 1991; Grant, 1996a), scholars now give more attention to interorganizational learning (Lane & Lubatkin, 1998; Holmqvist, 2004; Greve, 2005) and the possibility that firms use collaborations as a means to rebalance their knowledge bases in favour of greater exploratory capabilities (Lavie & Rosenkopf, 2006). The notion that firms form partnerships in order to further learning is central to much theorizing of inter-organizational dynamics (Barringer & Harrison, 2000; Kogut, 1988; Mowery, Oxley & Silverman, 1996).

How this learning occurs in actual practice manifests itself in a number of specific processes. Co-creation of routines and repertoires of joint activities (Larsson, Bengtsson, Henriksson & Sparks, 1998) enables each partner firm to contribute unique insights towards the development of shared solutions to organizational challenges. Extension – "a process whereby one organization extends its experience to others" (Holmqvist, 2004: 72) – and internalization – "which is accomplished by an organization internalizing experiences as retrieved in interorganizational rules" (Holmqvist, 2004: 72) – are particular methods by which organizations combine and deploy disparate knowledge sets via joint learning. Lavie & Rosenkopf (2006) find that firms also seek to manage the

nature of learning produced through strategic alliances by balancing exploitation and exploration across function, structure, and attribute domains.

Despite the professed benefits of these dynamics, however, the result of inter-organizational processes with a presumptive learning focus is not always wholly productive. This is evident in the description of learning races recounted by Hamel, Doz & Prahalad (1989); in such cases, partners to an erstwhile collaborative venture see greater value in exploiting the partnership for their own gain than in building the joint capabilities alluded to above. While benefits occur even in such contexts, these outcomes constitute company-level knowledge accumulation rather than true inter-organizational learning.

2.5 Knowledge and Routines

Given the focus of this chapter on forms of organizational learning, an important question is: learning of what? Given that knowledge is the primary outcome of the learning process (Fiol & Lyles, 1985), a description of this topic is warranted here. Typologies of several types used to describe and assess knowledge remain prevalent in the literature (cf. Argote, McEvily and Reagans, 2003). One such characterization to which researchers have devoted significant attention is the tacit/explicit comparison. According to this view, knowledge exists partially in diffuse form as unarticulated tacit knowledge, as well as in more codified form as explicit knowledge – with the distinction between these forms blurred rather than strongly demarcated (Nonaka & von Krogh, 2009). Organizations encode these disparate types of knowledge in routines (Adams, Brusoni & Malerba, 2013), which consist of "repetitive patterns of interdependent

organizational actions" (Parmigiani & Howard-Grenville, 2011: 417). These routines, in turn, provide the basis for both stable, predictable patterns of activity and change (Nelson & Winter, 1982). Their paradoxical nature places routines at the intersection of learning and innovation; while they constitute the microfoundations of firm-level capabilities (cf. Teece, 2012), they nevertheless diffuse across firm boundaries through mechanisms such as employee mobility (Aime, Johnson, Ridge & Hill, 2010; Wezel, Cattani & Pennings, 2006).

Both experiential and inter-organizational learning, with their emphasis on direct and ongoing company involvement in particular operational activities, lead to the creation of knowledge that is anchored in the immediate context of use – that is, local knowledge. The issue for such knowledge is its 'stickiness', or the relative difficulty of moving it between areas within the firm (or the strategic partnership) where it can best be put to use (Szulanski, 1996; von Hippel, 1994). The added challenge with inter-organizational learning comes from the need to transfer knowledge across organizational boundaries that may represent distinct cultures and procedures.

Vicarious learning, by contrast, represents an attempt to internalize the experience of an outside party without having to create this competence from scratch. Firms only imperfectly replicate routines and processes external to the organization, however. Without the detailed knowledge provided by hands-on experience, a misspecified actions-outcomes relationship (Levitt & March, 1988) is more apt to occur. Since the building of firm-level capabilities tends to be deliberate, long-term, and path-dependent in nature (Teece, Pisano & Shuen, 1997), the vicarious learner may use those components and capabilities already

resident in the firm as inputs into the process it seeks to replicate. Vicarious learning thus results in the generation of knowledge that is non-local in character; this knowledge originates in a different context and must be made salient to the organization's particular setting. 'Stickiness' in this case entails making non-local knowledge intelligible in a new context on the basis of insights furnished by existing organizational competencies.

2.6 Technological Innovation

2.6.1 Characterizing Innovation: Definitions and Types

Innovation is the motive force underpinning growth of the capitalist system of production. Joseph Schumpeter, who introduced the term, makes this point forcefully (1942: 83):

> The fundamental impulse that sets and keeps the capitalist engine in motion comes from the new consumers' goods, the new methods of production or transportation, the new markets, the new forms of industrial organization that capitalist enterprise creates.

Schumpeter (1939) argued that the function of the entrepreneur is to effect innovation by recombining existing components in novel ways. Researchers have subsequently pursued this theme of novelty as a process of recombinant search in scholarship on technology (Fleming, 2001; Fleming & Sorenson, 2001). As the locus of these combinatorial efforts expands beyond the limited technological bases that characterized new product development in the past towards more varied sources of knowledge in the present, complexity and uncertainty increase. Innovation – the development and commercial introduction to markets of new

processes, new products, or new service offerings – is a critical element of success for firms competing in rapidly evolving industry sectors. Given the uncertainty involved in creating technologically innovative products, the management literature has accorded considerable attention to the issue of how organizations manage the learning associated with processes of innovation. As suggested in the previous section, scholars view knowledge and learning to be important precursors to innovation. The well-established concept of absorptive capacity (Cohen & Levinthal, 1989; 1990) testifies to this idea: having built up a significant stock of knowledge internally, a firm is better able to recognize, value, and assimilate useful external knowledge than is an organization less endowed with such absorptive ability. Knowledge accumulation of this sort is also a key antecedent to productive inter-organizational collaboration that targets the development of new innovations, as Lane & Lubatkin (1998) posit with their notion of relative absorptive capacity.

The so-called dynamic capabilities of the firm provide a less static view of the means by which past learning positions an organization for continued innovation. Such capabilities entail "organizational processes, shaped by the firm's asset positions and molded by its evolutionary and co-evolutionary paths" and involve "exploiting existing internal and external firm-specific competences to address changing environments" (Teece, Pisano & Shuen, 1997: 518; 510). The conception of organizations as builders of dynamic capabilities implies the unfolding of unique learning processes over time. These skills enable such companies to innovate in ways not easily replicated by competitors.

Multiple terms are used in the literature – 'breakthrough', 'discontinuous', 'disruptive', 'revolutionary', 'radical', and the like – to characterize innovation of a path-breaking nature. Radical innovation is defined as a product built upon a technological basis new to the industry in question, and that generates significant customer benefit in comparison to existing competitive offerings. This notion of radical innovation as incorporating aspects of both technological and market novelty is consistent with many existing studies in this domain (cf. Abernathy & Clark, 1985; O'Connor, 1998; Zhou, Kim & Tse, 2005; Amara, Landry, Becheikh & Ouimet, 2008).

Such innovations either build upon or erode the competencies of established firms. Tushman & Anderson (1986: 442. Emphasis added) suggest that

> [t]he hallmark of competence-*destroying* discontinuities is that mastery of the new technology fundamentally alters the set of relevant competences within a product class. […] Competence-destroying discontinuities are so fundamentally different from previously dominant technologies that the skills and knowledge base required to operate the core technology shift.

Competence-*enhancing* discontinuities, for their part,

> are order-of-magnitude improvements in price/performance that build on existing know-how within a product class. Such innovations substitute for older technologies, yet do not render obsolete skills required to master the old technologies. (Tushman & Anderson, 1986: 442)

In contrast, incremental innovations can be conceived of as modest improvements in technological parameters that yield small (yet often important) benefits in existing markets. These innovations do not introduce new technologies

into a given sector, and are thus distinct from the discontinuities discussed above. Moreover, they serve to extend the knowledge bases of incumbent firms. For this reason incremental innovations tend to be competence-enhancing in nature, and allow organizations to bring current capabilities to bear in their development.

New entrants to an industry are often credited as the predominant sources of radical innovations. The common belief is that these organizations are less beholden to major customers interested in sustaining, as opposed to disruptive, technologies (Christensen & Bower, 1996). They have also not yet settled into the familiar learning routines that produce innovations in close proximity to existing areas of competence (March, 1991; Levinthal & March, 1993). Furthermore, new entrants are not "handicapped by a legacy of embedded and partially irrelevant architectural knowledge" (Henderson & Clark, 1990: 18) inimical to the creation of radically new offerings.

Recent research, however, suggests that large incumbent organizations may be more important sources of radical innovation than traditionally believed (Chandy & Tellis, 2000; Ahuja & Lampert, 2001; Sorescu, Chandy & Prabhu, 2003). Such views are consistent with Schumpeter's (1942) later work – often referred to as 'Schumpeter Mark II' – which posited that the accumulated knowledge, research expertise as institutionalized in industrial R&D laboratories, and financial resources of large firms would enable these companies to out-innovate their smaller rivals (Malerba & Orsenigo, 1997). This is especially the case for innovations of a competence-enhancing variety, as defined above.

2.6.2 Additional Antecedents to Innovation

In addition to the numerous learning- and knowledge-related precursors to innovation summarized in the previous sections, extensive research focused on antecedents of creative activity can be usefully categorized according to the level of analysis under consideration: external environment, industry, firm, or individual.

Several aspects at the level of the overall environment within which an organization is established have a bearing on the innovative activity that results. Innovation policy, which "explicitly aims to promote the development, diffusion and efficient use of new products, services and processes" (Isaksen & Karlsen, 2011) sets the premises for new product development in particular sectors. The creation of geographically-defined clusters of related and supporting firms provides the physical, technical, and intellectual materials necessary for robust innovation (Gertler, Wolfe & Garkut, 2000; Saxenian, 1991; 1994). Of particular importance in this regard is the technological infrastructure – networks of firms, research and development programs, and business services – available to organizations intent on bringing novel offerings to fruition (Feldman & Florida, 1994). Agglomeration economies of this type extend beyond the mere direct provision of necessary services, however; in a study of garment production in New York City, Rantisi (2002) finds that local institutions play an intermediating function by providing organizations with the ability to observe and learn from the actions of competitors. In situations where market-based institutions are weak or non-existent, the innovation-enhancing effects of business groups may be substantial, as these entities help to develop the critical infrastructure needed to

foster growth and creativity (Mahmood & Mitchell, 2004). While the preceding studies are focused on the generation of new products and services, research on the adoption of innovation provides an important complement to discussions of environmental antecedents. Here the role of information cost and quality emerges as a major determinant of organizational decisions to adopt (Fischer, Arnold & Gibbs, 1996; Jensen, 1988).

Scholars have also examined considerations at the industry level. Inter-firm linkages are a well-studied phenomenon in this respect; indeed, the ability of such arrangements to foster organizational creativity has been well documented. Pennings & Harianto (1992) find that technological networking – the use of licensing programs, joint ventures, and long-term contracts for purposes of developing a new technology – is the best predictor of technological innovation in their study of the implementation of home banking innovations by U.S. commercial banks. According to these authors, firms with an extensive history of networking were also more likely to implement the innovation with strategic partners. Linkages of different types and with a variety of alters have been considered in past research. Among the important drivers of innovation are cooperative agreements struck by small firms with larger partners (Shan, Walker & Kogut, 1994), horizontal cooperative strategies and cross-industry cooperations (Kotabe & Swan, 1995), and structural, institutional, and resource-based links between organizations (Goes & Park, 1997).

At the firm level, plausible antecedents to innovation can be either structural or cultural in nature. Beginning with the former, Bridges & O'Keefe (1984) identify the centrality of technology policy to innovation outcomes,

concluding that both "technology policy and unique structural arrangements appear to be necessary precursors to preinnovation conditions […] that support radical process adoption" (Ettlie, Bridges & O'Keefe, 1984: 693). Forms of control exercised at the organizational level also bear upon innovative activity. Past research has found evidence of specific control patterns – high levels of socialization, low formalization, and moderate centralization – in R&D units with a greater focus on the development of new product offerings (Nobel & Birkinshaw, 1998). Distinctions of this type are also evident between project teams that have developed either radical or incremental innovations (Cardinal, 2001).

Scholars have raised cultural considerations at the firm level for their potential to facilitate innovation. Organizational receptivity to change – the degree to which a firm adapts to change, examines its fundamental assumptions, searches for new ways to look at problems, and deals with new challenges constructively – predicts the success of technical innovations to a greater extent than that of administrative innovations (Zmud, 1984). Similarly, communication patterns differ among R&D units, such that departments involved in the generation of new products demonstrate a greater extent of contact with external entities than do those responsible for the mere adaptation of existing offerings (Nobel & Birkinshaw, 1998). In a broader sense, the overall orientation of the firm reveals much about resulting innovation performance. Atuahene-Gima & Ko (2001) analyze product innovation in Australian firms across a number of different industries; the authors conclude that market- and entrepreneurship-oriented firms generate better new product performance and are more effective in the innovation

process than their less balanced peers. Innovation-supportive cultures that value teamwork and promote risk-taking are likewise better able to foster robust new product development (Jassawalla & Sashittal, 2002).

Finally, individual characteristics are important antecedents to technological innovation. Scholars have cited a positive relationship between favourable management attitudes towards an innovative activity and the ultimate success of the undertaking in question (Zmud, 1984). Beekman, Steiner & Wasserman (2012) posit that in nonprofit organizations, entrepreneurial orientation – traditionally measured as a unitary firm-level construct – can be better conceived of as "comprised of multiple [senior management, board members, and professional staff] perspectives, all of which are essential to innovation" (Beekman, Steiner & Wasserman, 2012: 23). In addition to such perceptual considerations, individual skills and abilities represent more objective predictors of innovation. While scholarly references to absorptive capacity have focused primarily on its properties as a firm-level concept, in their seminal article on the topic Cohen & Levinthal (1990) identify prior related knowledge and diversity of background as determinants of the individual expertise upon which organizational absorptive capacity – and subsequent innovation – is built.

2.7 Research Questions

The experiential nature of learning has been the predominant focus in research on technological innovation, whether at the organizational (Van de Ven & Polley, 1992; Holmqvist, 2004) or inter-organizational level (Doz, 1996; Powell, Koput & Smith-Doerr, 1996; Larsson, Bengtsson, Henriksson & Sparks,

1998; Holmqvist, 2004). In contrast, much of the work on vicarious learning remains oriented towards organizational decisions to adopt practices or technologies developed or put in use elsewhere (cf. Haunschild & Miner, 1997; Baum, Li & Usher, 2000; Greve, 2000). Scholars devote less attention to the question of whether firms use vicarious learning – whether alone or in combination with insights from first-hand experience – to actively develop new innovations. In industries characterized by intense competition, market uncertainty, and expanding technological frontiers, the ability to gain sufficient innovative competence through direct experience alone is called into question. Learning vicariously in such settings may thus represent an important means by which organizations complement their historical expertise and drive new product offerings to commercialization.

As highlighted above, scholars have found that similarity between organizations on important traits explains the tendency for firms to learn vicariously in a variety of contexts. Similarity is most often operationalized based on organizational size (Haveman, 1993; Kraatz, 1998; Baum, Li & Usher, 2000; Srinivasan, Haunschild & Grewal, 2007), though research has also employed measures of relative market position (Kraatz, 1998) and common membership in an industry sector (Baum & Dahlin, 2007). This literature has not yet explored technological overlap as a basis for vicarious learning in detail, though. Yet in high-technology industries, complex products derived from new insights or unique combinations of disparate fragments of knowledge underlie sustained competitive advantage. Given both the uncertainty inherent in these settings and the tendency to search locally for solutions to organizational challenges,

technological overlap could play a key role (albeit a currently under-examined one) in the extent to which learning is successfully translated into innovation.

At the organizational level, learning in the context of technological innovation has been characterized as a trial-and-error process (Van de Ven & Polley, 1992) where firms adapt courses of action in response to observed outcomes. Research has also posited the recombination of familiar components[2] (Fleming, 2001), particularly in conditions of high interdependence between such components Fleming & Sorenson, 2001), as a means by which learning may be made manifest in innovative products. Fleming argues that inventors will take greater inventive risk when the components with which they work are well-understood, thereby increasing the likelihood of generating new breakthroughs.

As noted above, inter-organizational similarity is key for firms intent on identifying referents in processes of vicarious learning. Yet if the recombination of components and knowledge is one means by which organizations seek to innovate, then it is reasonable to expect that the relative congruence in technological bases between two firms could reliably predict the extent to which a focal company views vicarious learning as a potentially promising activity. We might expect the benefits of using comparator organizations to persist across a range of environmental circumstances. This being said, situations characterized by

[2] While the term *component* is generally associated with distinct parts of a physical product (e.g. the mask and the wafer surface in Henderson & Clark's (1990) photolithographic aligners), Fleming views them as encompassing inventive material in general, whether instantiated in a physical product or not: "'components' will denote the constituents of invention, along the lines of what Schumpeter calls 'factors' (1939, p. 88)". (Fleming, 2001: 118)

emerging novelty or uncertainty magnify the importance of using similar others as referents for learning purposes. As Terlaak & Gong (2008: 847) state, "comparable organizations are especially critical when the value of the practice is not universal, since learning from them allows observers to hold constant firm traits that are tied to variations in the practice's value". Such uncertainty may be especially germane where organizations are pursuing the development and ultimate commercialization of innovations – particularly when such innovations involve new technologies and market segments.

In my thesis, I seek to explain the role played by experiential, vicarious, and inter-organizational learning in generating technologically innovative products. More formally, my main research questions can be stated as follows:

> 1) How are experiential, vicarious, and inter-organizational learning involved in the development of technologically innovative products?
>
> 2) Does the overarching learning process differ materially across innovation projects within the same industry sector?
>
> 3) What characteristics of the underlying innovations account for differences in the types of learning used and the interactions between these types as the development process unfolds?

The following chapters are oriented around the common theme of organizational learning and technological innovation. My first empirical paper employs qualitative research to further specify the relationships between these learning processes and technological innovation. In the subsequent chapter I report the results from a large-sample test of the relationships between

experiential learning, vicarious learning, and technological innovation. Using a data set consisting of new medical device innovations approved for marketing purposes by the U.S. Food and Drug Administration (FDA), I examine the individual and joint roles of the three forms of organizational learning – experiential, vicarious, and inter-organizational – described above in explaining innovation performance.

CHAPTER 3: SEQUENCES OF LEARNING IN TECHNOLOGICAL INNOVATION – TOWARDS A PROCESS MODEL (QUALITATIVE PAPER)

3.1 Introduction

Organizational learning occupies a central place in both the theorization of innovation processes and their actual unfolding in specific industrial contexts. Learning at the organizational level occurs when firms generate new knowledge, understanding or insight that facilitates either new behaviours or the improvement of existing ones (Crossan, Lane & White, 1999; Fiol & Lyles, 1985; Huber, 1991). As such, learning and innovation are intimately linked. Indeed, short of the wholesale replacement of incumbent firms in ongoing cycles of disruptive change, it is difficult to conceive of processes leading to new, technologically innovative offerings that would not also foster learning on the part of their organizational champions.

Past research has focused on several methods by which companies engage in learning. The first, and undoubtedly most well-established, approach can be labelled *experiential learning*. According to this view, firms gain relevant insights through their own direct experience with routines and patterns of activity. These mechanisms create salient knowledge that can then serve to inform future action of a related nature. A second form of learning, *vicarious learning*, has also surfaced in the organizational literature (Baum, Li & Usher, 2000; Bingham & Davis, 2012; Kraatz, 1998; Srinivasan, Haunschild & Grewal, 2007). Research in this vein suggests that organizations glean useful knowledge from observing activities undertaken externally, using inference and other attributions to

reconstruct the relevant processes. The observation in question may entail examining academic literature or attending technical presentations in an effort to gain insight into underlying processes in place at other firms. Given the increasing incidence of formal collaborations such as joint ventures and strategic alliances engaged in by many firms, *inter-organizational learning* has also emerged as a way to expand existing organizational knowledge (Larsson, Bengtsson, Henriksson & Sparks, 1998). The proximity afforded by these alliances creates an environment conducive to the sharing of expertise and the mutual pursuit of strategic goals, both of which augur for greater learning benefits over time.

While researchers have examined these forms of learning separately in an effort to more fully delineate their roles in organizational processes, the ways in which they interact and complement each other over time to produce beneficial outcomes remains an understudied phenomenon (cf. Bingham & Davis, 2012 for a recent and notable exception). The inter-relations among these diverse forms of learning throughout the process of technological innovation represent an important area of inquiry for management scholars in a world where the knowledge economy has become the new paradigm. In this paper I address this lacuna. Using data collected through both archival sources and interviews with scientific researchers, executives, and industry association representatives in the biopharmaceutical and medical device sectors, I specify the roles played by experiential, vicarious, and inter-organizational learning at the stages of innovation from initiation through to commercialization and post-market testing. These findings offer useful insights into the locus and sources of learning related to innovation processes in technologically complex settings.

3.2 Theoretical Development

3.2.1 Experiential Learning

The examination of organizational learning derived from direct experience can be traced back to manufacturing-centric studies of learning curve effects (Rapping, 1965; Wright, 1936; Yelle, 1979), where researchers observed that experience with a particular process leads to steadily decreasing unit costs. In a more general sense, scholars attribute importance to firm-level absorptive capacity (Cohen & Levinthal, 1989; 1990), by which a greater stock of accumulated knowledge enables an organization to identify and value relevant new knowledge outside firm boundaries. Research on the knowledge-based view of the firm (Argote & Ingram, 2000; Grant, 1996a) goes even further, arguing that knowledge is *the* basis for sustained competitive advantage at the organizational level.

Firms obtain experiential learning by several routes. We can identify three general approaches in this respect: trial-and-error learning, learning through experimentation, and learning through recruitment. Trial-and-error processes involve the adaptation of future courses of action based on the consequences experienced from earlier activities (Bingham & Davis, 2012; Van de Ven & Polley, 1992). Organizations undertaking trial-and-error learning can thereby incorporate the lessons of the past into subsequent behaviours, informed by the notion that their prior activities produced particular results.

Learning through experimentation, in contrast, involves introducing deliberate variations into organizational activities so as to develop knowledge

concerning causal relationships (Miner, Bassoff & Moorman, 2001). In the context of innovation, this includes the use of experimental products (Brown & Eisenhardt, 1997) and small-scale probes designed to gather market information (Lynn, Morone & Paulson, 1996). The circumscribed nature of experimental learning sets it apart from trial-and-error processes, since experimentation tends to incur lower costs and presents fewer risks to the initiating firm than does the more comprehensive effort underlying trial-and-error learning.

A final form of experiential learning is learning through recruitment; that is, the hiring of individuals or teams with knowledge and skills not currently possessed within the organization. Although recruitment is an important means by which a firm can gain new understanding that facilitates new behaviours, its ultimate effectiveness may be determined by intervening factors such as the identification of causal processes and the creation of adequate routines to learn from these external recruits. That is, recruitment needs to be accompanied by broader structural changes if it is to have a material impact on learning; a mere grafting of new hires onto an organization is unlikely to contribute meaningfully to learning by itself. For this reason, we might consider learning through recruitment to be a secondary learning process that follows on from the insights gained through trial-and-error or experimentation.

Gaining first-hand experience through experiential learning allows organizations to generate insight into plausible mechanisms by which actions yield particular outcomes. The resulting causal attributions tend to be more confidently made, given the close contact to the overall process that the firm enjoys. Despite the undeniable benefits accruing to direct experience, however,

there are several reasons why learning that is limited to such an immediate domain may not be enough to support technological innovation. The pace of technological change in most industries is one reason that firms cannot rely on experiential learning only. In order to achieve an experience-based understanding of the many technical bases underlying sophisticated new products, a would-be innovator requires both time and resources. Such investments may be too great for all but the largest organizations; even large firms might more efficiently allocate assets towards specialized areas of expertise in which they can more readily establish or sustain competitive advantage.

In addition, even where this strategy is possible, the benefits of such a circumscribed experiential approach to innovation are questionable. Competency traps (Leonard-Barton, 1992; Levitt & March, 1988) may arise as the ongoing building of expertise in areas of technical familiarity limits any reorientation towards emerging technologies, even when such a change may be critically necessary. In a related sense, myopia may lead organizations to privilege short-run considerations and lessons from success over other data sources (Levinthal & March, 1993). The speed of learning also presents firms with a further dilemma. Rapid adaptation favours reliability over uncertainty, with the counter-intuitive result that fast learning can bias an organization against alternatives that, while initially appearing unfavourable, may nevertheless be better long-term choices (Denrell & March, 2001). Finally, firms engaged in experiential learning cannot always assure the accurate causal attributions alluded to above. Schwab (2007) highlights the possibility that actors surmise inappropriate linkages between causes and effects, creating the likelihood of dysfunctional superstitious learning

within organizations. Considering these important limitations, additional forms of learning can supplement direct experience in organizations that seek to innovate. Vicarious learning may be a valuable complement in this respect.

3.2.2 Vicarious Learning

Where hands-on experience with a given practice or technology is either unavailable or considered inadequate, firms may engage in a process of inference whereby they attribute observed outcomes to unobserved processes undertaken in other organizations. Outcome-based imitation (Haunschild & Miner, 1997) of this kind can lead to the modification of internal structures and strategies in an attempt to attain some desired result.

It would nevertheless be difficult to conceive of a situation in which an organization intent on learning vicariously could observe and draw lessons from every relevant source. Limited time and financial resources conspire against such ambitious plans. Just as important is the fact that such voluminous information flows would overwhelm individual cognitive capacities. In deference to this limitation, researchers conceive of organizational decision-makers as boundedly rational 'naïve intuitive statisticians' (Terlaak & Gong, 2008; cf. Peterson & Beach, 1967) "who, within their cognitive limits, use the observation of others to infer whether adoption of an observed practice provides a technical value to their firm" (Terlaak & Gong, 2008: 848). Given the prohibitive costs of obtaining information on all potentially valuable learning referents, firms look for similar others to emulate. Similar organizations will face many of the same challenges as

– and might respond in ways appropriate for – the observing firm. Bresman (2010: 86) specifies the value of similarity in his examination of external learning:

> Vicarious learning activities allow teams to improve based on the experience of others. Thus, these activities involve others who have experiences associated with tasks that are similar enough to yield applicable lessons learned.

Past research has measured similarity based mainly on organizational size; scholars have conducted studies of this sort in the context of market entry by savings and loan associations (Haveman, 1993), curricular changes in colleges (Kraatz, 1998), nursing home chain acquisition location decisions (Baum, Li & Usher, 2000), and new product development in the digital camera market (Srinivasan, Haunschild & Grewal, 2007). Other bases of similarity represented in the literature are market position (Kraatz, 1998; Rhee, Kim & Han, 2006), common membership in an industry sector (Baum & Dahlin, 2007), and geographic proximity of competitors (Kim & Miner, 2007).

Perhaps due to the increasingly pervasive notion that observation focused solely on successful cases risks undersampling from the true population of interest (Denrell, 2003), researchers have more recently considered whether organizations may also learn vicariously through the failure of others (Ingram & Baum, 1997; Kim & Miner, 2007). While the observation and inference process may be used to learn from others' failures in addition to their successes, the reason for studying failure is to gain knowledge that will enable a firm to avoid the negative outcome experienced by the earlier organization.

3.2.3 Inter-Organizational Learning

Vicarious learning, while focused on referents outside the organization itself, relies on indirect methods of observation and inference in order to generate new knowledge. By contrast, inter-organizational learning occurs when the firm is directly linked to the external party from which it presumes to obtain insights. The ever-growing use of formal contractual collaborations such as strategic alliances, as well as the continued elaboration of industry-level networks, has brought with it increased attention to the learning dynamics inherent in such arrangements (Doz, 1996; Hamel, Doz & Prahalad, 1989; Lane & Lubatkin, 1998; Larsson, Bengtsson, Henriksson & Sparks, 1998). I explore two specific approaches to inter-organizational learning in this paper: learning from others through direct contact and learning from partnering or other formal collaboration.

Learning from others through direct contact occurs when proximity to key constituents provides a mechanism by which the organization derives insights that inform future behaviours. These constituents may include suppliers, subcontracting firms, regulators, and lead users (Lilien, Morrison, Searls, Sonnack & von Hippel, 2002; von Hippel, 1986), among others. The role of knowledge brokers, individuals and organizations "bridging multiple domains and moving ideas from where they are known to where they are not" (Hargadon, 2002: 44), is often an important factor in this phenomenon. Direct contact provides the learning organization with an opportunity to shorten learning cycles by obviating the need for imperfect inference of observed processes, though the extent to which the third party in question will be willing to share important insights completely is often uncertain.

Learning from partnering involves lessons imparted through knowledge sharing activities undertaken in the context of strategic alliances and other contractual agreements. Routines and repertoires of action designed to create and capture knowledge generated through inter-organizational activities are particular paths through which this type of inter-organizational learning unfolds (Larsson, Bengtsson, Henriksson & Sparks, 1998).

The summary above reflects the ongoing attention accorded to processes of organizational learning in the management literature. This scholarly work has yielded key findings on the interaction between experiential and vicarious learning activities (Bresman, 2010; Kim & Miner, 2007; Schwab, 2007), as well as the extent to which researchers accord differing degrees of importance to direct experience or observation and inference over time and in different circumstances (Baum & Dahlin, 2007; Terlaak & Gong, 2008). Despite the numerous insights that have accumulated in this vein, some important gaps in our understanding remain. Little is known about the sequencing of learning processes over time. Bingham & Davis (2012) provide an important exception in their study of the temporal ordering of learning processes as they relate to international expansion activities by entrepreneurial firms. This paper extends the line of research of these authors by examining learning sequences as they occur in innovation development activities. In contrast to international expansions, technological innovation unfolds over a longer trajectory of time and generally involves a number of complex sub-processes that contribute to the eventual success or failure of the project as a whole. As such, the development of innovative products represents an

interesting context within which to advance the research agenda of learning dynamics.

This paper proposes to contribute to management theory and practice by specifying in greater detail the respective roles played by experiential, vicarious, and inter-organizational learning activities throughout the process of technological innovation. Overall findings support the idea that the forms of learning shift and evolve as the process of discovering, developing, and commercializing a new innovation unfolds. I also describe the distinct ways in which the sequencing of forms of learning may take place within a given innovation project over time.

3.3 The Process of Innovation

The process of innovation, wherein organizations conceive and develop new products or services for eventual market introduction, consists of several distinct stages. Although researchers have developed different models of this process, common elements tend to include periods of initiation, development, and implementation (Van de Ven, Polley, Garud & Vankataraman, 1999). During initiation, external events and organizational initiatives help to set the stage for what will eventually be a more active pursuit of work related to the new offering. The development period that follows is characterized by a significant degree of flux or fluidity, as companies successively target design parameters, technical specifications, and other fundamental aspects of the proposed innovation for investigation. Finally, during implementation the innovation is "adopted and institutionalized as an ongoing program, product, or business or it is terminated

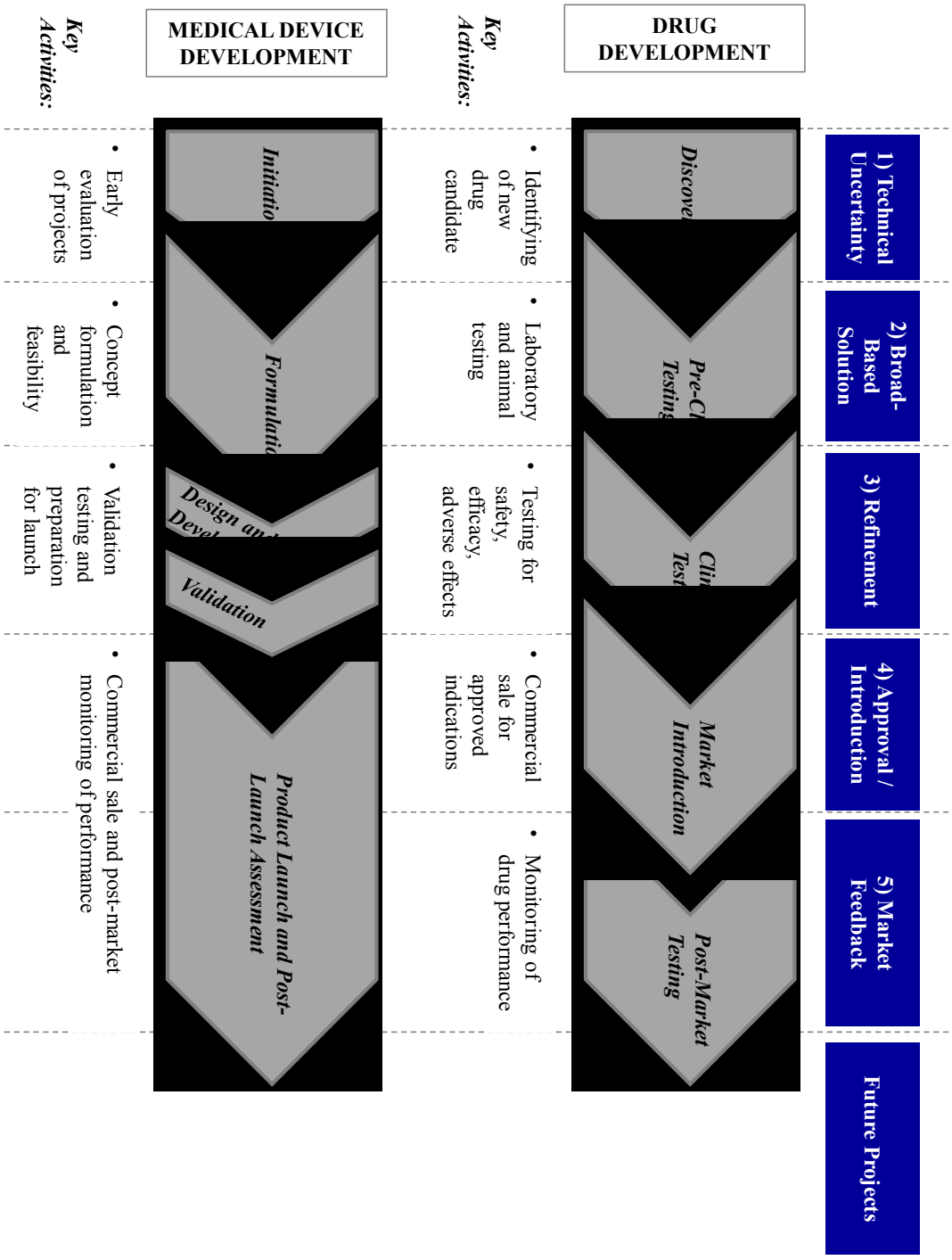
and abandoned" (Van de Ven, Polley, Garud & Venkataraman, 1999: 25). Those projects that successfully navigate this stage are introduced to the marketplace, after which their organizational sponsors incorporate feedback from end users and other interested parties into new iterations of the product or service.

In this paper I expand the three-stage model of the innovation process described above, in an effort to describe more fully the types of learning taking place at particular points in development. I identify the following sequence of steps in the overall process: 1) an initial period of Technical Uncertainty, where generalized search and basic scientific activities are undertaken without a specific marketable product having yet been identified; 2) the settling upon a Broad-Based Solution – that is, the creation of an initial (though still ambiguous and in need of specification) product idea; 3) Refinement of this product, which involves decisions related to design and function, as well as coordination with regulators and other parties in advance of commercialization; 4) Approval and Introduction into the marketplace; and 5) Market Feedback, or the gathering of usage data related to the new product, which can then serve to inform further development efforts. As a final step designed to capture the persistence and usefulness of learning for subsequent initiatives, I consider the transition to Future Projects within the firm.

Figure 2 provides a schematic representation of the innovation process as it is conceived of in this paper. In order to better anchor my analysis in the empirical setting studied, I also map the stages of organizational activity and regulatory approval held to occur in the drug and medical device development sectors (cf. Mossinghoff, 1999; Pietzsch, Shluzas, Pate-Cornell, Yock & Linehan,

2009) to my representation of the process. I describe these segments in more detail in the next section.

FIGURE 2: THE DRUG DISCOVERY AND DEVELOPMENT PROCESS



3.3.1 The Development Process – Therapeutic Drugs and Medical Devices

Within the context of this paper, I take the innovation process to include the full set of activities originating with the discovery of a potentially useful therapeutic treatment or device and proceeding to the eventual commercialization of a product based on this novel insight. Accordingly, it will be useful at this point to describe some of the more important steps involved in biopharmaceutical and medical device innovation – that is, in identifying, developing, and marketing a branded product that addresses a particular disease or medical condition.

As Figure 2 shows, five stages are discernible in the innovation process for drug development: *Discovery*, *Pre-Clinical Testing*, *Clinical Testing*, *Market Introduction*, and *Post-Market Testing*. The *Discovery* phase entails identification of a potentially promising new drug candidate. The insights uncovered at this early point often originate in basic research activities focused on understanding the biological behaviour of disease and the chemical pathways of physiological processes. Given the esoteric nature of the knowledge involved in discovery, this stage is typically led by researchers affiliated with university labs. Key findings are published in specialized academic journals. If the candidate entity looks to have high commercial potential – if, for example, it addresses a well-defined yet underserved disease category or offers the possibility of a significant improvement over current treatment options in the market – university researchers may form a small biotechnology company to carry this development forward.

In *Pre-Clinical Testing*, researchers perform multiple studies to assess the safety of the drug candidate for eventual human use. These tests are carried out in animal models so as to observe any negative reactions that may outweigh the intended benefit of disease treatment. Where the outcomes from pre-clinical testing are sufficiently positive to warrant continued development, these results provide data useful in determining dosage regimes for the next phase of tests on humans. The biotechnology firm takes responsibility for the design and implementation of pre-clinical trials, often in association with other firms that specialize in this domain. Such specialist entities include contract research organizations (CROs) and contract manufacturing organizations (CMOs); these companies tend to have a well-established expertise in conducting trials, as well as in generating and interpreting the associated results.

The next step, *Clinical Testing*, involves testing of the drug candidate on human subjects. The regulatory agencies whose responsibility it is to approve new drug treatments for human diseases mandate such activities. Although the specific tests required may vary across national jurisdictions, this stage generally incorporates those aspects of the process adhered to by the U.S. Food and Drug Administration (FDA). This regulator stipulates the completion of three separate tests prior to approval. Phase I testing entails the recruitment of healthy individuals to determine the overall safety and relevant dosage of the drug. In Phase II, researchers undertake tests on patients to observe efficacy – how well the drug works at treating the disease in question – and side effects. Phase III necessitates the enrollment of larger patient populations, usually across multiple sites, to monitor the effects from long-term use and provide further evidence of

efficacy as compared to already available treatments. During the Clinical Testing stage collaboration between biotechnology and pharmaceutical companies begins in earnest. Agreements may take the form of licensing contracts, joint ventures, or outright acquisitions. As in the previous stage, firms enlist CROs to help identify and recruit trial participants, as well as to gather and analyze the attendant test data.

Assuming favourable results from the previous phase and approval by the regulatory authorities, the next stage to unfold is *Market Introduction*. This involves the commercial sale of the drug for disease indications approved by regulators. Given the generally well-established sales and marketing capabilities of large pharmaceutical firms, these organizations tend to be the primary actors at this point.

Once the drug has become available for sale in the national market, regulators activate an ongoing phase of *Post-Market Testing*. The national authorities generally undertake such testing for two different reasons. First, at the behest of the regulatory agency, testing for safety surveillance may be pursued in order to ensure the absence of any long-term problems that had not revealed themselves during the more circumscribed Clinical Testing stage. Second, the pharmaceutical company sponsoring the drug may itself choose to undertake post-market testing in an effort to discover potential new markets for the drug or separate disease indications for its use.

The medical device innovation process goes through a similar but not identical set of steps: *Initiation*, *Formulation*, *Design and Development*, *Validation*, and *Product Launch and Post-Launch Assessment*. In the *Initiation*

stage, the originating company proceeds through the early evaluation of candidate projects addressing particular market needs. In contrast to the Discovery stage for drug development, the degree of basic uncertainty surrounding the innovation is typically lower for a medical device at this point; nevertheless, one can see a fair amount of ambiguity regarding final design and functioning here.

Next is the *Formulation* stage, where the nascent product undergoes design modifications and early prototyping. Important considerations at this stage involve the feasibility of the product from both a market need and a manufacturing standpoint.

In *Design and Development*, researchers subject the medical device to a battery of tests intended to ensure compliance with regulations related to quality, safety, and performance in the marketplace. It is generally also at this stage that data are submitted to the FDA by the sponsoring company for regulatory approval purposes. This is followed by the *Validation* stage, wherein organizations generate formal design plans and manufacturing prints.

The final stage is *Product Launch and Post-Launch Assessment*. Analogous to the post-market activities undertaken in the drug development process, the medical device company during this phase will generally pursue improvements through the collection of user feedback.

This synopsis of the biopharmaceutical and medical device innovation processes, while admittedly simplified, nevertheless provides us with a useful way in which to conceive of organizational learning as it relates to innovation. Indeed, as I show in the remainder of this paper, the learning process is active at all stages

of development. The contours of this process, however, – the methods, combinations, and sequence of learning – vary in important ways as the cycle of activities unfolds.

3.4 Empirical Setting

As stated above, I undertook this research in the biopharmaceutical and medical device sectors, each comprised of numerous companies, industry associations, research institutes, and other actors working towards the discovery, development, and commercialization of new treatments for human disease. There are several reasons why I considered this setting particularly useful to study processes of organizational learning as they relate to innovation. First is the centrality of ongoing innovation to the financial success of these companies. While the ability to innovate is key in many industries that rely upon advanced technologies for the creation and refinement of their market offerings, it is especially germane to biopharmaceuticals because of the much discussed 'patent cliff', a term invoked to denote the sharp drop in pharmaceutical revenues expected as many of the major blockbuster drugs lose their patent protection in the coming years.[3] Second, the diversity of actors involved in innovation processes in these sectors would seem to create fertile ground for the new insights required of innovation. These actors include, among others, scientific researchers at academic institutions; technology transfer personnel affiliated with major

[3] A particularly stark case of patent cliff concerns can be seen at the large American pharmaceutical firm Eli Lilly, which stands to lose U.S. patent protection on eight significant drug products – which taken together generated roughly three-quarters of Lilly's worldwide revenues in 2009 – within the next seven years (Eli Lilly and Company, 2009; Wilson, 2010).

universities; executives at biotechnology and pharmaceutical companies; product design and engineering consultancies; directors of industry associations; and venture capitalists, angel investors, and other funders. Finally, a substantial and growing body of academic literature relates to biopharmaceutical innovation. Researchers have devoted scholarly attention to such topics as the role of firm competencies and learning strategies (Bierly & Chakrabarti, 1996; Galambos & Sturchio, 1998), inter-organizational collaboration (Baum, Calabrese & Silverman, 2000; Oliver, 2001; Whittaker & Bower, 1994), and network position and membership (Liebeskind, Oliver, Zucker & Brewer, 1996; Powell, Koput & Smith-Doerr, 1996; Rothaermel & Hess, 2007) in this industry. These past studies comprise a useful foundation upon which to build new insights.

While there are important commonalities across the firms in this setting, I also sought to introduce sufficient variation into my sample to allow for the creation of robust theoretical insights. The innovation projects studied occur in firms from two geographical locations (Canada and the United Kingdom); many of these initiatives are currently at different stages of development (from early pre-clinical testing through to regulatory approval and commercialization) and relate to dissimilar disease categories (oncology, bacterial infections, and glucose monitoring, to name a few). By assembling a sample of firms that, though from broadly similar sectors, nonetheless demonstrate important distinctions, I seek to build theory that is generalizable while recognizing the attendant limitations.

3.5 Data Collection and Analysis

In this research I adopted a process orientation to study the ways through which innovation projects unfold over time. In contrast to variance models, which examine the impact of variables on observed outcomes but do not account for temporal ordering among predictors, "process theories take sequence and ordering to be critical. An outcome is explained in terms of diachronic patterns – who does what when and what happens next – rather than in terms of the synchronic presence of higher or lower levels of specific attributes" (Langley & Tsoukas, 2010: 6). By examining the particular activities occurring at various stages of the innovation process, as well as the transitions in these patterns between phases, I endeavoured to better understand the sequencing of events in this phenomenon and their possible implications for the resulting outcomes.

I undertook two separate but related data collection stages for this project. The first (spanning from February 2011 through to December 2011) was designed to ensure an overall familiarity with the biopharmaceutical and medical device sectors, the key participants at the particular phases of the development process, and the major challenges facing the industry. To this end I gathered a substantial corpus of background material in the form of trade publications, academic articles, white papers and policy position statements prepared by industry lobbying groups, and corporate reports. I also undertook interviews with the Executive Directors of three large industry associations, the Vice-President of a national lobbying organization, and a number of well-placed informants in institutions working at the intersection of academic research and commercial

applications, all in order to supplement the knowledge drawn from these archival sources.

In the second stage (June 2011 through September 2012) I conducted interviews with past and present executive leaders – founders, chief executive officers, chief scientific officers – of biopharmaceutical and medical device companies pursuing discovery and development activities. The associated companies were generally small organizations based in the Montreal, Toronto, and Oxford (UK) areas. Table 3 lists the pertinent details for each of the organizations included in my sample. I completed a total of 32 interviews across the two project phases.

TABLE 3: KEY DETAILS OF ORGANIZATIONS IN THE RESEARCH SAMPLE

Stage One – Background Interviews (February to December 2011)

Company *	Category	HQ Location
BELLONA	Industry association	Ottawa, ON
ICARUS	Academic institution	Montreal, QC
LOKI	Industry association	Toronto, ON
MERCURY	Industry association	Montreal, QC
ROMA	Lobbying group	Toronto, ON

Stage Two – Examination of Specific Innovations (June 2011 to September 2012)

Company *	Innovation Project		HQ Location	Interviewees
	Description	Current Status		
CALYPSO	• Chromatin targets in cancer therapy	• Entering Phase III testing	Oxford, UK	Chief Medical Officer
GALILEO	• Glucose monitoring system	• In preparation for FDA 501(k) submission	Oxford, UK	Chief Technology Officer; VP Regulatory Affairs & Quality
GRATIA	• Modulation of apoptosis (programmed cell death) suppressors in cancer cells	• Entering Phase III testing	Montreal, QC	Founder / Former Chief Scientific Officer and Interim CEO
	• Inhibition of biosynthesis in cancer cells	• Stalled in development post-acquisition		

Company *	Innovation Project		HQ Location	Interviewees
	Description	Current Status		
IRIS	• T-cell receptor technology for cancer treatment	• Phase I/II	Oxford, UK	Chief Scientific Officer
OMEGA	• CRTH2 antagonists in asthma and chronic allergies	• Phase IIb	Oxford, UK	Director of Discovery & Development Projects; Director of Development and CMO
PAN	• Plasma energy as basis for surgical instruments	• FDA 501(k) approval	Oxford, UK	CEO; Operations Manager; Subcontractor for product design and manufacturing
PLUTO	• Biosimilar for treatment of breast cancer	• Pre-clinical testing	Toronto, ON	Founder; CEO; Director of Research
SATURN	• Diagnostic platform for assays	• FDA approved / in approval process	Toronto, ON	CEO; CFO
SOL	• Targeted secretion inhibitors	• Early pre-clinical development	Oxford, UK	Chief Development Officer
TELLUMO	• Use of monoclonal antibodies to target toxins produced by bacterial infections	• Currently in clinical testing (Phase II high dosage study)	Montreal, QC	CEO; Co-inventors of antibody patent (2)

***** Disguised company names are used to maintain the confidentiality of respondents

During these encounters I asked for details regarding key steps, obstacles, and particularly valuable sources of learning related to specific innovation projects with which the interviewees had direct experience. To reduce self-serving bias or retrospective rationalization, I asked each interviewee to identify additional individuals with whom I could discuss the same development projects as well as relevant sources of archival data to substantiate my findings. Just as important, I sought out a variety of viewpoints on each project; where possible, I contacted university researchers responsible for the patents underlying the drug in development; senior members of affiliated organizations, such as joint venture partners or licensees; and early investors in the focal company. By proceeding in this way, I attempted to obtain as faithful a recounting of the innovation process as possible.

As part of the data collection initiative, I decided to allow overlap in the time between stages. The result was an ongoing iteration between research into general issues of learning and innovation in the biopharmaceutical and medical device industries, on the one hand, and examination of key concerns as constituted in specific innovation processes, on the other. Structuring my data gathering in this fashion allowed me to refine my thinking and elaborate new areas of inquiry as they were revealed to me by sources, whether first- or second-hand in nature. In a more general sense, making use of multiple and diverse data sources throughout this analysis allowed me to triangulate my findings (Eisenhardt, 1989), thus adding robustness to the insights reported here.

I employed an interview guide approach (Patton, 2002) in this paper. Rather than selecting from a fully defined list of questions, I solicited my respondents for details regarding broad "topics or subject areas within which the interviewer is free to explore, probe, and ask questions that will elucidate and illuminate that particular subject" (Patton, 2002: 343). This allowed me to maintain some consistency in the set of major themes and questions across individuals (thus facilitating subsequent analysis), while also providing me the freedom to probe into unanticipated topics raised during the discussions. Each interview was audiotaped with permission from the interviewee; otherwise detailed handwritten notes were taken. The interviews – which lasted anywhere from 30 minutes to two and a half hours, and were conducted in either English or French depending on the preference of the interviewee – were then transcribed by hand.

Next I coded the transcripts in the qualitative software package NVivo. I identified a set of first-order codes so as to gain an initial perspective on concepts that seemed to be particularly well represented in the data. These were then subjected to further study through axial coding, wherein "categories are related to their subcategories to form more precise and complete explanations about phenomena" (Strauss & Corbin, 1998: 124). With the data thus coded to allow for the elaboration of insights into forms of learning and knowledge identified by the respondents as useful, I then re-coded all transcripts according to the particular stages of the innovation process (technical uncertainty, broad-based solution, etc.) described above. The result of these efforts was a complete dataset cross-coded from a thematic and process-level perspective, one that enabled me to discern

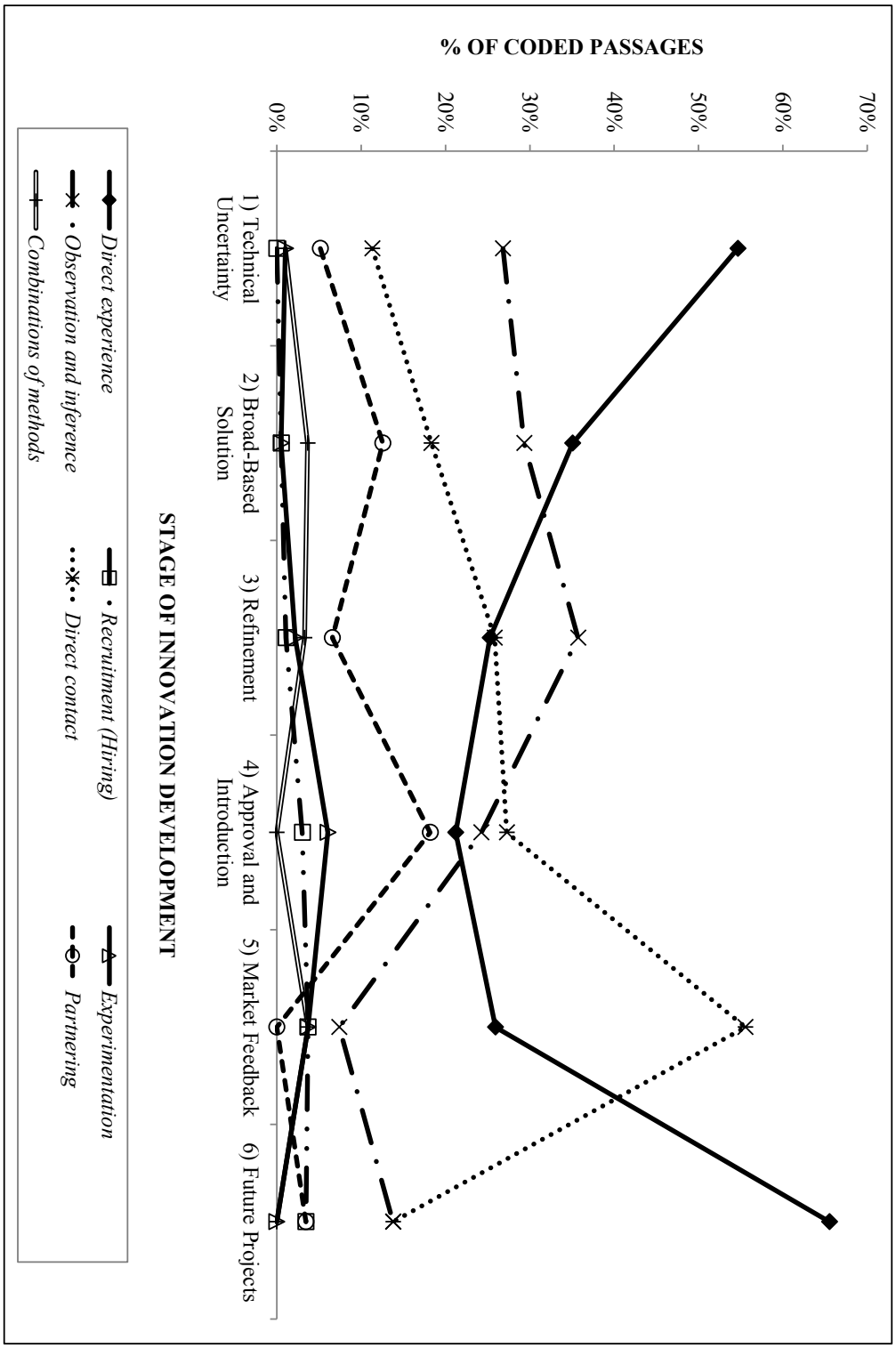
more accurately not only important forms of learning, but their relative occurrence (or non-occurrence) at different stages. This process of analytical refinement, interspersed with periodic returns to the relevant literature for guidance with regards to emerging patterns, ultimately led to the identification of several major themes recurring across the interviewees and innovation projects in my sample.

3.6 Results

3.6.1 Forms of Learning at Successive Stages in the Innovation Process

Figure 3 provides an initial overview of findings related to the forms of organizational learning most prevalent at different stages of the innovation process. This exhibit shows the proportion of total learning-related passages coded from the full set of interview transcripts that corresponded to forms of experiential, vicarious, or inter-organizational learning at each point in the life of the innovation projects studied. In addition to these project-specific matters, numerous respondents highlighted the importance of general organizational issues (e.g., securing funding, developing human resources, ensuring the adequacy of management processes). I therefore discuss the role of forms of learning as they relate to organizational considerations in a separate sub-section below.

FIGURE 3: PREVALENCE OF FORMS OF ORGANIZATIONAL LEARNING THROUGHOUT THE INNOVATION PROCESS



Several general observations can be made on the basis of these data. The stage of Technical Uncertainty is perhaps the most challenging point of the innovation process in biopharmaceutical and medical device development. Arriving at a detailed understanding of the complicated pathways by which diseases establish themselves in human systems – and identifying suitable drug candidates or new medical devices for treatment purposes – is an arduous task. Direct experience (trial-and-error processes) is the most important form of learning during this ambiguous initial period of development. Even with the involvement of basic research and design laboratories, the stochastic nature of this step is often evident, as expressed in the following quotation from the General Manager of one of the industry associations interviewed for this paper:

> "often, discoveries come from … this random research. Or from non-directed research. […] So one – we're beginning to come back to this source, to permit this type of research [in pharmaceutical companies]." *(Mercury)*[4]

While it remains valuable throughout the entire innovation development process, learning from direct experience declines proportionally in importance until the introduction to market of the new offering. At this point we can discern an uptick in the use of trial-and-error processes that carries over into the evaluation and pursuit of subsequent projects.

Learning through recruitment and learning through experimentation (the other two forms of experiential learning considered in this research) are less

[4] Interviews with respondents at Mercury (Montreal-based industry association) were conducted in French. I translated quotations in this paper attributed to Mercury interviewees verbatim, with parenthetical comments or clarifications added as necessary to maintain the overall meaning and context of each statement.

common as these firms move their innovation projects forward. It does appear, however, that both recruitment and experimentation become more useful as new offerings make their way towards the commercialization phase. In the case of recruitment this is not surprising, since the basic research or design skills of organizational personnel required for the early elaboration of a possible new product are eventually superseded by the need for more market-oriented abilities. For experimentation this trend is somewhat more unexpected; we might anticipate that the use of low-risk experiments would generally take place earlier in the development cycle so as to save time and expense in downstream processes. Instead, in this sample of firms we see continued use of small-scale experiments preceding market introduction, mainly as a means to gain insight into cause-effect relationships:

> "You know, you believe you know how something works, but it's only once you've done it a few hundred times you start to learn. You start to say, 'Well, actually, this isn't quite what we thought it was going to be. It's now behaving like this. But if we do this, it will behave even better." *(Pan)*

This paper also produced evidence that organizations engage in a process of vicarious learning. Learning from others through observation and inference was strongly represented at the initial stage of Technical Uncertainty, and rose proportionally through to the period of Refinement before falling in importance subsequently. Since publications are the primary means by which new scientific insights are communicated to the broader academic community, it would be expected that much of what may be termed vicarious learning occurs through this

medium. Indeed, the central role of publications was mentioned by several respondents here.

> "the experience of other, you really gain access through publication, primarily. That's the primary … avenue for gaining that type of experience." *(Gratia)*

> "it [learning of a vicarious nature] is going to generally be attending conferences, reading papers, seeing patents and talking to peers within the industry or the particular area of research." *(Roma)*

Coupled with the proportional decrease in use of experiential learning mentioned above, the emergence of observation as an important tendency as the innovation process unfolds provides some evidence of a possible substitution effect (Schwab, 2007) between direct firm-level feedback and vicarious information. The increasing reliance on observation and inference is also at least partly attributable to the greater availability of external information at later points in the innovation process. Specifically in the biopharmaceutical and medical device sectors, a significant amount of third-party data on clinical trial results, for example, can be consulted by the focal firm. Respondents from a number of firms explicitly indicated the importance of observation in this vein:

> "you look at how other companies have done this. What agents they were combining with. What particular patient group. And you may see that they have lifted patients routinely but they've excluded patients over a certain age or with a certain … you know, other disease. With heart disease or liver disease, whatever it is. So you infer things about the effect of the agent." *(Calypso)*

> "particularly in the readouts, where other cancer trials have been performed, […]. And we can look at these other trials and we can look at the results we get back, and they can help

> us interpret what our agent is actually doing in humans." *(Iris)*

A particularly interesting issue for purposes of organizational learning was also revealed in these interviews – namely, the role of inter-organizational similarity in generating relevant lessons. Tellumo's situation provides an illuminating example in this respect. The company is currently developing a drug candidate that incorporates monoclonal antibodies to target toxins produced by specific bacterial infections. Since the intended market for this product is limited, Tellumo is seeking FDA approval for its candidate as a so-called 'orphan drug'. Orphan drug designation, which for FDA purposes generally involves diseases affecting fewer than 200,000 people in the United States, offers both market exclusivity and tax incentives to encourage the development of therapeutics that might otherwise be considered unattractive by their biopharmaceutical sponsors. The potential for learning vicariously from the experience of other orphan drug sponsors was highlighted in my interviews.

> "I mean, this is an orphan drug. Many companies have been built around orphan drug development. So looking at how various companies have taken products like this forward – it's not exactly the same clinical domain or the same clinical trial – is how do they, how do they manage the process, how did they take it to market." *(Tellumo)*

Other bases of similarity may also determine the applicability of the learning provided. Size-based similarity could be one such aspect in drug development processes. The notion of learning from other organizations of a similar financial size implies that the most promising path to successful

commercialization differs when one has the limited resources of a small biotechnology concern, for example, as opposed to the deep pockets of a pharmaceutical company.

> "I'm more likely to go and talk to other smaller biotech companies and find out how did they do their development or their job or their discovery, then find out how they did it more effectively. […] finding out how big pharma does it, although … instructive, may not necessarily be the way that you [as a biotech firm] can do it." *(Tellumo)*

The declining proportion of learning through observation and inference shown in Figure 3 between the periods of Refinement and Market Feedback should also be noted. It may be that vicarious learning is considered to be of less value by innovating firms at these late stages. However, the uptick in observation for future projects undertaken by these organizations suggests that the later stages of development also offer an opportunity for the firm to internalize externally-sourced lessons in a manner conducive to subsequent development efforts.

Finally, the role of inter-organizational learning exhibits some important dynamics throughout the innovation processes considered in this paper. Learning from others via direct contact is a strategy pursued with greater intensity as development progresses. The prominent role of organizations such as CMOs and CROs in drug development, or subcontracting design firms in medical devices, creates the opportunity for organizations to learn from proximity. This was alluded to in an interview with the CEO of Pluto.

> "But what we have done is looked at the way technology is run and business is conducted at our contract manufacturing site. So we actually made sure that our own staff were down

> at the site when they were running the process runs. So that's a learning experience for our staff, by observing what's happening." *(Pluto)*

The spike in learning through direct contact during the Market Feedback stage can be explained by the user feedback sought out by innovating firms. Customer experiences represent a useful source of design refinements, additional indications for use, and general improvement of the new product in question.

> "being able to sit down with some … chosen clinicians and surgeons and saying, 'Okay, this is what we're going to do. What do you currently use, or how would this currently be done?'" *(Pan)*

> "once you have a product on the market, then to take it to the next step […] sort of question small little tester areas. You can start to get a feel from what has been off-label use, watching what's going on out there. That might give you some indications in terms of where you want to take it." *(Bellona)*

> "Whenever you go to a meeting on research in the ICUs there's always a kernel [of insight] there." *(Galileo)*

The second mode of inter-organizational learning – learning from partnering – also evinces an increasing importance as development progresses. Given the growing tendency towards alliances and other formalized collaborations in the industry (Baum, Calabrese & Silverman, 2000; Oliver, 2001; Whittaker & Bower, 1994), this result is for the most part expected. The decline in this type of learning during Market Feedback indicates a preference for (and availability of) more direct methods of contact with clinicians and end users as opposed to a reliance on the external partner for such knowledge.

Figure 3 also includes a final learning mode that has not been discussed to this point: learning from combinations of methods. Both the interview transcripts and archival sources provide preliminary evidence of the concurrent use of multiple forms of learning.

> "we use a blend of our own expertise and expertise of our client – observing others" *(Pluto)*

> "And the limitations of publication, they're – I'm not dismissing them, they're extraordinarily important. […] But without the sort of hands-on, real experience with the drug, its target, the science, the clinical development … you're only as good as your ability to interpret what the outside world is, is telling you. […] And so it's the ability to, it's the ability to be able to judge what the outside world is saying, wrongly or rightly, but I think that that becomes an absolutely critical component of the innovative success." *(Gratia)*

However, further analysis of the project-level detail from this paper reveals more in this regard than a cursory examination of the aggregated data would suggest. After briefly identifying the roles played by forms of learning in general organizational concerns, in the following section I argue for the existence of distinct combinations of forms of organizational learning, both when innovation projects are initially conceived and as they develop over time.

3.6.2 Organizational Considerations

Many of the organizations included in my research sample are smaller, less experienced entities without a significant history of financial or innovative success. In several cases the project studied here represents the first attempt at development on the part of the firm. Perhaps because of this lack of past

experience, the data on broad organizational issues reflect an abiding focus on learning from others through observation and inference. Respondents indicated that learning through the observation of competitors was particularly helpful with regards to innovation-supporting activities such as financing and marketing:

> "we do, in general, look at the way – not so much at the clinical development, at the corporate development. The way other companies are developing. Where they're getting financing, how they're positioning themselves. […] at the business development, marketing of the company, we are looking to other people to see how they do that." *(Pluto)*

Consistent with the findings of other researchers (Kim & Miner, 2007), evidence of the value of learning from failure – both self-generated and vicarious – is also apparent in interview responses.

> "as an industry we haven't been as effective as we could have been, and we made a lot of mistakes, many of which we've seen in the U.S. but like many – if you're raising children, sometimes they have to make their own mistakes before they learn from them." *(Tellumo)*

> "And the best thing you can find are people who have failed at something." *(Pluto)*

> "Also the errors they've made, because [our competitor] had a lot of problems. They've made some pretty serious strategic errors. So there's quite a lot of lessons from the management point of view to learn about what not to do in terms of product focus." *(Pluto)*

> "Yeah, you can learn from the failures of others. […] Not as well as learning by your own failure, mind you. I think those are always the best lessons. Nothing like a scar to keep you focused later." *(Bellona)*

In a broader sense, company executives do not necessarily limit

themselves to their immediate industry for learning opportunities. This was certainly the case when more general strategic or administrative issues were involved, as described in the following excerpts from the interview conducted with Tellumo's CEO:

> "I think … you know, business is business. So from a – running a company, you can learn from any business. […] And so you can learn a lot of organizational … matters from observing many different industries." *(Tellumo)*

> "So I think, you know, some general management, you can learn from any industry. How to grow, you know, from a strategic point of view. How do you penetrate different markets. Whether you take a drug … forward or you take a consumer product, a lot of the strategies could be similar." *(Tellumo)*

3.7 Distinct Learning Sequences in Innovation Projects

Table 4 summarizes the main findings related to organizational learning in the eleven innovation projects studied. In assembling this exhibit I disaggregated the coded passages from the complete study dataset into the eleven constituent innovation projects. By doing so I sought to unpack the broad tendencies observed for organizational learning, thereby allowing for finer-grained analysis of learning dynamics and sequences underlying the innovation process. The major forms of learning evident at each stage in the biopharmaceutical and medical device innovation process are, as for Figure 3, determined based on the instances of each learning type identified in my interview transcripts and archival data. Representative quotations or summary notes are shown in each cell to illustrate the type of learning identified.

TABLE 4: LEARNING SEQUENCES IN INNOVATION PROJECTS

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
CALYPSO	• Chromatin targets in cancer therapy	**DE:** "So they were involved in other compounds or other companies before […]. So I suppose you have a – […] specific notion of certain past molecules which may or may not be informative to the current project."	**DE:** "So a very good understanding of the science. And that's of course combined with an understanding of … you know, the issues around structure."	**O / DE:** "you look at how other companies have done this. What agents they were combining with. What particular patient group. […] So you infer things about the effect of the agent. […] that starts to give you some clues."		**C / DE / O:** "the data we often use for getting this advice, as well as one-to-one conversations, is through advisory boards."	**DE / C / P:** "there are examples where […] a new molecule is coming along and it is going to be a game-changer, potentially. And you have to have that in mind when designing new clinical trials."

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
GALILEO	• Glucose monitoring system	**DE:** "The key issue was that we had the expertise. So it was people who had done this before."	**O:** "We looked at the technology that they [competitors] had"; identification of opportunity based on academic literature	**O / C:** contact made with CRO enabled company to identify favourable locale for regulatory trials		**C:** "Whenever you go to a meeting on research in the ICUs there's always a kernel there."	
GRATIA	• Modulation of apoptosis (programmed cell death) suppressors in cancer cells	**DE:** "I would characterize it again as hands-on, understand, get down and dirty and understand its pathway. And make decisions based primarily on your own experience."	**DE:** working at the bench level with the compound and seeking to understand how the therapeutic mechanism would unfold in treatment	**DE:** "you're integrating information and knowledge, both first-hand knowledge and experiential knowledge, from so many directions"			

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
	• Inhibition of biosynthesis in cancer cells	**DE:** "targeting a novel pathway in cancer which had been recently validated, not yet too many successes had been developed but […] we could develop, we had a good story, we could raise money"	**DE:** "we set up a discovery process which was probably fairly high-risk, […] and it was to seek, actually seek, the drug which has a particular characteristic without knowing its mechanism."				

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
IRIS	• T-cell receptor technology for cancer treatment	**DE:** "Initially it was all based around the scientific understanding of T-cell receptors. […] that's where our main expertise is, is in protein engineering and particularly with T-cell receptors."	**O:** "there are also some companies that have so-called biospecific antibodies. […] we could learn quite a lot from, from their observations."; "we also studied all the other essays and data, and all the information that was available, because in a way at least part of the path that we were going down had been trodden by them before."	**O:** "particularly in the readouts, where other cancer trials have been performed, […]. And we can look at these other trials and we can look at the results we get back, and they can help us interpret what our agent is actually doing in humans."			**DE:** "So that sort of knowledge base and that system that we've built up has really helped us progress other products at a much faster rate."

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
OMEGA	• CRTH2 antagonists in asthma and chronic allergies	**DE:** past work by executive member in prostoglandin biology forms the experimental evidence and intellectual underpinning of ongoing work	**O / DE / C:** membership in professional bodies and associations for sharing of knowledge; inferences based on observation of new clinical trial announced for specific drug candidate	**O / C:** initiating of direct contact with regulators to get advice on key aspects of approval process; monitoring of sources such as Quintiles for published clinical trial data			**DE:** work carried out on experimental models for the lead compound inform subsequent innovations being pursued

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
PAN	• Plasma energy as basis for surgical instruments	**O / DE:** "we actually got to the point where we were trying to do the final product development and do it the way that this research paper did."	**C / DE / O:** "So there's a whole host of knowing what your customer wants that is influencing the design."	**C / DE / O:** "really taking feedback from getting devices out there and surgeons coming back […] and saying, 'You know what? Okay, you've developed this thing for liver surgery. Really, what I want it to do is this'."; "So what we were looking at is saying, 'Well, what would the – what is the current competition going to be?'"	**DE:** "it's not that complex a product. There's lots of different techniques and technologies in – you know, high-powered electronics, there's fluidics, there's gas control, there's all of that, and effectively pneumatics. Which one or more of us have all done before."	**C:** "being able to sit down with some … chosen clinicians and surgeons and saying, 'Okay, this is what we're going to do. What do you currently use, or how would this currently be done?'"	**DE:** "doing more of what we know we have to do, which is, having understood what the requirements are of the users in those areas, to build a product that does the job."

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
PLUTO	• Biosimilar for treatment of breast cancer	**O / DE:** "we have indeed learned lots from other companies […] by our presentations of papers at those meetings as well as the material that we're publishing in scientific journals."	**O / C / P:** "at least for now that we are in need of going to experts […] for sophisticated mouse development and experimentation"; "by looking actually at some detail, you know, in the activities, documentation, approaches of the company."	**C / O:** "consultants who had experience in the biotech and pharma area […]. And so the … consultants we had were, expertise that we didn't really have within our own organization"	**C / O / P:** "our knowledge base there was people who are consultants who are all former industry people"; "we do look fairly closely at what other companies are doing for – other biosimilar development companies"		**DE:** "the idea is that we use the same platform for all our drugs. And any development that you do on any drug […] adds to our knowledge base of the platform."
SATURN	• Diagnostic platform for assays	**DE:** assay technology "didn't exist prior to" the company. Bulk of the learning involved in early stages was hands-on and internal	**DE:** Personnel "didn't know what they didn't know", and was forced to drive the innovation forward using own expertise	**DE:** New offerings are now more efficiently moved along than they had been in the past	**O / P:** openness to new partnerships, issues such as "market potential" and "competitors" as useful learning sources		

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
SOL	• Targeted secretion inhibitors	**DE:** understanding cell systems, ensuring that engineered molecule attaches to correct cells and has proper effect	**DE:** firm began with a focus solely on research activities, adding development activities to its in-house capabilities; important learning from observation of organizations working with complementary technologies	**C / P:** development deal focused on basic research; transferring of technology to partner CMO	**C:** transferring of technology to partner CMO		

Company	Innovation Project	STAGE OF DEVELOPMENT					Future Projects
		Technical Uncertainty	Broad-Based Solution	Refinement	Approval and Introduction	Market Feedback	
TELLUMO	• Use of monoclonal antibodies to target toxins produced by bacterial infections	**DE / O:** technology transfer offices "are really critical. The bridge between academia and industry, that bridge – somebody has to understand enough to make that bridge."	**DE / O / P:** "every antibody has its own … nuances to it that, you know, that is where you rely on your experiences"; university liaison was able to recommend useful potential partner	**O / DE / P:** lessons learned from experiences of organizations that had previously sought to develop and commercialize similar drugs	**P / O / C:** "talking to […] CEOs of companies that have done this before, trying to understand what the potential pitfalls are, when should I be doing certain things"		**DE:** "we have other things that we're testing now in the lab. So that knowledge, the things that we've learned there, definitely applies to these new products."

Codes for forms of learning:

Experiential learning:

DE = Learning from direct experience
R = Learning through recruitment (Hiring)
X = Learning through experimentation

Vicarious learning:

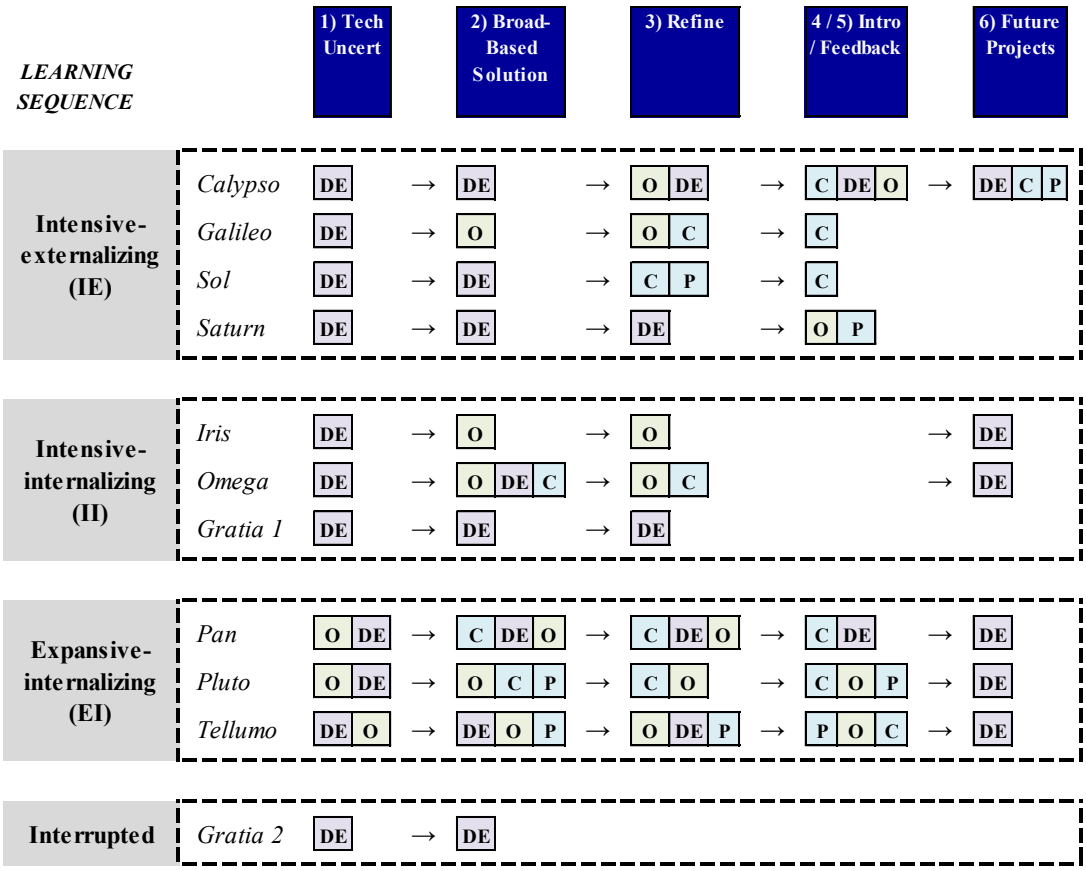
O = Learning from others through observation and inference

Inter-organizational learning:

C = Learning from others through direct contact
P = Learning from partnering or other formal collaboration

From the innovation project data described here, three distinct learning sequences can be discerned: intensive-externalizing (IE), intensive-internalizing (II), and expansive-internalizing (EI). Each of these sequences differs in terms of the form(s) of learning employed early on in the innovation process, the subsequent evolution in usage of learning types (experiential, vicarious, and inter-organizational) over time, and the degree to which there is evidence of attempts to build the resulting insights into the organizational knowledge base for future use. Figure 4 provides a summarized view of the innovation projects included in each sequence.

FIGURE 4: DISTINCT LEARNING SEQUENCES[5]



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Inter-organizational learning:

C = Learning from others through direct contact
P = Learning from partnering or other formal collaboration

[5] For clarity of presentation, stages 4 and 5 of the innovation process are combined in this diagram.

3.7.1 The Intensive-Externalizing (IE) Sequence

Four projects (Calypso, Galileo, Sol, and Saturn) follow what is termed here an 'intensive-externalizing' (IE) learning sequence as they navigate the process of technological innovation. This sequence evolves as follows: during the stage of initiation or discovery, an organization places primary emphasis on learning from direct experience. As the project advances, greater reliance is placed upon externally-oriented learning, both vicarious and inter-organizational. Later periods represent a continuation of the external trend, through instances of direct contact and possible formal partnering.

3.7.2 The Intensive-Internalizing (II) Sequence

Conformance to the 'intensive-internalizing' (II) sequence can be seen in the data from Iris, Omega, and Gratia (first project – modulation of apoptosis suppressors in cancer cells; see Table 3). As in the 'intensive-externalizing' path, initial emphasis is on learning from direct experience. The number of modes of learning then expands to include mechanisms that draw upon external expertise. In contrast to the IE sequence, however, firms that follow an II progression demonstrate a return to learning from direct experience as they move into future innovation projects.

3.7.3 The Expansive-Internalizing (EI) Sequence

The final sequence identified in this paper corresponds to the evolution of the Pan, Pluto, and Tellumo innovation projects. The 'expansive-internalizing' (EI) sequence begins with a focus on multiple forms of learning at the onset of a

new development project. Active use of both experiential (trial-and-error) and vicarious (observation and inference) processes on the part of these organizations can be found during the phase of Technical Uncertainty. This expansive use of learning continues throughout the development stages, persisting even as the new offering is introduced in the marketplace. As future projects begin to be identified and developed, learning from direct experience comes to the fore.

3.7.4 The Interrupted Sequence

One of the innovation initiatives undertaken by Gratia (second project – inhibition of biosynthesis in cancer cells; see Table 3) is categorized as 'interrupted' in this learning sequence typology. Following its acquisition by a large pharmaceutical company, this early-stage project became stalled in development. Its future disposition remains uncertain. While we cannot draw firm conclusions from this particular instance, it is interesting to note that the organization that championed this project focused considerably on experiential learning as it attempted to move the compound forward.

3.8 Conclusion

As expected based on past findings from the learning literature, the importance of experiential learning emerges as a key theme in my study of innovation processes. The biopharmaceutical and medical device firms represented in my sample may follow different overall sequences of learning, but in all cases the necessity of direct experience is evident at early stages of their development projects. As the innovation process unfolds, firms then begin to

make more extensive use of the external forms of learning – vicarious and inter-organizational – available to them. While the initial Technical Uncertainty and Broad-Based Solution phases require the mobilization of hands-on expertise, it is during the Refinement stage that dynamics of observation and inference become central learning mechanisms. Given the extensive availability of outside information (clinical trial results and academic studies) at this point, a reorientation towards the external is perhaps not surprising, yet we still require an explanation of how organizations make sense of the vast information from which they could learn. Here the role of inter-organizational similarity emerges as a consideration for vicarious learning. Indeed, similarity between the focal firm and a target company based on size or disease category is a primary basis upon which respondents in this study identify referents from whom to learn vicariously.

However, the early importance of experiential learning and the subsequent transition to external sources of knowledge for these companies hides some interesting variation across the projects. In particular, organizations that follow the 'expansive-internalizing' path attempt vicarious learning at an earlier stage in their innovation process than do firms associated with the other sequences. The absence of close technological peers from whom lessons could be derived is a reality for Pan and Pluto, two EI firms in the sample. Rather than dissuading these organizations from engaging in vicarious learning, though, the lack of close referents encouraged these organizations to engage in more distant search for knowledge useful to their own innovation initiatives. Novelty of the underlying technology base may thus drive both the motivation to pursue vicarious learning and the selection of specific referents for this purpose.

CHAPTER 4: LEARNING AND INNOVATIVE PERFORMANCE – A LONGITUDINAL STUDY OF U.S. MEDICAL DEVICE APPROVALS (QUANTITATIVE PAPER)

4.1 Introduction

The role of organizational learning in fostering innovation continues to be a focus for management research. Past research has examined processes such as trial-and-error learning (Van de Ven & Polley, 1992) and vicarious learning (Bresman, 2010) for their contribution to innovation output. Scholars have focused on knowledge-enhancing activities that enable innovation, including the reuse and recombination of familiar technical components (Fleming, 2001; Fleming & Sorenson, 2001), explorative inter-firm collaborations (Galambos & Sturchio, 1998; Oliver, 2001), and participation in broad networks (Powell, Koput & Smith-Doerr, 1996; Schilling & Phelps, 2007). Researchers have also begun to consider how diverse types of knowledge and learning processes may interact to drive the creation of new offerings. Rothaermel & Hess (2007) describe the joint importance of individual, firm, and network effects on innovation output, while Bresman (2010) finds evidence of an interaction effect between internal and vicarious learning in the performance of product development teams. Building upon these and other related studies, the current paper seeks to examine the impacts of three particular forms of learning – experiential, vicarious, and inter-organizational – on subsequent innovation. Panel data from 1998 through 2012 for a set of 472 publicly traded American firms in the medical device sector support the hypotheses that vicarious learning dynamics (both individually and in

interaction with experiential learning) are important explanatory factors for the observed counts of approved innovations.

The remainder of the paper is structured as follows. In the next section I present the theoretical background informing this research and formulate a set of hypotheses relating learning to innovation. The Methodology section introduces my empirical setting, key variables, and analytical approach. I discuss the Results in greater detail subsequently.

4.2 Theory and Hypotheses

4.2.1 Experiential Learning

Learning from direct experience comprises first-hand involvement with the processes, challenges, and solutions entailed in addressing a particular facet of organizational operations. From its origins in the study of learning curve effects related to the manufacture of industrial products (Yelle, 1979), the study of experiential learning has since expanded in both theoretical scope and phenomena of interest. Some key insights include the description of absorptive capacity as a firm-level facilitator of external opportunity identification (Cohen & Levinthal, 1990) and examination of the role of knowledge as the basis for sustained competitive advantage (Argote & Ingram, 2000; Grant, 1996b).

Organizations can make use of direct experience in a number of different ways, each of which provides rich learning opportunities. Trial-and-error processes, for instance, allow actors to adapt or otherwise correct subsequent activities based on the outcomes realized from past behaviour (Van de Ven & Polley, 1992). In learning through experimentation, organizations seek to assess

cause-effect linkages by incorporating deliberate – often minimal – variations into their processes (Miner, Bassoff & Moorman, 2001) and observing the resultant consequences. Improvisational learning, in contrast, involves a real-time assessment of action and the development of insight at the moment these activities occur (Moorman & Miner, 1998). Finally, in a somewhat less generative and more exploitative sense, firms can leverage direct experience through recruitment of individuals with knowledge not otherwise resident in the organization.

Regardless of the specific form that it takes, experiential learning offers substantial benefits for organizations intent on driving innovation. First-hand experience provides organizations with insight into cause-and-effect relationships, boundary conditions, and potentially complicating environmental factors that would not otherwise be available to these firms. Causal attributions formed by trial and error or experimentation tend to be more confidently made, given the close contact to the overall process giving rise to them. In addition, the temporal co-occurrence of action and insight inherent in improvisational learning imbues it with a deeply contextual character that stands the firm in good stead as it initiates activity in similar settings. Experiential learning also creates repositories of knowledge that can be drawn upon by an organization to address future challenges. As a result, firms with a history of learning from direct experience should be more easily able to navigate technical obstacles and other hindrances to innovative efforts. The preceding points lead to the first hypothesis to be tested in this paper:

H1: *Experiential learning* is positively related to firm-level innovation performance, such that the greater the accumulated direct innovation experience the higher the subsequent levels of innovation by a focal organization.

4.2.2 Vicarious Learning

Experiential learning, while undoubtedly important, is not the only way in which organizations generate knowledge and insights to be used in subsequent activities. Indeed, constraints of several kinds (time, physical and financial resources, existing capabilities) often make direct experience with a process or technology infeasible. In such cases, firms can substitute techniques of inference whereby observed outcomes are attributed – either more or less precisely – to unobserved processes undertaken in other organizations. Outcome-based imitation (Haunschild & Miner, 1997) of this kind can foster the modification of internal structures or the pursuit of new strategies in an attempt to attain results similar to those of the observed organization.

Past research has sought to identify particular circumstances wherein this type of vicarious learning is prevalent. High salience of outcomes, as represented by the premiums paid to investment banking firms advising on acquisition opportunities (Haunschild & Miner, 1997), for example, fosters vicarious learning. Recent activities by either large firms or firms similar to the focal organization also serve to encourage imitative behaviour (Baum, Li & Usher, 2000). Internal assessments can likewise provide the impetus for these knowledge-generating searches. In their study of railroad accident rates, Baum & Dahlin (2007) conclude that vicarious learning comes to the fore as an individual

organization's aspiration-performance gap increases – that is, as actual performance deviates from expectations.

Given the uncertainty inherent in technological innovation, vicarious learning could be a worthwhile undertaking for firms seeking to develop new products. The ability to learn from the experience of other successful innovators presents the possibility of shortening product development times. More importantly, the firm that learns vicariously identifies a template for action that offers a higher probability of success than that available through undirected trial-and-error processes. From whom, then, does the would-be innovating firm seek to derive these insights? The similarity between learner and object of learning is an important consideration in this respect. Similar organizations face many of the same challenges, may be expected to respond to those difficulties in the same ways, and more generally speaking "have experiences associated with tasks that are similar enough to yield applicable lessons learned" (Bresman, 2010: 86). Past research has tended to measure similarity in terms of such characteristics as organizational size (Baum, Li & Usher, 2000; Haveman, 1993; Kraatz, 1998; Srinivasan, Haunschild & Grewal, 2007) or market position (Kraatz, 1998; Rhee, Kim & Han, 2006).

In this paper I focus on two different bases of inter-organizational similarity: common membership in an industry sector (Baum & Dahlin, 2007) and geographic proximity (Kim & Miner, 2007). Companies operating in the same sector of economic activity overlap in many important respects. They generally compete for the same customer segments, make use of similar technologies, and

bring to market product offerings that are broadly consistent with each other. This being the case, vicarious learning from such close technological peers offers possible lessons that are immediately and obviously relevant for ongoing operations. Furthermore, successful past innovation by technologically similar companies presents a salient outcome to the learning organization. By observing and attempting to reconstruct the sequence of activities that led to commercialization of a new product, an organization can reduce uncertainty in the innovation process. Where more such exemplars exist – multiple innovations by a single peer company or by several technologically proximate organizations – the benefits increase commensurately. The learning organization can therefore piece together insights from a diversity of relevant sources as it seeks to determine the most productive means by which to advance its own innovation agenda. My second hypothesis formalizes the expected relationship between technologically-centered vicarious learning and future innovation.

> H2: *Vicarious learning from close technological peers* is positively related to firm-level innovation performance. The greater the extent of past innovative success on the part of its technological peers, the higher the subsequent levels of innovation by a focal organization.

Geographic proximity may also aid the vicarious learning process. Firms in close physical proximity can be expected to share many of the same issues regarding resource availability, regulatory oversight, and ultimately strategic options. State-level environmental laws may restrict the use of key manufacturing inputs, thus creating the need for flexible workarounds to maintain profitability. The geographical clustering of firms also fosters important network effects that

enable the accumulation of knowledge, institutions, and supporting structures not available to more dispersed actors (Saxenian, 1991). The experiences of close geographic peers should therefore provide germane lessons to attentive organizations. Firms that seek to learn vicariously will look to organizations well-versed in the same physical and institutional climates – that is, geographically proximate companies – for appropriate lessons. To the extent that these firms have been able to develop technological innovations successfully in the past, the set of actions undertaken to do so will presumably be of substantial interest and value to the focal firm.

> H3: *Vicarious learning from close geographic peers* is positively related to firm-level innovation performance. The greater the extent of past innovative success on the part of its geographically proximate peers, the higher the subsequent levels of innovation by a focal organization.

4.2.3 Inter-Organizational Learning

Experiential learning entails direct contact with a given procedure or sequence of related activities, while vicarious learning relies on indirect methods of observation and inference to generate knowledge. Inter-organizational learning, the final form of learning considered in this paper, occurs when the firm is linked with the actor from whom it seeks to obtain insights. Such collaborations, which span the spectrum from short-term project-based commitments to more encompassing undertakings such as joint ventures and strategic alliances, have important implications for firm-level learning (Hamel, Doz & Prahalad, 1989; Lane & Lubatkin, 1998). In more productive co-operative arrangements the partners develop new routines and repertoires of activities (Larsson, Bengtsson,

Henriksson & Sparks, 1998) that can be deployed in subsequent initiatives both within and outside the partnership.

The extension of these beneficial effects to innovative success is natural. Organizations that are able to maintain – and learn from – a greater number of partnerships enjoy access to knowledge that might otherwise be difficult to obtain. Regardless of whether the venture in question is focused on innovation per se, the resulting information can be applied towards new creative endeavours as needed by the learning organization. A direct relationship between the degree of inter-firm collaboration and future innovative success is thus predicted, as summarized in Hypothesis 4:

> H4: *Inter-organizational learning* is positively related to firm-level innovation performance, such that higher levels of partnering activity will foster higher subsequent levels of innovation by a focal organization.

4.2.4 Interactions between Types of Learning

While I posit that experiential learning may enhance subsequent innovation for a given firm (Hypothesis 1), such learning may not in and of itself suffice. Rapid technological change is the norm in many industries, a situation that makes exclusive reliance on own experience inefficient for the purposes of creativity. Staying abreast of all changes in such fast-advancing segments would necessitate an investment of time and resources beyond the means of almost any organization. Even if such an approach were indeed possible, it is by no means assured that the implications for innovation would be wholly (or even mainly) positive. Learning dysfunctions such as competency traps (Leonard-Barton, 1992;

Levitt & March, 1988), strategic myopia (Levinthal & March, 1993), and incorrect specification of cause-effect relationships (Schwab, 2007) militate against the benefits of experiential learning.

Considering these limitations, the supplementation of direct experience with other complementary forms of learning should be beneficial. Organizations may obtain significant benefit from the use of vicarious learning in the context of a well-established knowledge base derived from experiential learning. The active search for relevant peer companies from which to derive useful lessons affords a firm the opportunity to compare its own past activities with those of other successful actors. Decisions can then be made as to whether new, equally effective strategies might be implemented, given their observed effectiveness in other settings.

While vicarious learning is expected to have an independently positive effect on future innovation (Hypotheses 2 and 3), I argue that more indirect learning is realized when the focal firm can build upon its own experiential learning. This joint learning enables the organization to assess the value (or lack thereof) of external information more fruitfully; important knowledge is retained while details extraneous or irrelevant to the firm's particular circumstances are discounted. At the same time, this combination of internal and external foci serves to dampen the negative characteristics of experiential learning. Vicarious learning provides the firm with an additional means to test its understanding of causal processes and the possible consequences of strategic decisions. In sum, the interaction of experiential and vicarious learning holds out the promise of better innovative outcomes:

H5: Vicarious learning from technological peers is more beneficial when built upon established experiential learning. Innovation performance will be positively impacted by the *joint role of experience-based learning and technologically-proximate vicarious learning*.

H6: Vicarious learning from geographic peers is more beneficial when built upon established experiential learning. Innovation performance will be positively impacted by the *joint role of experience-based learning and geographically-proximate vicarious learning*.

4.3 Methodology

4.3.1 Empirical Setting and Sample

The setting for this research project is the U.S. medical devices sector, which consists of organizations pursuing "technologies used in the diagnosis, cure, mitigation, treatment, or prevention of diseases or conditions that do not achieve their primary treatment effect by pharmacological, immunological, or metabolic means" (Pietzsch, Shluzas, Pate-Cornell, Yock & Linehan, 2009: 1). Since the phenomenon of interest was innovation performance, I began with a list of approved new products from the PMA Approvals - Medical Devices section of the U.S. Food and Drug Administration (FDA) website. For each product, the available data included the following: Application Number; Date of Approval; Device Trade Name; Company Name; City, State, & Zip; Description. The initial sample was comprised of all such innovations recorded by the FDA from May 1994 through December 2012 – a total of 667 separate products. I limited the analysis to approval data from April 1999 onwards, as this was the month during which the FDA Modernization Act of 1997 was fully enacted. The Act in many

ways represents a qualitative shift in the regulation of medical devices for the American market, as it directs the FDA to exempt low-risk instruments from premarket notification requirements, and to focus post-market surveillance on those products presenting the greatest risk to human health and safety. This reduced the sample of innovations to 469. However, pre-April 1999 data were preserved in a separate data file in order to facilitate the testing of experiential and vicarious learning effects based on historical innovation performance in my models.

Next I undertook cleaning of the data to ensure consistent formats across the records. I searched by company name in the Corporate Affiliations database to identify the primary SIC code for the innovating company. I subsequently excluded approved projects from companies whose primary line of business was not medical devices. That is, my sample was based on the subset of firms whose primary membership was identified as the medical device industry – Primary Standard Industrial Classification codes 3841, 3842, 3843, or 3845 (Munroe, Craft & Hutton, 2002). Since learning effects might be confounded with company size and financial resources, I endeavoured to control for these alternate explanations of innovation in my analyses. This necessitated the availability of extensive company-level data, which led me to focus on publicly held U.S. firms; I therefore excluded from further consideration either privately held firms or companies domiciled outside the United States.

As described in further detail below, the analysis undertaken for this paper involved counts of innovations by firm-year for medical device companies.

Restricting my sample to those firms who had successfully brought products to market (based on FDA approval data) would introduce the possibility of bias, as this would essentially amount to sampling on my dependent variable. To address this issue, I next constructed a listing of all companies active in the medical device sector from 1998 through 2012. Using the COMPUSTAT North America database, I ran a search on the same SIC codes used to define industry membership above, extracting the records for all firms that had reported results for any or all of the years from 1998 to 2012. The result was a listing of all companies who had been potential innovators during the timeframe of my study – both those who had successfully brought new medical devices to market and those who had not.

Finally, I matched the two datasets (innovation data from the FDA and company history from COMPUSTAT) to associate the innovations with my broader listing of medical device firms. Records were updated where necessary with data on hierarchical company structure from the Corporate Affiliations database and mergers or acquisitions from SDC Platinum. In the majority of cases where company-level records from COMPUSTAT were incomplete (ending prior to 2012), I was able to link these missing years to acquisition events, which I treated as company terminations. Therefore, when a company was acquired by or merged with another medical device firm, I assumed an immediate decay in acquired knowledge; that is, the presumption was an absence of innovation-fostering learning as a result of the transaction. In this sense, the reported effects are presumably understated and therefore conservative indicators of experiential learning.

The final sample, adjusted to remove cases where product approvals could not be matched with company-level data or where other detailed firm-level information was not available, consisted of 472 firms and 143 separate firm-year innovations. Firm-level innovation counts for the period of the data sample range from a minimum of zero to a maximum of 31, with a total of 424 firms (89.8% of the total) recording no innovations over the timeframe of the analysis. The dataset formed an unbalanced panel. Multiple yearly observations are included for each firm, though not all firms have records for each of the years in question. A total of 3,870 separate firm-years make up the panel.

4.3.2 Variables

4.3.2.1 Dependent Variable – Count of Innovations. The dependent variable for my paper (*INNOVCOUNT*) is a discrete count of medical device innovations for each in-sample company from the years 1999 through 2012. As indicated above, the basis for construction of this variable was the PMA Approvals - Medical Devices list maintained by the FDA. For each of the firms included in my sample, the number of innovations approved by this government agency in the year in question was summed up and assigned to the firm.

4.3.2.2 Independent Variables. In order to test the hypotheses developed in the previous section, I operationalized independent variables for three distinct forms of learning: experiential, vicarious, and inter-organizational.

Experiential learning. The concept of experiential learning holds that individual actors – whether people, teams, or organizations – gain expertise and

knowledge through direct participation in specific activities. By involving themselves in the practice in question, these actors obtain greater insight into such complex patterns as cause-effect relationships. This knowledge can be used to inform future activities in the same general domain, leading to an increased facility with the particular activities in question and (other things being equal) a higher likelihood of success in these subsequent endeavours.

In this paper I measure experiential learning using two variables: the number of unique patent grants by firm and by year (*PATENTS*) and a three-year rolling window of past innovations by the focal firm (*PASTINNOV*). The role of patents as an indicator of organizational knowledge is well-established in the management and innovation literatures (Henderson & Cockburn, 1994; Jaffe, Trajtenberg & Henderson, 1993; Rosenkopf & Nerkar, 2001), and its importance to ongoing innovative ability can be readily discerned. Patents represent legally defensible claims to the financial returns proceeding from new discoveries. As such, patent portfolios reflect the technical proficiency and future prospects of firms in such technologically advanced settings as medical devices.

Patent data were identified through a search of the Derwent Innovations Index database. The database, which includes all patents assigned to individual inventors and/or organizations in specific technical sectors from 1963 to the present, was first searched by company name, which is linked to the 'Patent Assignee Codes' field. Since the majority of retrieved records indicated multiple assignees for each patent, these assignees were distributed into separate columns in an Excel file in order to facilitate further counting. The Derwent index also returns a 'Date' field in search results, which enabled me to determine the year of

each patent grant per the original listed record. Having collected and sorted the data in this fashion, I then matched each patent to the medical device company listing in my overall sample, a process that yielded firm-year counts of assigned patents for each of these companies.

Likewise, the history of past innovation by a particular firm can be considered to be a key measure of past experiential learning. I constructed a three-year rolling window of past medical device innovations for each firm as another learning-related measure. Although the FDA innovation data used for my dependent variable count incorporated records from 1998 onwards, the information used to measure past innovation necessitated the collection of earlier approval data. Both the *PATENTS* and the *PASTINNOV* variables were lagged by a year in an attempt to better ascertain the direction of causality in their relationships to future innovation performance. In terms of measuring experiential learning, then, the predictors of firm i's innovation count in 2000 (for example) were patent grants for firm i in 1999; and total approved innovations for firm i in the years 1997, 1998, and 1999.

Vicarious learning. In addition to learning from their own direct experience with a given process or technology, organizations can also derive important insights through observation of activities occurring elsewhere in their environment. The attempt to reconstruct cause-effect relationships by means of inference enables would-be innovators to glean important information that might not be available through first-hand learning. Such vicarious learning can occur in numerous ways, but two particularly salient ones involve the use of technological

and geographic peers. In this paper I operationalize potential learning via technological peers as a count (three-year rolling window) of past medical device innovations by companies with the same Standard Industrial Classification, or SIC, code as the focal firm (*SAMESIC*). Firms categorized within the same SIC code work within similar technical boundaries and often develop commercial offerings that target the same overall market segments. As a result, activities of their SIC peers are greatly relevant to the operations of any given firm, and can be expected to serve as a key source of competitive intelligence for learning purposes. Using the Corporate Affiliations database, I identified the primary SIC code for each of the firms in my data sample. I then derived a count measure that aggregated the number of approved innovations by firms in each of the medical device sector SIC codes (3841, 3842, 3843, and 3845) on a yearly basis.

Learning via geographic peers was in turn measured by three variables: *SAMEZIP*, a count of past innovations by companies with the same five-digit U.S. ZIP code as a given firm; *SAMEREGION*, which counts past innovations by companies with the same secondary regional prefix (first three digits of the ZIP code) as a given firm, and *SAMEPRIMST*, the number of past innovations by companies with the same primary state prefix (first digit of the ZIP code) as a given firm. The inclusion of these variables, each of which expands the geographic distance between the target firm and the presumptive organization engaged in learning, provides an opportunity to discern the role played by physical proximity in organizational learning. ZIP code information was obtained from the COMPUSTAT records for each firm in question. As for the previously described measures of vicarious learning, a count of innovations for each year by

unique ZIP code was subsequently constructed. All four variables – technological and geographic – were lagged by a year in the analyses reported in this paper.

Inter-organizational learning. Organizations also learn from the partnerships and collaborations entered into with other companies. Arrangements such as strategic alliances afford ample opportunities to obtain new knowledge and create routines that facilitate future innovation. To this end, an *ALLIANCES* variable representing the number of extant alliances and joint ventures for the focal firm in the year in question was included in my analysis. SDC Platinum was the primary source of partnership information for this purpose. Queries were run to identify inter-firm collaborative agreements negotiated by firms in the medical device sector (SIC codes 3841, 3842, 3843, and 3845), including the date of agreement and the date of termination (if any). All partnerships recorded in SDC Platinum for the in-sample firms – whether between two medical device organizations or between a device firm and a non-device counterpart – were represented in this measure. In order to capture learning effects resulting from inter-organizational relationships entered into prior to 1998, I extracted a report on alliance formations and terminations from 1994 to 2012. Start dates for each alliance or joint venture were identified using the 'Alliance Date Announced' field, and all such collaborations were assumed to have remained in effect throughout the time period of this paper unless a date of termination was also reported in the query. Yearly counts of extant alliances for the medical device firms in my sample range from a minimum of zero to a maximum of 16, with a

total of 374 firms (79.2% of the total) recording no partnerships over the timeframe of the analysis.

Interaction effects. Finally, I also tested for interactions between forms of learning as they relate to innovation performance. Since vicarious learning may be most effective if undertaken with an existing background of first-hand experience, separate variables were incorporated to test for the joint influence of these particular learning types. An interaction measure between experiential learning and learning from technological peers (*PATENTS_x_SIC*) was thus added to the model, as were interactions between experiential learning and learning from geographic peers (*PATENTS_x_ZIP*, *PATENTS_x_REG*, and *PATENTS_x_STA*).

4.3.2.3 Control Variables. While the three forms of learning described and operationalized above could presumably account for much of the future innovative success enjoyed by these companies, alternative explanations are also possible and were controlled for here. In particular, both the level of financial resources and the degree of research expenditures could confound my analysis if not incorporated into the models. To this end, I included a logged measure of both total assets (*LNASSETS*) and capital expenditures (*LNCAPEX*) for the previous year for each firm. In order to control for secular changes in the industry or the broader environment over time, I also added a set of time period dummies to the analyses.

In addition to the variables reported here, a number of additional measures were considered in preliminary models but excluded from further study. These included *PATENTSSQ* (a squared measure of the yearly patent counts variable), *PASTINNOVSQ* (past innovations squared), and *LNREVENUE* (log values of total revenue by year for each firm). Models fitted with these supplementary measures showed evidence of muticollinearity in the form of high variance inflation factors, which makes the interpretation of individual coefficients more difficult. I ran three separate unconstrained count regression models (Poisson, negative binomial, and zero-inflated negative binomial) with each of the *PATENTSSQ*, *PASTINNOVSQ*, and *LNREVENUE* variables excluded in turn; results from the Bayesian Information Criterion (BIC) statistic summarized in Table 5 indicated a better fit of each more parsimonious model, and variance inflation factors from the final model displayed no major multicollinearity concerns.

TABLE 5: COMPARING MEASURES OF FIT FOR REGRESSION MODELS

Model 1 – Independent variables plus *PATENTSSQ*, *PASTINNOVSQ*, and *LNREVENUE*

Model 2 – *PATENTSSQ* variable dropped

Model 3 – *PATENTSSQ* and *PASTINNOVSQ* variables dropped

Model 4 – *PATENTSSQ*, *PASTINNOVSQ*, and *LNREVENUE* variables dropped

	Δ BIC* (Model 2 vs. Model 1)	**Δ BIC* (Model 3 vs. Model 2)**	**Δ BIC* (Model 4 vs. Model 3)**
Poisson Regression	-4.559	-1.896	-1.637
Negative Binomial Regression	-6.735	-1.785	-1.921
Zero-Inflated Negative Binomial Regression	-15.349	-15.956	-10.231

* Negative values for BIC indicate support for the more parsimonious model

4.3.3 Analysis

The dependent variable in this paper – yearly number of approved innovations by firm – is a count-based measure. The categorical nature of the outcome is non-linear in nature; this being the case, linear regression methods are inappropriate in the current context. In linear models, the effect of changes in an independent variable is the same regardless of both the starting value of that measure and the level of any of the other predictor variables included in the equation. In contrast, non-linear models are characterized by the fact that "*the*

effect of a change in a variable depends on the values of all variables in the model and is no longer simply equal to one of the parameters of the model" (Long & Freese, 2006: 116. Emphasis in original). Specific approaches for dealing with the count nature of my dependent variable were therefore required. In addition, the panel structure (cross-sectional time series) of the dataset necessitated the use of analytical approaches that would take into account the complications of repeated observations.

The natural first choice for such data is the Poisson regression model. This baseline model is built on an assumption that the observed count for each observation i is Poisson distributed with a mean μ_i defined by a vector of covariates x_i. Interpretation of the Poisson model then consists in determining how changes in each of the independent variables affect both the mean and the probability of observing specific counts for the outcome measure. This regression model offers flexibility in that consistent estimators can be obtained even if the dependent variable itself is not Poisson distributed (Cameron & Trivedi, 1998).

However, the Poisson approach assumes equidispersion of the dependent variable; that is, the mean and variance are taken to be equal. Count data often display properties of overdispersion, such that the variance is larger than the mean. Table 6 displays the results of two tests for overdispersion of the dependent variable used in this paper. The first section of the table presents summary statistics for *INNOVCOUNT*. Here we have some initial evidence that the mean and variance of the outcome variable are not in fact equal (Mean: $0.037 \neq$ Variance: 0.263^2). A more formal metric is provided by running a negative binomial regression and testing the hypothesis that the resulting overdispersion

parameter alpha (α) is equal to zero. As seen in Table 6, the chi-square test statistic: $\chi^2(1) = 8.19$, which is rejected at conventional levels of significance. The assumption of equidispersion is violated, and a regression model that accounts for this characteristic of the data may yield more appropriate results.

TABLE 6: TEST FOR OVERDISPERSION OF INNOVATION COUNTS

```
Variable         |    Mean   Std. Dev.    Min      Max |  Obs
-----------------+--------------------------------------+----------
INNOVC~T overall |  .03697   .26312         0        4 |  N = 3868
         between |           .13280         0  2.06667 |  n =  472
         within  |           .19835  -2.02970  2.60840 |Tbar=  8.2


Negative binomial regression          Number of obs   =       3609
                                      LR chi2(16)     =     276.91
Dispersion     = mean                 Prob > chi2     =     0.0000
Log likelihood = -397.91514           Pseudo R2       =     0.2581

------------------------------------------------------------------------------
   INNOVCOUNT |   Coef.  Std. Err.      z  P>|z|  [95% Conf Intrvl]
--------------+---------------------------------------------------------------
      PATENTS | -.00001    .00044  -0.02  0.981   -.00088   .00086
    PASTINNOV |  .20967    .08265   2.54  0.011    .04766   .37166
      SAMESIC |  .00821    .01245   0.66  0.510   -.01621   .03262
      SAMEZIP |   .03220   .21570   0.15  0.881   -.39057   .45497
   SAMEREGION |   .08169   .07519   1.09  0.277   -.06568   .22907
   SAMEPRIMST |   .02017   .01314   1.54  0.125   -.00557   .04592
    ALLIANCES |   .10934   .04580   2.39  0.017    .01957   .19911
PATENTS_x_SIC |  -.00021   .00018  -1.15  0.250   -.00056   .00015
PATENTS_x_ZIP |  -.00187   .00119  -1.57  0.115   -.00419   .00046
PATENTS_x_REG |   .00065   .00040   1.64  0.101   -.00013   .00143
PATENTS_x_STA |  -.00007   .00011  -0.68  0.498   -.00028   .00014
     LNASSETS |   .47862   .12451   3.84  0.000    .23457   .72266
      LNCAPEX |  -.01875   .09611  -0.20  0.845   -.20712   .16962
  YR1997_2000 |   .45009   .36285   1.24  0.215   -.26109  1.16127
  YR2001_2004 |   .44417   .30796   1.44  0.149   -.15943  1.04776
  YR2005_2008 |   .03880   .31358   0.12  0.902   -.57580   .65340
  YR2009_2012 |      0  (omitted)
        _cons |-13.18101  1.41715  -9.30  0.000  -15.9586 -10.4035
--------------+---------------------------------------------------------------
     /lnalpha |  -.25429   .50958                -1.25305   .74447
--------------+---------------------------------------------------------------
        alpha |   .77547   .39516                  .28563  2.10533
------------------------------------------------------------------------------
Likelihood-ratio test of alpha=0:chibar2(01) = 8.19Prob>=chibar2 = 0.002
```

A better choice for dealing with this data may be the negative binomial model, which explicitly adds an overdispersion parameter (α) to account for unobserved heterogeneity among observations (Long & Freese, 2006). Finally, excess zeros in the data – non-instances of innovations in the firm-year counts, for present purposes – can also be factored in through use of zero-inflated variants of both the Poisson and the negative binomial models. These approaches allow for two underlying processes that may generate zero counts: membership in a 'true-zero' group and observation of a zero value in the count process (Cameron & Trivedi, 2009). In essence, two functions are fitted by zero-inflated approaches: one to predict the binary outcome of being in the count vs. no-count (innovator vs. non-innovator) group, and one to model the actual number of counts observed.

The Poisson regression model and its zero-inflated variant are non-nested (Greene, 1994), as are the negative binomial and the zero-inflated negative binomial. Computing likelihood-ratio tests is therefore infeasible as a means of assessing the fit of each model to the data at hand. Vuong (1989) proposes a test statistic that allows for the comparison of non-nested approaches based on predicted probabilities. Table 7 shows the results of the Vuong test as applied to the medical device approval data for this paper. As shown in the output at the bottom of the figure, the statistic is marginally significant ($z = 1.41$; $Pr > z = 0.0786$). We can conclude that the zero-inflated negative binomial model offers a somewhat better fit than the standard negative binomial regression.

TABLE 7: VUONG TEST FOR FIT OF ZERO-INFLATED MODEL

```
Zero-inflated negative binomial regression  Number of obs =   3609
                                            Nonzero obs   =     98
                                            Zero obs      =   3511

Inflation model = logit                     LR chi2(16)   =  72.96
Log likelihood  = -378.1999                 Prob > chi2   = 0.0000

------------------------------------------------------------------------------
  INNOVCOUNT  |   Coef.  Std. Err.      z    P>|z|     [95% Conf. Interval]
--------------+---------------------------------------------------------------
INNOVCOUNT    |
     PATENTS  | -.00028   .00049    -0.58   0.564    -.00125     .00068
   PASTINNOV  |  .05283   .06632     0.80   0.426    -.07716     .18281
     SAMESIC  | -.01277   .01760    -0.73   0.468    -.04726     .02172
     SAMEZIP  | -.21609   .34742    -0.62   0.534    -.89702     .46484
  SAMEREGION  |  .01139   .11928     0.10   0.924    -.22239     .24517
  SAMEPRIMST  |  .05397   .02504     2.16   0.031     .00488     .10305
   ALLIANCES  | -.00466   .04475    -0.10   0.917    -.09237     .08306
PATENTS_x_SIC | -.00016   .00015    -1.09   0.274    -.00045     .00013
PATENTS_x_ZIP |  .00038   .00133     0.28   0.777    -.00223     .00299
PATENTS_x_REG |  .00069   .00032     2.14   0.032     .00006     .00132
PATENTS_x_STA | -.00008   .00011    -0.75   0.455    -.00029     .00013
     LNASSETS |  1.11881   .24807     4.51   0.000     .63261    1.60502
      LNCAPEX | -.56759   .25336    -2.24   0.025   -1.06416    -.07102
  YR1997_2000 |  .47789   .37785     1.26   0.206    -.26269    1.21846
  YR2001_2004 |  .56256   .29741     1.89   0.059    -.02035    1.14547
  YR2005_2008 | -.02144   .29236    -0.07   0.942    -.59446     .55158
  YR2009_2012 |       0  (omitted)
        _cons |-15.5591   2.25760    -6.89   0.000   -19.9839   -11.13428
--------------+---------------------------------------------------------------
inflate       |
      PATENTS | -.00036   .00072    -0.50   0.617    -.00177     .00105
    PASTINNOV |-1.65224   .61023    -2.71   0.007   -2.84827     -45621
      SAMESIC | -.01874   .03402    -0.55   0.582    -.08542     .04793
      SAMEZIP | -.27730   .65075    -0.43   0.670   -1.55275     .99814
   SAMEREGION | -.11274   .28019    -0.40   0.687    -.66191     .43642
   SAMEPRIMST |  .05357   .03622     1.48   0.139    -.01741     .12455
    ALLIANCES | -.54860   .21361    -2.57   0.010    -.96728    -.12993
     LNASSETS |  1.20987   .46318     2.61   0.009     .30205    2.11768
      LNCAPEX | -.86787   .41033    -2.12   0.034   -1.67211    -.06364
        _cons |-8.40631   4.34285    -1.94   0.053   -16.9181     .10551
--------------+---------------------------------------------------------------
     /lnalpha |-29.7639   428.384    -0.07   0.945   -869.380    809.8524
--------------+---------------------------------------------------------------
        alpha |1.18e-13   5.08e-11                                0    .
------------------------------------------------------------------------------
Vuong test of zinb vs. standard negative binomial: z = 1.41 Pr>z = 0.0786
```

However, in addition to the reliance on objective measures to determine the appropriateness of a particular approach, it is important that the underlying

rationale of the model make substantive sense as well (Long & Freese, 2006). The alpha parameter incorporated into the negative binomial model reflects unobserved heterogeneity that may exist among observations. Given the observed overdispersion in these data, the negative binomial offers a more plausible means to account for unobserved differences among medical device firms to generate successful product approvals. Zero-inflated models, in turn, allow us to account for observed zero values on the basis of two separate processes: one that models true zeros and one that models zeros occurring by chance in a counting process.

With regards to the sample considered in this research, there is no a priori expectation that all firms would have the same capabilities to innovate. Indeed, some of the observed zero counts in my data may be the result of structural impediments to innovation inherent to the firm in question. I have attempted to control for such effects through the inclusion of control variables related to size and research spending; nevertheless, inter-firm differences in innovation ability may remain. For this reason it makes substantive sense to consider a regression model that takes into account both the ability (or lack of ability) to innovate as well as the prevalence of innovation by these organizations. The zero-inflated negative binomial model is a suitable candidate in this regard.

In the Results section I include the details from a number of regression models. These include time-series Poisson and negative binomial models, both with two-way (firm and time period) fixed effects, and a zero-inflated negative binomial. Given the apparent appropriateness of the zero-inflated negative binomial model as indicated above, however, the bulk of the analysis will be centered on the results from this regression model. In addition, while some

differences are evident in the outcomes of each model, several observed effects retain statistical significance despite these different specifications. I focus primarily on these robust results in the discussion that follows.

4.4 Results

The correlation matrix for the independent and control variables included in the count regression is displayed in Table 8 below. Although some of the values might arouse suspicions of multicollinearity, subsequent analysis revealed that all variance inflation factors were well below 5. This indicates that multicollinear relationships do not appear to be a major concern in my sample.

TABLE 8: CORRELATION MATRIX

	INNOVC~T	PATENTS	PASTIN~V	SAMESIC	SAMEZIP	SAMERE~N	SAMEPR~T	ALLIAN~S	LNASSETS	LNCAPEX
INNOVCOUNT	1.0000									
PATENTS	0.1073	1.0000								
PASTINNOV	0.5489	0.1507	1.0000							
SAMESIC	-0.0321	-0.0810	-0.0277	1.0000						
SAMEZIP	0.1158	-0.0060	0.2737	-0.0084	1.0000					
SAMEREGION	0.1250	-0.0076	0.2308	0.0819	0.5037	1.0000				
SAMEPRIMST	0.0018	-0.0259	0.0161	0.0466	0.2822	0.4776	1.0000			
ALLIANCES	0.4795	0.1789	0.6053	-0.0020	0.0559	0.0470	-0.0652	1.0000		
LNASSETS	0.2295	0.2357	0.2849	-0.0590	0.0484	0.0269	-0.0252	0.3895	1.0000	
LNCAPEX	0.1745	0.1762	0.2197	-0.0305	0.0728	0.0683	0.0335	0.3004	0.8277	1.0000

Table 9 shows the coefficients, standard errors, and t-statistics for the explanatory variables across three regression models: fixed-effects Poisson (POISSON_FE), fixed-effects negative binomial (NEG BIN_FE), and zero-inflated negative binomial (ZERO NEG BIN). While the emphasis here is on the results from the zero-inflated model, some brief interpretation of the other regressions is also in order at this point. One can note the overall similarity in parameter estimates across the POISSON_FE and NEG BIN_FE models. The overdispersion in the medical device approvals data does not materially impact the coefficients associated with the predictor variables, but it does introduce inefficiency in the form of downward-biased standard errors. Indeed, an inspection of Table 9 reveals that the t-statistics for the standard negative binomial model are consistently smaller than those from the Poisson, due to the underestimated errors inherent in the latter. Overdispersion affects the statistical significance (if not the general direction of effects) of the coefficient estimates in this case, which lends further support to the decision made to explicitly model this attribute using a negative binomial approach.

TABLE 9: REGRESSION RESULTS – LEARNING AND COUNTS OF INNOVATION

	POISSON_FE	NEG BIN_FE	ZERO NEG BIN
PATENTS	0.0021+	0.0021	-0.0003
	(1.76)	(1.48)	(-0.58)
PASTINNOV	-0.0468	-0.0468	0.0528
	(-1.15)	(-0.70)	(0.80)
SAMESIC	0.0145	0.0145	-0.0128
	(0.43)	(0.39)	(-0.73)
SAMEZIP	-1.0378**	-1.0378**	-0.2161
	(-3.35)	(-3.48)	(-0.62)
SAMEREGION	0.4231**	0.4231**	0.0114
	(2.82)	(2.69)	(0.10)
SAMEPRIMST	0.0630**	0.0630*	0.0540*
	(2.85)	(2.47)	(2.16)
ALLIANCES	-0.1314	-0.1313	-0.0047
	(-1.34)	(-0.96)	(-0.10)
PATENTS_x_SIC	-0.0006**	-0.0006+	-0.0002
	(-3.43)	(-1.69)	(-1.09)
PATENTS_x_ZIP	0.0018*	0.0018+	0.0004
	(2.00)	(1.66)	(0.28)
PATENTS_x_REG	-0.0002	-0.0002	0.0007*
	(-0.95)	(-0.61)	(2.14)
PATENTS_x_STA	-0.0001+	-0.0001	-0.0001
	(-1.82)	(-0.74)	(-0.75)
LNASSETS	0.5260*	0.5260*	1.1188**
	(2.36)	(2.10)	(4.51)
LNCAPEX	-0.0413	-0.0413	-0.5676*
	(-0.45)	(-0.32)	(-2.24)

YR1997_2000	0.1190	0.1190	0.4779
	(0.20)	(0.20)	(1.26)
YR2001_2004	0.3150	0.3150	0.5626**+**
	(0.87)	(0.82)	(1.89)
YR2005_2008	-0.2011	-0.2011	-0.0214
	(-0.76)	(-0.65)	(-0.07)
o.YR2009_2012		0.0000	0.0000
		(.)	(.)
_cons		1.5527	-15.5591******
		(0.01)	(-6.89)

NOTE: t statistics in parentheses. + $p<0.1$ and * $p<0.05$ and ** $p<0.01$

Turning now to the results from the zero-inflated negative binomial model, we find confirmation of some (though not all) of the posited relationships between forms of learning and technological innovation. Hypothesis 1, which held that direct experience accumulated by an organization would lead to higher levels of innovation, is not supported in this paper. Neither measure of experiential learning – number of unique patent grants (*PATENTS*) and past innovations by the focal firm (*PASTINNOV*) – was a significant predictor of medical device innovation. In fact, the patents variable has a negative coefficient associated with it, indicating that more patents seem to temper the innovative activity observed subsequently – though, again, the effect did not attain any of the conventional significance levels necessary to make stronger inferences regarding this possible relationship.

Hypothesis 2 posited that past innovative success by close technological peers would be associated with higher levels of innovation by a focal

organization. The coefficient for *SAMESIC*, a count of past medical device innovations by companies with the same SIC code as the focal firm, is negative and non-significant. We conclude that there is no support for technologically-focused vicarious learning by the companies in this sample.

However, I find confirmation for Hypothesis 3, which posits a vicarious learning for innovation based on geographic proximity. *SAMEPRIMST*, the number of past innovations by companies with the same primary prefix (first digit of the ZIP code) as a given firm, is positive and significant. Firms in the same primary area as past innovators tend to be more proficient at developing new medical devices that are ultimately approved for sale in the market. Equally interesting is the pattern of effects across the three variables used to operationalize geographically-focused vicarious learning in this research. The coefficient for *SAMEZIP* – past innovations by companies with the same ZIP code as a given firm – is negative (though non-significant); *SAMEREGION* – past innovations by companies with the same secondary regional prefix as a given firm – is positive (and again non-significant); and *SAMEPRIMST* is positive and significant. No support is found for Hypothesis 4 on the posited impact of partnering activity on subsequent levels of innovation. The *ALLIANCES* variable representing the number of extant alliances and joint ventures for the focal firm in each year does not achieve significance in this analysis.

Finally, I obtain support for some of the hypothesized interaction effects between forms of learning. While the joint role of experience-based learning and technologically-proximate vicarious learning captured in the *PATENTS_x_SIC* variable is not supported, there is evidence of a similar joint effect between

experience and geographically-proximate vicarious learning. *PATENTS_x_REG* is positive and significant, in support of Hypothesis 6. This suggests that the focal organization may learn more from the innovative activities of geographically proximate innovative peers when its own direct innovative experience is higher.

The control variables included in my analysis also influence the observed innovation counts. The logged measure of total firm assets for the previous year (*LNASSETS*) is related to higher levels of innovation. Not surprisingly, organizations in my sample with greater financial resources are adept at bringing more numerous new devices to market. However, the analogous variable for capital expenditures (*LNCAPEX*) has a negative coefficient in the zero-inflated model, indicating that higher capital spending is associated with a lower rate of innovation. It may be that a significant portion of these expenditures goes towards items that are only tangentially related to new product development (physical infrastructure, for example) rather than to such direct innovation-generating activities as research and development.

4.5 Conclusion

The findings from my quantitative study of medical device innovations by U.S. firms indicate the importance to successful new product development of a mixed approach to organizational learning. While a narrow focus on either experiential or inter-organizational learning does not materially improve the likelihood of future innovation, vicarious learning (as measured by past innovations by firms with the same primary state prefix as the focal company) does show a positive and statistically significant relationship with subsequent

counts of firm-level innovations. Technologically proximate vicarious learning, by contrast, is not associated with higher levels of subsequent innovation on the part of the focal firms in this study. Since my sample consists solely of organizations within the broad medical device domain, I cannot claim that a technological basis for learning is completely absent; however, the role of geographic – rather than technological – proximity emerges as the more significant dimension for innovation-enhancing external learning.

In addition to these main effects, an interactive effect between experience and geographically-proximate vicarious learning was found in this study. Based on this result, I conclude that an organization may benefit more from having geographically close innovative peers when also possessing more direct experience upon which to build new insights. When the firm uses direct experience in combination with external search, the limitations of each approach in isolation are tempered and the chances for innovation are improved.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

5.1 Discussion of Key Findings

In my thesis I have investigated the importance of three particular forms of organizational learning – experiential, vicarious, and inter-organizational – at particular stages in the process of technological innovation. In the first section of this concluding chapter I discuss the key findings across my two empirical papers and then identify more specific takeaways from each of my studies.

The two papers differ in several respects as described below, providing complementary insights into the role played by organizational learning in generating new innovations. The qualitative study described in Chapter 3 ("Sequences of Learning in Technological Innovation – Towards a Process Model") is an inductive undertaking that seeks to build rather than to test theory. It focuses on specific stages of the process of drug and medical device innovation as carried out by small entrepreneurial firms in the UK and Canada. The purpose of this theory-building exercise was to examine how organizations use experiential, vicarious, and inter-organizational learning as the new product development process unfolds. As discussed in more detail below, the findings from this first empirical paper provide evidence of the importance of all three learning types in biopharmaceutical and medical device new product development. The next step was to test more rigorously and explore these emerging insights using a larger sample of firms, which led to the quantitative paper from Chapter 4 ("Learning and Innovative Performance – A Longitudinal Study of U.S. Medical Device Approvals"). In contrast to the process model

study, this quantitative analysis is deductive (hypothesis-testing) in nature. It focuses less on the process of innovation per se than on explaining innovation outcomes by types of learning. The dependent variable is the number of approved innovations realized by U.S.-based publicly traded firms in the medical device industry over a period of several years. As in the first study I find support for interactive effects of types of organizational learning involved in technological innovation. Organizations with more direct experience with innovation in the industry appear more likely to learn from the innovative success of other firms within the geographically proximate region.

Having approached the phenomenon of technological innovation from the perspective of both its overall process and its ultimate outcome, certain key findings emerge from my thesis. First is the notion that firms in knowledge-intensive industries with sophisticated product offerings benefit from supplementing their internal expertise with that of external referents and collaborators. This relates to my first research question – "How are experiential, vicarious, and inter-organizational learning involved in the development of technologically innovative products?" The relative importance of different forms of learning shifts over the course of a new product development cycle (Chapter 3), and the interaction of these learning types is associated with successful innovation outcomes (Chapter 4).

My empirical findings also illuminate the distinctions, as described in the literature review (Chapter 2), between characteristics of knowledge generated from experiential and inter-organizational learning, on the one hand, and vicarious learning, on the other. Where interview respondents highlighted the use of direct

experience in their innovation projects, a recurring theme is the need to overcome internal 'stickiness' in order to transfer the resulting knowledge to the places where it will benefit the development effort ("that knowledge, the things that we've learned there [in past projects], definitely applies to these new products" *(Tellumo)*; "So that sort of knowledge base and that system that we've built up has really helped us progress other products at a much faster rate" *(Iris)*). By contrast, the challenge in vicarious learning is one of making knowledge derived from an external setting comprehensible for the acquiring firm ("So you infer things about the effect of the agent. […] that starts to give you some clues" *(Calypso)*). In this case 'stickiness' has to do more with cognitive reasoning than internal transfer.

My second research question concerned the possible existence of numerous viable processes by which industry peer organizations mobilize forms of learning over time – "Does the overarching learning process differ materially across innovation projects within the same industry sector?" Data from my first paper on eleven biopharmaceutical and medical device innovation projects revealed the existence of three distinct learning sequences: 1) intensive-externalizing (IE), 2) intensive-internalizing (II), and 3) expansive-internalizing (EI). While the industry setting within which this research was conducted is interesting in its own right, my findings also point to some more general statements regarding forms of learning in innovation processes.

During the Technical Uncertainty and Broad-Based Solution phases, learning from direct experience is a major component of the organizational

learning process. Regardless of the distinct learning sequence – intensive-externalizing, intensive-internalizing, or expansive-internalizing – the firms studied here have followed, a common denominator is the reliance on experiential learning in the early stages of a new product innovation. In subsequent stages, firms begin to look for external sources of knowledge, pursuing strategies of vicarious learning and inter-organizational learning (direct contact and formal partnering) with higher frequency.

A plausible explanation for this pattern is that the knowledge and expertise gained through experiential learning provides a basis for making sense of externally observed innovation. Given the need for firms to identify the most relevant exemplars from which to draw lessons through observation, it could be the case that a certain level of direct experience is a necessary pre-requisite to more distant forms of learning. Such a sequence of learning in the face of uncertainty would be consistent with basic notions of absorptive capacity (Cohen & Levinthal, 1990), which presume the need for a foundation of knowledge within the organization upon which future insights can be built.

However, the occurrence of the third learning sequence observed in my research (expansive-internalizing) adds an interesting wrinkle to this story. Organizations that adhere to the EI learning path incorporate vicarious learning methods into their repertoires quite early on in the innovation process. As indicated above, the majority of the organizations in the qualitative study are small and recently founded; as such, it seems unlikely that firm-level absorptive capacity would provide a complete explanation for the differences in learning sequences found in practice. In these cases the novelty of the underlying

technology is likely to be an important factor in this regard. This addresses my third and final research question – "What characteristics of the underlying innovations account for differences in the types of learning used and the interactions between these types as the development process unfolds?"

Two of the three organizations that made use of the expansive-internalizing sequence (Pan and Pluto) are developing products whose technical bases are significantly different from those of the majority of competitive firms in their segments. Pan is developing a surgical device that makes use of plasma energy to perform cutting and coagulating functions, while Pluto is synthesizing a plant-based biosimilar drug designed to treat breast cancer. Here the very lack of close technological referents has made vicarious learning more necessary, prompting both Pan and Pluto to engage in distant search activities intended to draw in lessons from any potentially useful source. This recalls the finding by Bingham & Davis (2012) of 'seeding' processes in foreign country entries, whereby management teams with little previous international experience undertook vicarious learning or learning from external parties prior to more experiential trial-and-error learning.

For many of the firms studied, observation and inference becomes the key learning mechanism during the Refinement stage of innovation development. In such lengthy phases as clinical testing in biopharmaceutical and medical device innovation, organizations have the opportunity to incorporate lessons learned directly into new activities. Clinical trial results are often published and available for consultation, and the academic literature serves as another crucial input to this process.

In this phase – perhaps owing to the overwhelming amount of information that would result from a less discerning approach to learning – inter-organizational similarity emerges as an important factor in vicarious learning efforts. In this paper there were indications that respondents used similarity based on financial size or disease category to identify relevant referents for purposes of vicarious learning.

In later stages of development (Approval and Introduction, Market Feedback), we see a greater focus on inter-organizational learning, whether through direct contact or partnering. This is consistent with the broad trend favouring alliances and other collaborations in the biopharmaceutical sphere (Baum, Calabrese & Silverman, 2000; Oliver, 2001; Whittaker & Bower, 1994). Of particular importance here is direct contact with clinicians and other market actors. This represents a particular form of user innovation (von Hippel, 1986) wherein the originating organization and the end user help to co-develop subsequent versions or identify new applications for the innovation in question.

Data from my second paper on medical device innovations by U.S. firms provide corroborating evidence of the joint importance of the several types of learning for successful new product development. Results from my regression models indicate that only one independent measure of vicarious learning (past innovations by firms with the same primary state prefix as the focal firm) had implications for innovation performance. While this measure showed a statistically significant relationship with subsequent counts of innovations, neither experiential nor inter-organizational learning on their own were associated with

future innovations. However, there was empirical support for an interactive effect between innovation experience and geographically-proximate vicarious learning (the positive and significant coefficient on the *PATENTS_x_REG* variable) in my analyses. This suggests that when building upon a strong pre-existing foundation of direct experience, organizations may benefit more from the innovative activities of geographically proximate innovative peers.

5.1.1 Practitioner Implications of Learning Sequences

What are the implications for performance of pursuing a particular learning sequence? Although the continuing status of many of the innovation projects included in this research makes it difficult to draw any definitive conclusions, I advance some tentative ideas here. Organizations that favour the intensive-externalizing (IE) sequence tend to develop closer and more numerous inter-organizational linkages as their innovations move forward. While the amount of firm-level expertise continues to matter, the ability of IE firms to partner effectively and to create productive repertoires of joint activities (Larsson, Bengtsson, Henriksson & Sparks, 1998) will exert greater influence on the ability to realize innovation success. If learning from direct contact and partnering is to continue, organizations will need to pay attention to the structures and routines established to assimilate and use knowledge produced by either party to the arrangement (Lane & Lubatkin, 1998).

In contrast, firms adhering to either the intensive-internalizing (II) or expansive-internalizing (EI) learning sequence face a different set of performance-related concerns. Since the intent for both types of firms is to

internalize knowledge from sources both inside and outside company boundaries for use in future innovation projects, the need for effective search and retention mechanisms is paramount. Especially in the case of EI firms, which demonstrate use of a larger number of forms of learning at early stages in the innovation process, the ability to incorporate these insights into firm-level routines will predict the ultimate success of present and future development efforts.

5.1.2 Dysfunctions in the Learning Process

The discussion to this point has focused on the beneficial impacts of learning, based on the unstated assumption that organizations demonstrating the willingness and capability to learn continuously will generate more positive innovation outcomes. However, as noted in the Literature Review, learning can also have dysfunctional consequences. Superstitious learning, which "occurs when the subjective experience of learning is compelling, but the connections between actions and outcomes are misspecified" (Levitt & March, 1988: 325; cf. Schwab, 2007) is one such problem. In addition, fast learning may draw organizational attention away from alternative courses of action which, if selected, would represent better long-term choices (Denrell & March, 2001). The referents used for learning purposes also matter, as evidenced by the negative results obtained through focusing solely on successful cases (Denrell, 2003).

Table 10 summarizes some of the key themes relating to drawbacks and dysfunctions of learning uncovered through the interviews in the qualitative study. The findings are shown by form of learning, and some general points are expanded below.

TABLE 10: LEARNING DRAWBACKS AND DYSFUNCTIONS

Form of Learning	STAGE OF DEVELOPMENT				
	Technical Uncertainty	**Broad-Based Solution**	**Refinement**	**Approval and Introduction**	**Market Feedback**
Learning from direct experience (DE)	Deep expertise in early stages of discovery precludes the development of downstream capabilities	Difficulty of transitioning between open-ended search and more constrained regulatory process	Attempt to reorient attention towards process issues often problematic	Need to determine market fit based on technology being advanced	Need to determine market fit based on technology being advanced
Learning from others through observation and inference (O)	Difficulty of reconstructing development process based on limited information disclosed in research articles	Lack of relevant or useful lessons available from competitors	Lack of knowledge of key characteristics driving the innovation process at observed firms	Unwillingness of competitor firms to share potentially useful lessons	
Learning from others through direct contact (C)	Need for sufficient overlap in technical acuity to allow for meaningful knowledge sharing	Need for sufficient overlap in technical acuity to allow for meaningful knowledge sharing	Expectation of broad-based expertise of development partners		Difficulty of obtaining critical feedback
Learning from partnering or other formal collaboration (P)	Lack of ability to identify / assess prospective partners or referent organizations	Lack of ability to identify / assess prospective partners or referent organizations	Capabilities and openness of partner difficult to gauge initially		

Within the context of the process of technological innovation, the main drawback associated with learning from direct experience relates to the difficulty in transitioning between stages. The significant expertise accumulated at each point in the process makes re-orientation towards a phase requiring new skills and knowledge problematic. As Leonard-Barton (1992) found in her study of core rigidities, the deep competency that an organization has developed can impede or inhibit the move to new or different stages of the innovation process.

In the case of vicarious learning, a key problem identified is the uncertainty inherent in processes that are filtered through the lens of observation and inference. Since the information gleaned through vicarious learning is often incomplete, and access to knowledgeable insiders can be lacking, the firm has to rely on its ability to assess accurately the true nature of the underlying causal process. When the possibility for superstitious learning is high, a strong base of first-hand experience becomes more valuable as a complement to inferential activities.

Interviewees viewed learning from others through direct contact to be less useful when low technical overlap between the firms impeded knowledge sharing. Past studies have addressed the role of such overlap (Mowery, Oxley & Silverman, 1996; 1998), and its importance in the present setting is particularly clear with respect to the Technical Uncertainty and Broad-Based Solution stages of the innovation process.

Finally, learning from partnering depends on having an appropriate collaborator from whom to draw lessons. As is evident from the interview data, however, identifying and assessing prospective partners prior to agreement can be

difficult. Once the collaboration is in effect, the capabilities and openness of the partner may not live up to ex ante expectations, and the firm may find itself in an unbalanced and – from a learning perspective – ultimately unproductive relationship.

5.2 Contributions to the Learning Literature

As noted in the Introduction, a more thorough understanding of the interactions between experiential and vicarious learning in organizational processes entails examining whether these learning types are complementary or substitutive in nature (Posen & Chen, 2013; Schwab, 2007; Simon & Lieberman, 2010). Through the research reported here I conclude that in the biopharmaceutical and medical device sectors studied the relationship is primarily a complementary one. Experiential learning provides firms with deep context-specific knowledge, while inter-organizational learning expands the scope of this knowledge through active engagement with a partner organization. Vicarious learning, in turn, requires an inferential leap to abstract from the setting in which an observed innovation takes place. Each form of learning contributes a different perspective to the organization, and the joint use of these approaches may serve to augment the strengths and dampen the shortcomings of each in isolation.

The specific role of vicarious learning in the development of technological innovations constitutes a promising area of inquiry, one that has been under-researched to date. Much of the literature on vicarious learning examines organizational decisions to adopt practices or technologies developed elsewhere (cf. Baum, Li & Usher, 2000; Greve, 2000; Haunschild & Miner, 1997).

Additional insights may be revealed by shifting focus to the actual innovation process itself, for "while there is extensive support for vicarious learning in other strategic contexts, we know little about the nature of vicarious learning in NPD [new product development]" (Srinivasan, Haunschild & Grewal, 2007: 25). This research helps address the new product development lacuna in the learning literature.

5.3 Implications for Theory and Practice

I make several contributions to theory and practice with this research. The elaboration of learning sequences associated with technological innovation is an important undertaking, and this paper follows in the spirit of Bingham & Davis's (2012) study of the temporal ordering of learning processes in internationalization activities by entrepreneurial firms. Studying the numerous ways by which organizations structure their learning initiatives over time will serve to enrich our scholarly understanding of change and innovation.

Research on knowledge and technological innovation indicates the increasingly external locus of creative activity in industries such as pharmaceuticals and biotechnology, aircraft production, machine tools, and medical devices (Adams, Brusoni & Malerba, 2013; Arora & Gambardella, 1995; Gelijns & Rosenberg, 1995). Through my research I endeavour to demonstrate the particular ways in which this 'external turn' is made manifest in learning processes that are increasingly oriented to targets beyond firm boundaries and oftentimes beyond immediate industry or geographic locales.

In addition, the findings presented in this paper offer insights for executive and technical personnel tasked with fostering innovation within their particular firms. The creative methods of organizational learning pursued by the biopharmaceutical and medical device firms examined here should encourage other industry leaders to consider how to make better use of experience-based, vicarious, and inter-organizational processes in combination to augment internal knowledge. By doing so, they will increase the likelihood of bringing about successful technological innovation in their market segments.

5.4 Limitations

The key findings and contributions from the research reported here are subject to the following limitations. While both of the empirical studies considered innovation in human healthcare settings, the qualitative paper focuses on the new product development process among a sample of small and recently founded firms, whereas the quantitative study examines learning type antecedents of medical device innovations among a large sample of publicly listed device firms. Given these distinctions in both the data sample and the particular aspect of the phenomenon upon which I focused, any attempt to generalize across the studies should be made in a cautious manner.

The small overall number (eleven in total) of innovation projects included in the qualitative paper, as well as their concentration in two healthcare technology sectors, may further limit the generalizability of my conclusions. As is the case for most qualitative research of the type undertaken here, bias in the form of selective recall or retrospective rationalization by my interviewees is also a

potential concern. I attempted to minimize this issue by focusing on innovation projects that were currently underway or only recently completed, as well as by consulting numerous respondents and varied data sources for each project where feasible. Nevertheless, there is no objective means of assessing the extent to which these measures were successful in attenuating any bias in the collected data. Finally, despite the increasingly global nature of drug and device development activities, the Canadian and UK firms in my sample may face cultural, regulatory, and socio-political environments different from those of their industry peers in other countries.

Furthermore, the quantitative analysis of innovation counts in my quantitative paper was limited to U.S.-domiciled and publicly-traded firms in a single industry. The extent to which similar patterns of learning would be observed in non-U.S. device firms is an empirical question awaiting further research. The treatment of acquisition events as de facto company terminations in my dataset, while offering a conservative test of my learning-related hypotheses, does not capture any potential transfer of knowledge to the new parent resulting from these change-of-control transactions. Limitations with regards to the variables used to gauge learning in my regression models can also be identified. While patents are a key indicator of firm expertise, these instruments do not fully capture more tacit elements of knowledge that may also be important when assessing experiential learning. In turn, measuring inter-organizational learning as the number of formal partnerships managed by a firm presumes an equal benefit derived from each such collaboration, while in reality some alliances or joint ventures may offer significantly greater (or lesser) opportunities to learn than do

others. The coarseness of the available data makes it difficult to tackle these issues, since the SDC Platinum reports do not indicate the purpose of each new partnership (joint basic research undertaking, marketing and distribution arrangement, etc.). Moreover, there is a limited amount of information regarding terminations of collaborative ventures in this database, and the data that do exist make it hard to ascertain whether an alliance is cancelled due to successful attainment of the partners' goals or a lack of progress in this respect.

5.5 Directions for Future Research

Following from the discussion of the limitations above, some interesting possibilities for future studies present themselves. The underlying drivers of the expansive-internalizing sequence – which involves external learning from an early stage in the new product development process – identified in the qualitative study could be examined so as to determine what factors account for this varied approach to learning on the part of some organizations. Initial evidence points to the novelty of the underlying technology base of the firm as a motivation for the early pursuit of vicarious learning. A systematic examination of this tendency could test the robustness of this finding and identify moderating variables or boundary conditions for this relationship. In addition, an interesting question for future research involves the extent to which technological novelty may, by fostering earlier and more expansive search efforts, build organizational capacity to a sufficient level to minimize the need for inter-firm technological overlap (Mowery, Oxley & Silverman, 1996; 1998) in future search activities.

The extension of this line of research to the same industry settings in different institutional contexts (for example, biotechnology in emerging markets) would allow for greater insight into the roles played by such supra-organizational factors as technology policy and the legal environment in the forms and sequence of innovation-centered learning. Countries such as India have thriving pharmaceutical sectors built on basic manufacturing and the production of generic drugs (Collis & Smith, 2007), and are now making greater inroads into new drug development activities. In addition, intellectual property laws vary widely in terms of the protection that they afford to biopharmaceutical companies in developing nations; a recent ruling by the Indian Supreme Court against Novartis's application for a patent on their cancer drug Glivec (Nolen, 2013) reveals the difficulties that such cross-country differences present for innovation in this industry. Examining the degree to which the learning sequences and joint learning effects observed in my empirical papers are also operative in other contexts would address the generalizability concern alluded to in the previous section, as would considering these phenomena in wholly different economic sectors such as nonprofit organizations (Beekman, Steiner & Wasserman, 2012).

By the same token, further study of the role of patents in this activity is needed to understand the dynamics of vicarious learning. The importance of patents as an indicator of technical expertise is well-established, but the extent to which organizations attempt to learn from publicly available sources of patent data on competing firms is under-theorized. Although I uncover some preliminary evidence in my qualitative study that firms do engage in broad patent searches

when attempting to learn about other organizations, more in-depth study of this phenomenon should be a focus area for subsequent research.

Refinement of the measures in the quantitative paper could provide additional opportunities for new research. I used a three-year rolling window of past innovations as one indicator of experiential learning; however, assessing this construct based on whether the focal firm had successfully innovated at *any* point in the past would provide a less restrictive measure of learning. In a similar vein, using different time windows – five years or seven years, for example – for the variables intended to capture both experiential and vicarious learning effects would enable scholars to assess the robustness of the reported results and the rate of decay of organizational knowledge for innovation purposes. With regards to inter-organizational learning, examining alliances between medical device firms only or between firms within the same primary SIC code (rather than between a medical device firm and a partner in any other sector, as was done in this research) might reveal intra-sector effects that predict the incidence of subsequent innovation.

As well, future research into the performance implications of the learning sequences described in Chapter 3 would represent a useful extension of this thesis. The projects considered here are not yet sufficiently advanced in their development for us to make any compelling claims regarding the benefits for innovation outcomes of following any one of the three sequences. Nevertheless, this remains a plausible undertaking for management scholars in the near future. Gaining greater insight into the ultimate effects of diverse forms of organizational learning, their sequential use, and their complementary or substitutive nature is a

worthwhile future research program – one that holds significant promise for both the development of theories of organizational functioning and the effectiveness of managerial practice.

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APPENDIX I: INTERVIEW GUIDE FOR QUALITATIVE PAPER

I. Background

1) Thank the respondent for agreeing to be interviewed
2) Introduction of the researcher
3) Brief description of the purpose of the study
4) Explanation that:
    a. Participation is entirely voluntary
    b. The decision to decline to answer any question or even to withdraw entirely from the project remains available to respondent at all times
    c. Responses are attributed only with the permission of the respondent
    d. Pledge to confidentiality means that only the researcher has access to the interview materials, with said materials coded and stored in such a way as to maintain confidentiality and restricted access

II. Introductory Questions

1) Function and tasks of the respondent
    a. What is your role / position with the company?
    b. What are your key activities in this role?
    c. How long have you worked with this company?
2) Details regarding technological innovations developed and/or commercialized by the company
    a. Can you tell me a little about innovation X?
    b. When did work on this innovation first begin at your company?
    c. How closely involved have you been with this innovation over time?
    d. Are there particular points in the development of innovation X when you were more deeply involved?

III. The Learning Process

1) Basis of direct experience of the organization
    a. In your opinion, how much did the organization's expertise with previous innovations contribute to the development of innovation X?
2) Identification of referent firms for learning purposes
    a. General
        i. Which firm(s) in your industry do you believe to be the best sources of learning for your organization as you develop new innovations?
        ii. In your opinion, what is it about these firms that makes them valuable in this regard?

b. Specific to innovation X
    i. Which other firm(s) did your organization look to as exemplars or knowledge sources when developing innovation X?
    ii. Which of these referent firms were most useful for this purpose? Least useful?
    iii. In your opinion, what characteristics of these (less) useful referent firms account for their (less) beneficial impact on innovation in your organization?

IV. Key Organizations and Relationships

1) How common is it for organizations in your industry to collaborate externally in the development of innovations?
2) What form does this collaboration usually take?
3) Has this tendency changed over time? If so, how?
4) Which external actor(s) has/have been key in facilitating development of innovation X?
    a. Could you describe the role played in the process by this actor?
5) In your opinion, have previous collaborations benefited your organization's subsequent efforts to innovate? If so, how?

V. The Context of Innovation

1) Do different *forms* of knowledge matter more at different points in the process of developing innovations? If so, how do they differ?
2) Do different *sources* of knowledge matter more at different points in the process of developing innovations? If so, how do they differ?
3) Have these tendencies changed over time? If so, how?

VI. Closing Questions

1) Final thoughts
    a. Are there any other details that would be useful for me to know?
    b. Are there any other people that I should interview in connection with this project?
        i. Within your organization?
        ii. Outside your organization?