THE RISE OF PATIENT CENTRICITY IN THE PHARMACEUTICAL INDUSTRY

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by
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ABSTRACT

Despite a decade of public and private efforts to promote patient centricity in healthcare, there is still considerable ambiguity and skepticism regarding the concept and its business impact in the pharmaceutical industry. In this research, a novel methodology is developed to quantify firms' strategic orientation using public 10-K reports. The Strategic Orientation Ratio (SOR) was developed and first validated to examine customer centricity for 9 non-pharmaceutical companies. The SOR is then extended from customer centricity to patient centricity, and it was applied to measure the extent of patient centricity in 10 multinational pharmaceutical firms. The method was successfully validated by identifying the strategic orientation of non-pharma firms such as Walmart, Apple, and Amazon. Next, by the same method, the extent of patient centricity is quantified in 10 big pharmaceutical companies for 2005-2015. This revealed the extent to which patient centricity exists in pharmaceutical companies, and how this has changed over time. The combination of an expressed patient-centric strategic orientation, personalized medicine (measured by oncology products), and patient access (measured by sales) is shown empirically to have a significant positive effect on firm performance. This implies that not only is patient centricity "the right thing to do," it can also be a viable model for pharmaceutical firm competitiveness.

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RESEARCH MOTIVATION

For centuries, the pharmaceutical industry has prided itself as a leader in innovation. By focusing on product innovation, the industry has not only created some of the most sophisticated molecular designs in medicines, but it also has been richly rewarded as one of the most profitable industries in the global economy (Roberts, 1999). Hence, product innovation has always been both the strategic focus and the profit engine for the industry (Cool, 1993; Yeoh, 1999; Petrova, 2014).

Interestingly, patient centricity has become the new buzzword in the industry and gained general interest in recent years.

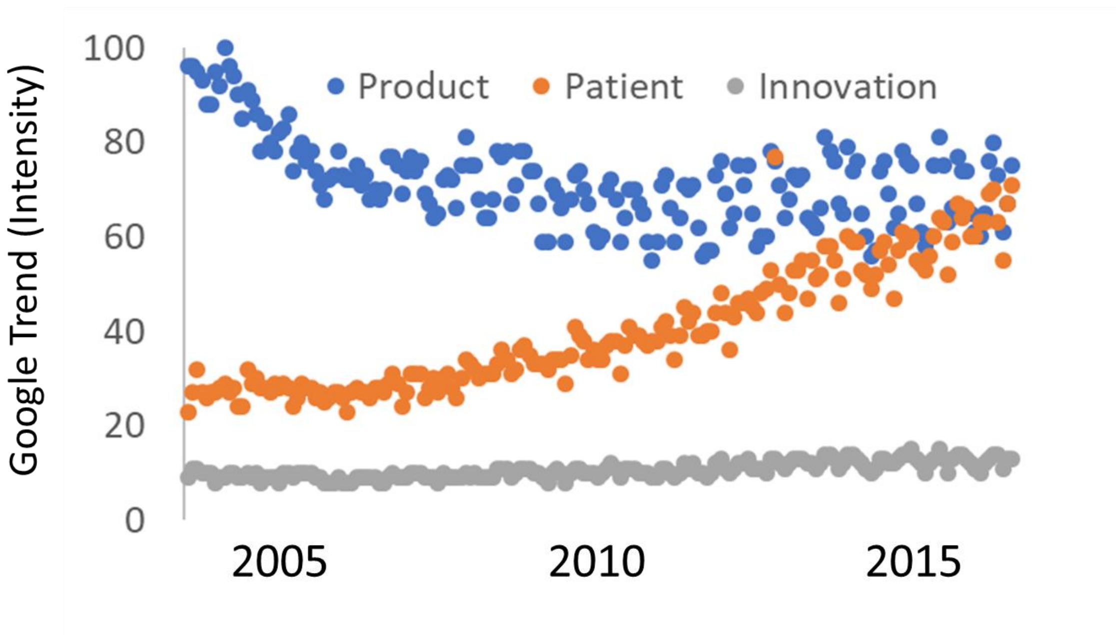


Figure 1. The search trend of 'patient', 'product', and 'innovation'.

Although significant public and private efforts have been advocating patient centricity across the healthcare ecosystems (Robbins, 2013; Getz, 2015; Stegemann, 2016; Yeoman, 2017), the rise of patient centricity in the pharmaceutical industry remains an ambiguous and suspicious move in the public's eyes (Howley, 2016; du Plessis, 2017).

Why the skepticism? Because this is not the first time that the pharmaceutical industry proclaims patient centricity. In 1952, George W Merck, the chairman of Merck & Co., was featured on the cover of Time magazine with the following words: "We try never to forget that medicine is for the people. It is not for the profits….The profits follow, and if we have remembered that, they have never failed to appear" (1952). These words made the pharmaceutical industry amongst the most respected and admired industries nearly half a century ago. The noble cause inspired many talented individuals to dedicate their careers in medicine development. However, the industry has changed incredibly since the 1960s. The landmark event of the 1962 Amendments to the US Food and Drug Act required all new drug products to demonstrate substantial evidence of efficacy based on double-blind placebo-controlled trials. This amendment consequentially affected the length of the R&D cycle time, the number of subjects required, and led to exponential increases in drug development cost. Subsequently, within the past two decades, many researchers have alarmed an industry-wide productivity crisis, i.e., the skyrocketed R&D cost and the decline in the number of annual new molecule entities (NMEs) approval despite substantial scientific and technological advancements (Scherer, 2001; DiMasi, 2003; Cohen, 2005; Munos, 2009; Comanor, 2013).

Meanwhile, the reputation of the pharmaceutical industry has dropped to an all-time low due to numerous corporate scandals taking place during the same period (Kessel, 2014). These incidents no doubt shattered the trust between the public and the pharmaceutical industry, and casted a cloud over new patient-centric initiatives such as ‘patient-centric trial design’, ‘patients in partnership’, and ‘Chief Patient Officer’. These tactics have understandably raised questions such as, “is this a PR ploy to disguise all the corruptions and scandals?’ and “is it a genuine strategy to correct the reputation and combat the productivity crisis?’ Furthermore, these new initiatives also cause confusion for many pharmaceutical employees. On the one hand, employees are proud to embrace patient centricity initiatives and feel re-energized by the once-noble calling “returning” to its roots, so to speak. On the other hand, many employees struggle to grasp a meaningful interpretation of these new initiatives and wonder, ‘if producing the safest and the most effective drugs to help patients is not patient-centric, then what is the true meaning of ‘patient centricity’?’

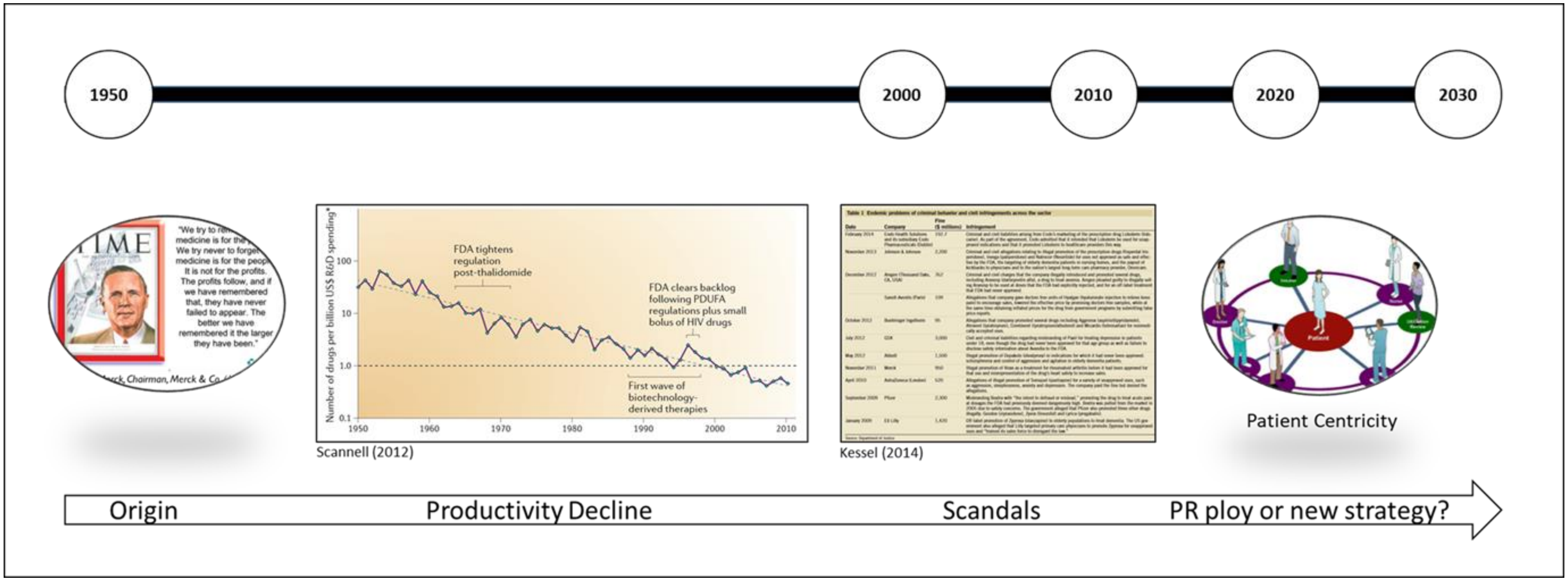


Figure 2. The timeline of patient centricity in the context of the pharmaceutical industry.

Research Gaps

Many scholars have examined the pharmaceutical industry for its innovation, productivity, profitability, trends, and evolution in the past century (Cool, 1987; DiMasi, 2003; Scherer, 2001; Cohen, 2005; Munos, 2009; Dunlap-Hinkler, 2010; Hannigan, 2013). However, no pharma executives so far (George Merck included) have ever stepped forward to explain how a product-centric industry can incorporate patient centricity into its corporate strategy in a transparent and measurable fashion similar to that of product innovation. Additionally, there is no research to date that delineates the relationship between patient centricity and profitability. Consequently, despite the good intentions and enthusiasm from many stakeholders, the lack of evidence arguing that patient centricity is a genuine, competitive strategy that will sustain and improve firm performance make it difficult for any CEOs or pharma executives to depart from the deeply rooted product-centric model. These gaps, if left unaddressed, could lead to some short-lived, superficial patient-centric activities, and continue to fuel the skepticism and distrust that lies between the public and the pharmaceutical industry. Worst of all, the industry could miss a transformative opportunity to better serve its patients in the future.

To address the gaps described above, I defined two objectives for this research. The first objective is to develop a measurement to quantify patient centricity, whereby we can assess whether it is a genuine strategy or a PR ploy in the pharmaceutical industry. The second objective is to analyze the relationship between patient centricity and firm performance. In the following two chapters, I will address the two research questions:

Chapter 2. “Can we measure patient centricity in the pharmaceutical industry?”, and Chapter 3. “Does patient centricity impact firm performance?”.

CHAPTER 2

MEASURING PATIENT CENTRICITY AS A STRATEGIC ORIENTATION

"You can't manage what you can't measure."

***Peter Drucker*.**

Introduction

Strategic management is critical to a firm's performance. It involves a long-term vision, planning, communication, knowledge management and seamless operation to accomplish business objectives and sustain competitive advantage over competitors (Porter, 1980; Porter, 1985; Mills, 2002; Mudambi, 2002; DeSarbo, 2005). A coherent strategy guides managers in resource allocation and influences a firm's operating activities (Yeoh, 1999).

Porter (1980) defined three generic competitive strategies that a firm may choose to compete for to be the market leader: Cost Leadership, Differentiation, and Focus. In line with Porter's theory, Treacy and Wiersema (1995) proposed the 'Three Value Disciplines', which are three essential operating capabilities that all firms possess. The three value disciplines include operational excellence, product leadership, and customer intimacy. According to Treacy and Wiersema (1995), although all three disciplines are valuable, a firm should choose to master only one primary discipline and maintain competence in the other two in order to succeed the market leadership, the reason being that each of the three disciplines serves a distinct strategic purpose. A firm that chooses to compete for Cost Leadership requires an organizational focus on its cost structure and less investment in R&D activities. On the contrary, a firm that competes for Differentiation invests heavily in

R&D and not so much in optimizing operational efficiency. By creating a singular strategic focus, a firm can fully align its entire operation model, including the company's culture, business processes, management systems, and platforms, toward gaining competitive advantage. Conversely, a firm that is less focused (i.e., oriented towards more than one disciplines) will likely suffer from conflict, resource diffusion, and poor performance.

Literature Review & Key Concepts

The relationship between organizational alignment and firm performance is an important concept in strategic management. Prior research suggests that the alignment between strategy and operation is critical to organizational performance (Joshi, 2003). According to Boyer and McDermott (1999), the alignment between strategy and operation is achieved when various levels of employees within an organization agree on what is most important for the organization to succeed. This overall alignment between the strategy and operation, which is defined as the strategic orientation, can create a 'tailwind' effect on organizational performance. The integral relationship between strategy, value disciplines and strategic orientations is illustrated in Figure 3. In this model, there is a singular competitive strategy supported by one value discipline. For instance, the cost leadership strategy is supported by a concentrated effort in achieving operational excellence. In so doing, every employee and business unit in the company is 'oriented towards' and 'centered around' optimizing the operational excellence as their top priority. (*n.b.* In this research, the terminologies of 'oriented' or 'orientation' are used interchangeably as 'centered' or 'centricity'.)

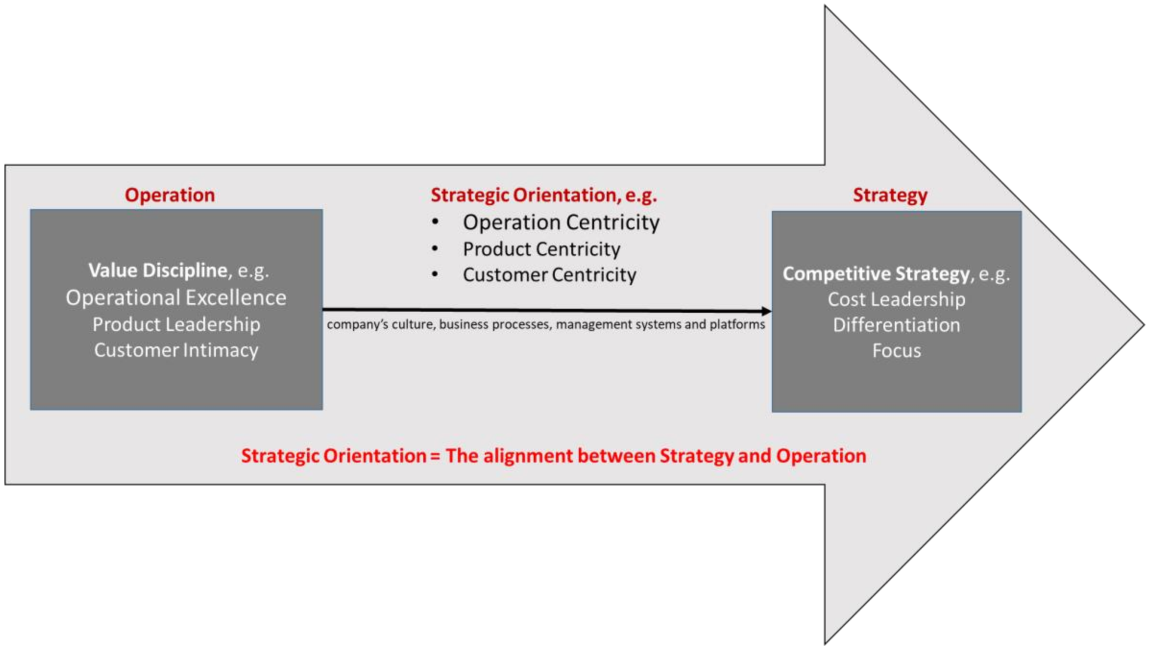


Figure 3. The strategic orientation is the alignment between strategy and operation.

Effective strategic management would aim to create a singular strategic orientation and drive the strategy-operation alignment as well as define measurements for success accordingly. In the section below, each type of competitive strategy, its corresponding value discipline, and its strategic orientation is further discussed.

Operation Centricity

A firm pursuing a cost leadership strategy focuses its resources on becoming the 'low cost' producer in its industry. This type of company exploits operational efficiency, supply chain management, and preferential access to raw materials and supplies in order to maximize cost advantage over their peers. If a firm can achieve and sustain said cost advantage, it will likely succeed in achieving market leadership in its industry. Walmart is one of the many companies competing in the variety store business, and is well-known for its “everyday low prices”. At the core of Walmart’s business model is operation centricity that focuses on operational excellence. It believes that value-for-money is an important determinant of consumer behavior worldwide. Therefore, the company has aimed to deliver the best prices for its customers since the first Walmart opened in 1962 by optimizing its lean and efficient operation. Its success is the result of an exploitation of its store's layouts, exceptionally efficient distribution system, and strict cost control (Spotts, 2005). This cost leadership strategy has sustained Walmart as the number one company on the Fortune 500 list for the past 5 years in a time when many other retailers struggle with bankruptcy.

Product Centricity

A firm pursuing product differentiation seeks to produce a unique and high-quality product in its industry. Product differentiation stems from product orientation, a dominant business strategy in many industries from 1920 to 1980. To differentiate the product in the market, the management strategy is to focus on R&D and product innovation in order to develop high-quality products that can be sold at premium price points. This strategy assumes a unique and high-quality product will sell itself because customers will recognize the product performance and be willing to pay significantly more money for the quality. Apple is a well-known company that competes in the consumer electronics industry using product differentiation. Since the 1980s, Apple has created a corporate culture of ‘think different’ and has made product design with superior user experience a hallmark of its differentiation strategy. Its innovative effort has led to many successful product launches, including the Macintosh computer, iPod, iPhone, iPad etc. This product differentiation strategy took Apple from near bankruptcy in the 1990s to a $1 trillion market capitalized company today.

Historically, the product differentiation strategy has worked particularly well in the ‘first mover’ scenario, a closed economy where limited choice is available. However, the big challenge is that in a rapidly changing marketplace where customers’ needs are constantly evolving, the incremental improvement after the initial disruption often becomes insufficient to satisfy the customers’ wants and needs. As soon as a competing offer comes on the market that can meet customers’ desires and wishes, the product differentiator runs the risk of losing a significant portion of its market share. This phenomenon was seen when Microsoft overtook Apple OS market in the 1990s, and then Android smartphones surpassed the iPhone market in Asia in the 2010s.

Unsurprisingly, even the stable and slow-moving pharmaceutical industry is not exempt from such competitions. As soon as the patents of blockbuster drugs expire, and cheap and effective generics become available, the blockbusters typically lose most of their revenue.

Customer Centricity

In contrast to the pure Cost Leadership or Differentiation strategy, the Focus gathers deep customer insight and customizes its products and prices to meet the customers’ needs thereby attracting (and emphasizing) customer loyalty. Customer centricity is a well-established business philosophy that evolves to respond to the ever-changing demands of customers. In 1954, Peter Drucker wrote in his landmark book, *The Practice of*

Management, that "*it is the customer who determines what a business is, what it produces, and whether it will prosper.*" (Drucker, 1954, p35). A customer-centric company embedded in the culture of customer loyalty as the top priority for the entire company. The management and employees aim to provide the best customer experience and build customer intimacy for the long term. It believes that by doing so, the customers will respond with loyalty and develop dependency over time, hence the business performance will sustain and grow. Since its founding in 1994, Amazon has focused on customer service with a mission statement to be the earth's most customer-centric company. In his letter to shareholders (2016, p1), Amazon CEO Jeff Bezos said, "customers are always beautifully, wonderfully dissatisfied, even when they report being happy and business is great. Even when they don't yet know it, customers want something better, and your desire to delight customers will drive you to invent on their behalf."

Amazon made use of two approaches in order to create a sense of intimacy with its customers. As a mega online retailer, Amazon leveraged its digital data and analytics capabilities to track not only what customers bought but also what else they looked at; how they navigated through the website; how much they were influenced by promotions, reviews, and page layouts etc. By applying machine-learning algorithms, Amazon was able to create a personalized online-shopping experience coupled with the convenience of home delivery. In addition, the Amazon marketplace offers a broad spectrum of goods and services, from books and entertainment programs to groceries and home appliances. With its wide variety of products, Amazon became the one-stop shop for its Amazon Prime customers, who inevitably allowed Amazon access to their lives and became dependent upon the online retail giant. By delighting its customers using various tactics mentioned above, Amazon has grown its market leadership globally and became the second company with $1 trillion market capitalization in 2018.

These three competitive strategies, their key attributes, their corresponding value disciplines, and strategic orientations are summarized in Table 1.

Table 1. The three generic competitive strategies and the three value disciplines.

Strategy (Porter, 1980)	Cost Leadership	Differentiation	Focus
Operating Discipline (Tracey & Wiersema, 1995)	Operational Excellence	Product Leadership	Customer Intimacy
Strategic Orientation	Operation Centricity	Product Centricity	Customer Centricity
Key attributes	Focus on operational efficiency and cost control to deliver low price and win over customers.	Focus on R&D and superior product to win over customers who are willing to pay a premium price for the quality.	Focus on customers' experience and tailor product and price accordingly to win over customer loyalty.
Leading Example (2000-2010)	Walmart	Apple	Amazon

Patient Centricity

In contrast to customer centricity, patient centricity is not a business philosophy. Instead, patient centricity emerged as part of a global movement of healthcare reform beginning in the early 21st century. There was a growing body of evidence demonstrating that patients who were more actively engaged in their healthcare experienced better outcomes and incurred lower costs (Fenton, 2012; Hibbard, 2013). As a result, many states and policymakers had rolled out public policies to focus on patient-centered care. For instance, the National Health Service (NHS) in the UK established a policy that aimed to empower patients and create a user-led NHS (Fox, 2005). Meanwhile, under the Affordable Care Act (ACA) and continued Medicare reform, the US healthcare model is gradually shifting from a fee-for-service to a pay-for-performance model to reduce healthcare waste.

In addition, the 21st Century Cures Act looked to place patients at the center of our healthcare system. In line with that effort, the Food and Drug Administration (FDA) established a nation-wide patient-focused drug development (PFDD) program with support from various consortia, e.g. FastCure, Patient-Centered Outcome Research Institute (PCORI). These policies not only impacted the country's healthcare institutions but also its reimbursement models and other players in the healthcare ecosystem, such as the pharmaceutical industry. Notably, several recent publications in the medical literature specifically discussed the definition of patient centricity and its suggestive practices in the pharmaceutical industry (Robbins, 2013; Yeoman, 2017; Stegemann, 2016). The definitions and key concepts are discussed below.

The Patient-Centered Outcomes Research Institute (PCORI), funded by the Affordable Care Act (ACA), stated that "Patient centricity is a dynamic process through which the patient regulates the flow of information…. to exercise choices consistent with his/her preferences, values and beliefs" (Robbins, 2013). This definition clarifies that patient-centric healthcare is distinct from the traditional provider-centric model. The idea of 'centricity' indicates that it is not an 'add-on' activity like empowerment or engagement in the provider-centric world. Instead, 'centricity' emphasizes that the patient is and remains at the center of the entire healthcare process, and it is the patient who has the authority to make decisions according to his/her choices, not healthcare providers.

Traditionally, there is a complex relationship amongst the 3Ps, namely the Payers, Providers/Prescribers, and Patients in the healthcare world, which is uniquely different from the consumer world. Pharma sales force targets prescribers to increase product prescriptions and negotiate prices with the insurance payers who are the paying party for the products while patients play a passive receiving role in this relationship. This model is predominantly a provider-centric and knowledge-based decision-making model. On the contrary, in the patient-centric model, it is important to raise health literacy so that patients can make the best and personalized decision. For instance, many patient advocacy groups and reputable healthcare institutions are providing online education for patients. In the clinical research context, FDA and NCI created several websites to inform patients about the benefits and risks of clinical trials to the extent that will enable them to make sound decisions whether to participate. Taken together, the patient centricity defined by PCORI contains similar attributes to that of customer centricity defined by Peter Drucker in the sense that both definitions declare it is the customer/patient who determines what the needs are, not the provider nor the payer.

Similarly, Stegemann (2016) defined patient centricity in the context of pharmaceutical product design, starting that, “Patient centricity is the recognition of the needs of an individual patient or distinct patient populations and their specific needs as the focal point in the overall design of a medicine...” This definition emphasizes that the focal point of medicine development should start by recognizing the needs of the individual and/or a target population. It suggests that a model shift from the traditional blockbuster approach of ‘one solution fits all’ to a more personalized and patient-centric approach. In addition, the authors expand the consideration of design beyond the regulatory requirements, e.g. safety and efficacy, to broadly cover physiological, physical, psychological and social aspects, and describe in detail how pharmaceutical companies can implement this concept throughout the pharmaceutical product design process.

An industry-patient collaboration initiated by AstraZeneca provided the third definition of patient centricity (Yeoman, 2017), which emphasizes an open and sustained engagement with the patient to achieve the best experience and outcome for the patient and their family. Notably, this definition emphasizes patient engagement, which could be considered an 'add-on' activity in the traditional provider-centric world (see PCORI's definition above).

Building on the concept of customer centricity and the literature review above, I synthesized a simple definition of patient centricity in the table below.

Table 2. Definitions of patient centricity in medical literature.

Definition	**Reference**
Patient centricity is a dynamic process through which the patient regulates the flow of information to and from him/her via multiple pathways to exercise choices consistent with his/her preferences, values, and beliefs.	Robbins (2013)
Patient centricity is the recognition of the needs of an individual patient or distinct patient populations and their specific needs as the focal point in the overall design of medicine including the targeted patients' physiological, physical, psychological, and social characteristics.	Stegemann (2016)
Patient centricity is putting the patient first in an open and sustained engagement with the patient, to respectfully and compassionately achieve the best experience and outcome for that person and their family.	Yeoman (2017)
Patient centricity is a strategy to meet patient's needs by personalized medicine approach that deliver the best patient experience and outcome.	This research

Data and Analysis

As described above, in some well-executed companies, their singular strategic orientation may be apparent in their corporate image and brand reputation. For example, Apple is well-known for its product innovation, and Walmart competes for "everyday low prices" backed by operational excellence. However, for the majority of public or private companies, their strategic orientations are not always apparent to the public.

Scholars of strategic management typically rely on interviews, surveys and/or discussions with industry executives and experts to collect strategic information and empirically examine the effect of strategic orientation on firm performance. However, the process of designing surveys and conducting interviews can be time-consuming and costly. In addition, there are many constraints related to these approaches, including confidential and non-disclosable information, subjectivity, participant bias, survey bias, potential low response rate, etc. These types of studies often derive qualitative insights from small sample size, which limits their generalizability and the external validity of the findings (Beiske, 2002). To overcome these challenges, the textual analysis is used to objectively quantify the strategic orientation of firms using their 10-K reports.

Textual Analysis - Word Frequency

Textual analysis is a broad method that includes a variety of processing techniques used in linguistic research. It is used to study natural human language and the content of communications such as emails, websites, social media posts, press releases, etc. In recent years, textual analysis such as natural language processing (NLP) has become a new tool that enables researchers to extract and analyze qualitative information from text-rich documentations (McKee, 2003; Li, 2010). Word frequency or word count analysis—the most common type of textual analysis in linguistic research—is designed to capture messages or concerns that are emphasized repeatedly throughout a piece of content (Hsieh, 2005). The key assumption implicit in this type of analysis is that repetition in communication reflects significance by way of emphasis; in other words, the higher the word frequency, the more important it is. Because the strategic orientation of a firm represents its organizational focus backed by its competitive strategy and operational disciplines, I hypothesize that the keywords that describe a firm's strategic focus (i.e., operation, product, and customer) will be repeatedly emphasized throughout management reports and can be found via word frequency analysis.

10-K, Item 1 Business Section

The US Securities and Exchange Commission (SEC) requires public-traded firms in the US to file annual reports using the Form of 10-K to disclose their business strategy, risks, operations and financial results for the fiscal year. All public firms' 10-K filings going back to 1996 are electronically archived on the Electronic Data Gathering, Analysis, and Retravel (EDGAR) system, which is a publicly accessible online system. Hence, these reports provide business transparency to the public and can be used as an open data source for our research. Many Wall Street business analysts and investors like Warren Buffet, the CEO of Berkshire Hathaway, study these 10-K reports in detail in order to derive predictions and investment decisions.

Similar to other disclosures, such as the press releases or companies' websites, the annual 10-K reports convey rich business information that is usually written by the communication and legal teams with the content typically reviewed and approved by the management. However, because the purpose of the 10-K report is to fulfill government-mandated business disclosure requirements, not publicity or marketing, the words in a 10-K are carefully selected to reflect the firm's actual business operation. Further, the language is much more factual, less colorful, and more consistent across firms as it is filed following SEC guidelines. To better protect against accounting fraudulence following the collapse of Worldcom and Enron in the early 2000s, SEC made a requirement that every 10-K report must include signed letters from the CEO and CFO to certify that all disclosures are accurate to their knowledge. Furthermore, the 10-K report also includes a letter from an independent auditor, and it details the scope of their certification of financial records as well as any material deficiencies it uncovered. Under such scrutiny from the public and auditors, these reports provide reliable and analyzable information, and researchers from various disciplines often use these records as the source data for their research (Loughran, 2011; Li, 2013).

To quantify the strategic orientation of a firm, Item 1 of the 10-K Form, which SEC guidelines designate as the business section, was extracted for textual analysis. Item 1 is where firm managers discuss firm products, services, strategies, markets and operations (Dyer, 2017; Banker, 2019). In addition, the regulation requires updated disclosure on business development in Item 1 to provide investors with timely information about the competitive position of a firm. As such, Item 1 is, a good place to start to understand how the company operates (Securities and Exchange Commission, 2011). I restrict the textual analysis to only focus on Item 1 because each item in a 10-K report covers a unique topic. By focusing on Item 1 alone, it will provide a uniform context for the analysis and reduce the measurement errors and the noise introduced by other sections.

Strategic Orientation Ratio (SOR)

The development of the strategic orientation ratio (SOR) involves the following steps. First, following theories developed by Treacy and Wiersema (1995) and Porter (1980), I created the terms of the three strategic orientations, namely, operation centricity, product centricity, and customer centricity. Second, I went through a manual review of the 10-K reports to identify the keyword(s) that reflect the core concept of each strategic orientation and performed the word frequency analysis using word count function in the Microsoft Word. The key assumption implicit here is that firms will communicate subjects of importance with emphasis by repetition. A firm's strategic orientation represents the firm's dominant value discipline across the entire operation; as such, it would be repetitively emphasized in its 10-K. The higher the word frequency, the more concentrated efforts it is. For instance, I evaluated the frequency of the following words: 'new', 'novel', 'innovation(s)', 'design', 'science', 'patent(s)', 'research', 'development', 'product(s)', 'best', 'better' and 'improve', to determine which word is the most reflective of the characteristics of product innovation. I found that the word 'product(s)' is highly associated with product-oriented companies. Similarly, the frequency of words such as 'customer(s)', 'clients(s)', 'user(s)' were evaluated for customer-oriented companies, and 'operation(s)', 'cost(s)', 'efficien(t, cy, cies)' were assessed for operation-oriented firms. As a result, the three keywords, 'operation(s)', 'product(s)', and 'customer(s)' appeared the most frequent, therefore were selected. Third, as suggested by Treacy and Wiersema (1995), a firm must master only one primary discipline and maintain industry standards in the other two, therefore I define the three SOR to be calculated as follows with the sum of the three SOR to be 100%.

$$\textbf{SOR-Operation} = \frac{\text{Operation}_{(\text{word counts})}}{(\text{Operation}_{(\text{word counts})} + \text{Product}_{(\text{word counts})} + \text{Customer}_{(\text{word counts})})} \times 100\%$$

$$\textbf{SOR-Product} = \frac{\text{Product}_{(\text{word counts})}}{(\text{Operation}_{(\text{word counts})} + \text{Product}_{(\text{word counts})} + \text{Customer}_{(\text{word counts})})} \times 100\%$$

$$\textbf{SOR-Customer} = \frac{\text{Customer}_{(\text{word counts})}}{(\text{Operation}_{(\text{word counts})} + \text{Product}_{(\text{word counts})} + \text{Customer}_{(\text{word counts})})} \times 100\%$$

Figure 4. Calculation of the three Strategic Orientation Ratio (SOR).

Results

Testing of Strategic Orientation Ratio (SOR)

To test the SOR measurement, I selected Walmart, Apple, and Amazon for their well-known strategic orientations, which were discussed extensively in the literature review section for this analysis. Their 10-K reports were manually downloaded through the publicly accessible online data source, Electronic Data Gathering, Analysis, and Retravel (EDGAR), for the fiscal year of 2005, 2010 and 2015. The 10-K filings' Item 1 section were extracted, and the frequency of the 3 keywords was analyzed using Microsoft Word's 'Find' function. Their SOR profiles are summarized in Figure 5.

This result suggests that the strategic orientation ratio (SOR) accurately reflects its corporate strategy and operating focus. Specifically, Apple concentrates on product innovation while Walmart exhibits operational focus and Amazon shows strong customer orientation. Consistent with 'the tendency for strategies to persist over time' (Ghemawat, 2010), this novel Strategic Orientation Ratio (SOR) also shows that in the period of the year 2005 to 2015, the core strategic orientation of each company is persistent and enduring over time. No randomness or a sudden shift of strategic orientation was observed.

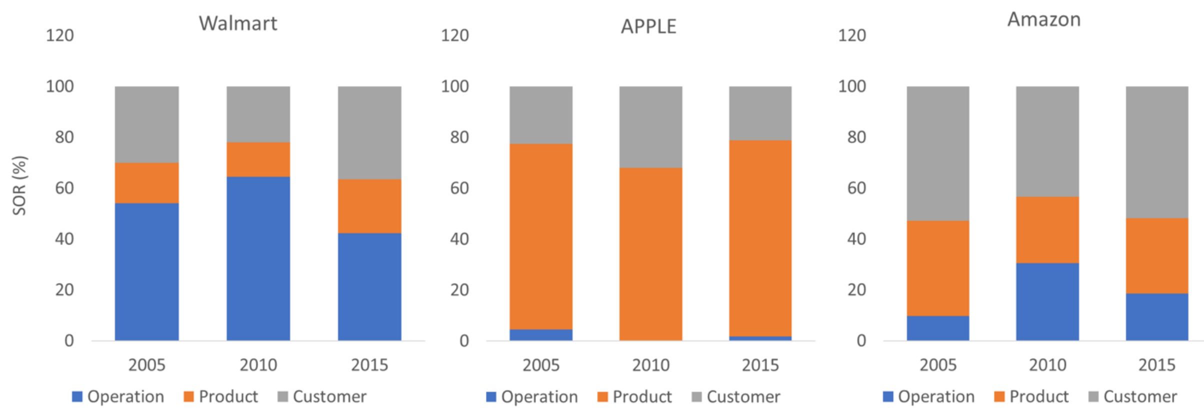


Figure 5. The Strategic Orientation Ratio (SOR) of Apple, Walmart, and Amazon.

Validation of Strategic Orientation Ratio (SOR)

To further validate the Strategic Orientation Ratio (SOR) as an indicator of a firm's strategic and operating activities, additional six Fortune 500 companies with known strategic orientation were selected for this validation (Table 3).

Table 3. Validation of Strategic Orientation Ratio (SOR) in six firms.

Strategic Orientation	Operation Centricity	Product Centricity	Customer Centricity
Validation Set	American Airlines, Waste Management	Nike, P&G	Nordstrom, Salesforce

Figure 6 shows that the Strategic Orientation Ratio (SOR) accurately reveals the strategic orientations of American Airlines and Waste Management being Operation Orientation. This finding is consistent with their corporate statement and industry reports indicating that operational excellence is their competitive force (American Airlines Website; Waste Management Website). The Strategic Orientation Ratio (SOR) also successfully identifies Nike and P&G as product differentiators as suggested by Treacy and Wiersema (1995). Evidently, both companies invest a significant portion ($billions) of their revenue in the R&D to develop innovative products and compete for market leadership. Nike sports research lab, founded in 1980, is a well-known R&D institute where the science of human performance was studied and forward-thinking products were developed. P&G has over 150 years of R&D history and the heritage of inventing household products that were built upon consumer and product research. In the retail industry, Nordstrom's exceptional customer service is legendary (Sally, 2016; Spector, 2012). Founder John Nordstrom stated,

> Our commitment is 100-percent to customer service. We are not committed to financial markets, we are not committed to real estate markets, we are not committed to a certain amount of profit. We are only committed to customer service. If we make a profit, that's great. But customer service is first.

With that corporate value and behavior, Nordstrom has turned their outstanding customer service into a billion-dollar annual business. In the e-commerce world, Salesforce pioneer the customer relationship management (CRM) platform and use it to help their 200,000+ customers (organizations) to manage their customer experiences. Their CRM platform successfully generated many happy customers and produced a billion dollars in revenue.

Together, these six industry examples plus Walmart, Apple, and Amazon demonstrate empirically that the strategic orientation ratio (SOR) can accurately classify firms’ strategic and operating position, consistent with their corporate image.

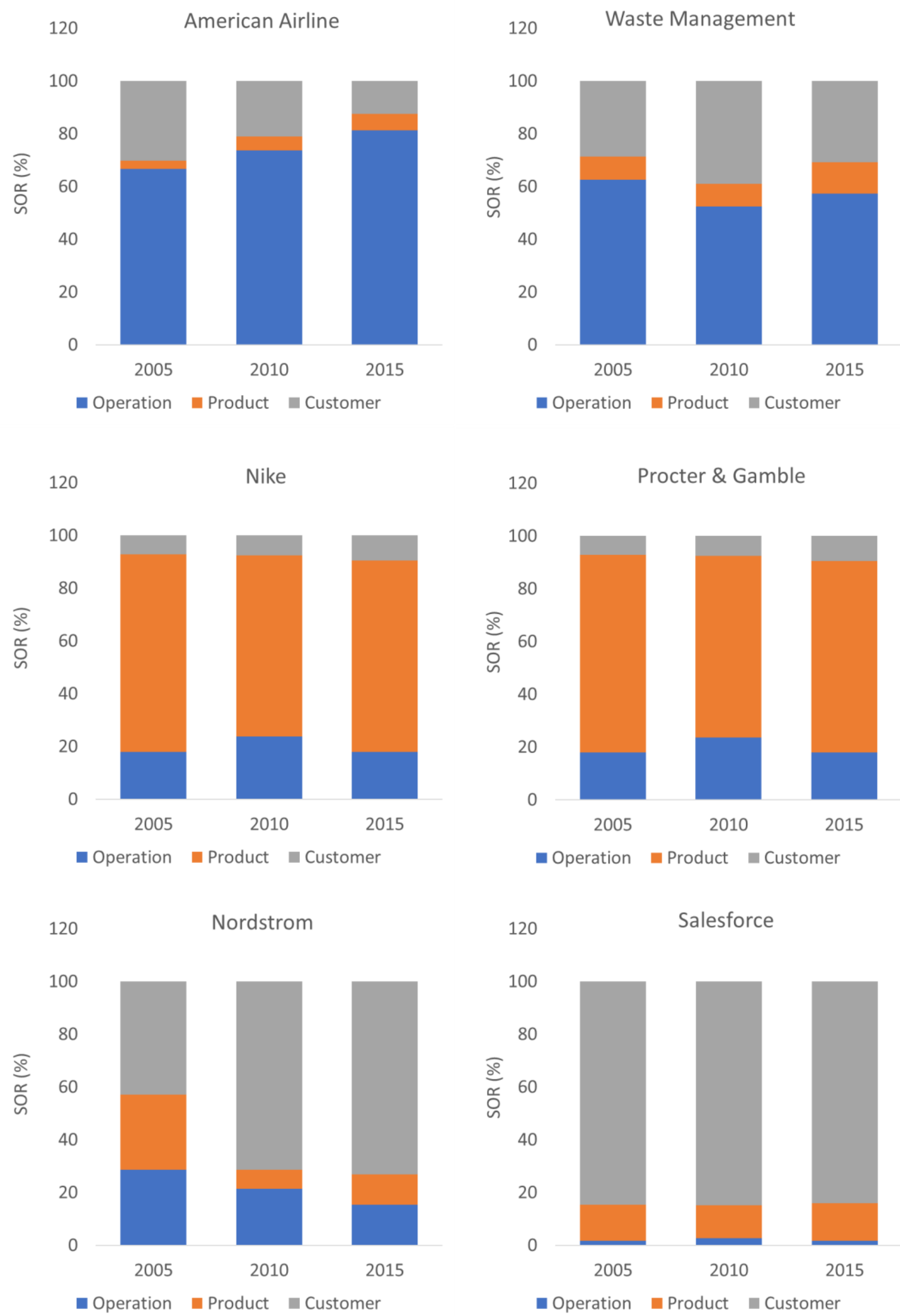


Figure 6. The validation of Strategic Orientation Ratio (SOR) in six industry examples.

Measuring Strategic Orientation Ratio (SOR) in the pharmaceutical industry

Next, I use the strategic orientation ratio (SOR) to analyze the pharmaceutical industry. As mentioned earlier, product innovation has always been regarded as the strategic focus and profit engine in the pharmaceutical industry. Therefore, one may assume that, in firms that are strongly oriented towards product innovation, the keyword ‘product’ will be discussed throughout their 10-K reports and their strategic orientation ratio (SOR) profile will likely be similar to that of Apple, Nike, and P&G. To measure patient centricity in the pharmaceutical industry, I took the point of view from Robbins (PCORI, 2013) that patients who consume pharmaceutical products are the key decision maker, although the process of purchasing products may involve other parties, such as insurers, doctors, and pharmacists. As such, the parallel concept between customer centricity and patient centricity is summarized in Table 4 below for consideration.

With that concept in mind, I replace the keyword ‘customer’ with ‘patient’ in this strategic orientation ratio (SOR) analysis. I hypothesize that if a firm has fully embedded patient centricity in its business, their patient centricity (SOR-patient) will be the dominant orientation in their 10-K reports, and the signal should persist over time just like one would with ‘product orientation’.

Table 4. Customer Centricity versus Patient Centricity.

Strategic Orientation	Customer Centricity	Patient Centricity
Key attributes	Focus on customer's needs and tailor the product and price accordingly to achieve the best experience and win over customer loyalty.	Focus on patient's needs and provide personalized medicine that deliver the best patient experience and outcome.
Keyword of Strategic Orientation	Customer(s)	Patient(s)

As mentioned in the introduction, there are a lot of skepticisms whether firms are advocating patient centricity as a PR ploy to disguise the corruptions and scandals, or patient centricity has become a genuine new competitive strategy to combat the productivity crisis. Therefore, in this research, the samples of pharmaceutical firms were chosen based on the industry productivity crisis reported by Munos (2009) and the pharmaceutical reputation commentary written by Kessel (2014). The assumption here is that for firms who are using patient centricity as a competitive strategy, the keyword of the patient(s) will appear in the 10-K frequently as a signal of emphasis and real effort. Conversely, if firms are using patient centricity mainly as a PR ploy, then those firms will likely not use their limited real-estate in the 10-K report to emphasize patient(s) because it is not an organizationally aligned strategic orientation. A total of ten multinational pharmaceutical firms, including Amgen, AstraZeneca, Bristol Myer Squids, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche, was selected as the representatives of the pharmaceutical industry for this analysis (Table 5).

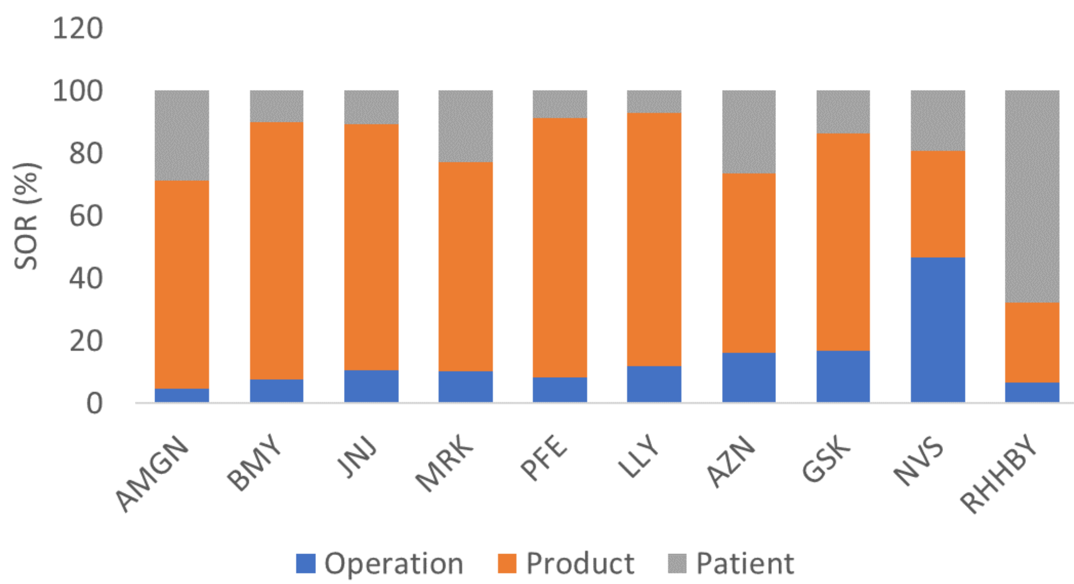
Table 5. Ten firms selected in this research.

Munos (2009)	Merger & Acqusition	Kessel (2014)	This Research (2016)
Merck		*Endo	Merck
Lilly		Johnson & Johnson	Eli Lilly
Roche		Amgen	Roche
Pfizer		*Sanofi	Pfizer
Wyeth	Acquired by Pfizer	*Boehringer Ingelheim	Johnson&Johnson
Abbott	Abbott spin off Abbive	GlaxoSmithKline	Bristol Myers Squibb
Upjohn	Acquired by Pfizer	*Abbott	Novartis
Johnson & Johnson		Merck	GlaxoSmithKline
Schering-Plough	Merged with Merck	AstraZeneca	Amgen
Burroughs-Wellcome	Become GlaxoSmithKline	Pfizer	AstraZeneca
Warner-Lambert	Acquired by Pfizer	Eli Lilly	
Bristol-Myers	Become Bristol-Myers Squibb		
Bristol-Myers Squibb			
Lederle	Acquired by Pfizer		
Sandoz	Acquired by Novartis		
*Bayer			
Novartis			
Smithline & Franch	Become GlaxoSmithKline		
Squibb	Become Bristol-Myers Squibb		
Sterling	Acquired by Bayer		
Ciba	Acquired by Novartis		

*Note. The following companies were excluded in the analysis due to incompleteness or availability of data: Endo, Abbott, Bayer, Sanofi and Boehringer Ingelheim.

The 10-K reports of the 10 firms from the 2015 fiscal year were downloaded from the EDGAR website, and the Item I sections were extracted for word frequency analysis. For the ex-US companies, e.g. AstraZeneca, GlaxoSmithKline, Novartis, and Roche, their annual reports were used for this analysis. In this analysis, the strategic orientation ratio (SOR) calculates the ratio of ‘operation’, ‘product’ and ‘patient’, respectively.

Upon quantifying the strategic orientation ratio (SOR) of these ten pharmaceutical companies, two interesting observations were noted. First, despite the fact that patient centricity has been buzzword amongst the industry for a decade, the Product Orientation unsurprisingly remains the dominant orientation in the pharmaceutical industry. Eight out of ten companies (8/10, 80%) reveal strong Product Orientation (SOR-Product) > 60%, in the year 2015 (Figure 7). Second, two companies show relatively different orientations: Novartis (NVS) exhibits a strong operational focus, whereas Roche (RHBBY) stands out with robust SOR-Patient at greater than 70%.



Ticker Symbol	Company Name
AMGN	Amgen
AZN	AstraZeneca
BMY	Bristol Myers Squibb
GSK	GlaxoSmithKline
JNJ	Johnson&Johnson
LLY	Eli Lilly
MRK	Merck
NVS	Novartis
PFE	Pfizer
RHHBY	Roche

Figure 7. The Strategic Orientation Ratio (SOR) of the 10 pharmaceutical firms (2015).

To further determine whether these strategic orientations persist over time, I analyze the Strategic Orientation Ratio (SOR) within each firm from 2005 to 2015. Over this period, I found that 9 out of the 10 companies put limited emphasis on patient-related efforts in their annual reports (< 30%, annually). Notably, Roche again stands out as the sole company that stressed patient-oriented efforts. Their robust signal of patient centricity (SOR-Patient) overcame product centricity in 2005 and grew stronger over time (Figure 8).

Roche's focus on patient centricity seems to reflect its brilliant strategy of combining the biotech powerhouse, Genentech Inc., as well as its own unique capability of Diagnostics. Genentech, founded in 1976, created a new model that uses biotechnology to develop breakthrough cancer therapies. In less than 25 years, this company produced 9 drugs on the market and 8 more in late-stage development, exclusively biologics. Roche took a majority stake in Genentech in the 1990s and then proceed to full acquisition in 2009. This strategic move enabled Roche to become the largest 'biotech' company in the world and the leader of personalized medicine:

> ***Personalized medicine (aka. precision medicine)***
> a form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease. In cancer, personalized medicine uses specific information about a person's tumor to help diagnose, plan treatment, find out how well treatment is working, or make a prognosis. Examples of personalized medicine include using targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose cancer (National Cancer Institute, 2019)

With the FDA stipulating that it will not approve the drug if the biomarker test to identify patients is not also available, Roche Diagnostics and Genentech jointly sped time to market from phase I to approval in 5 years, thereby maximizing exclusivity for the drug.

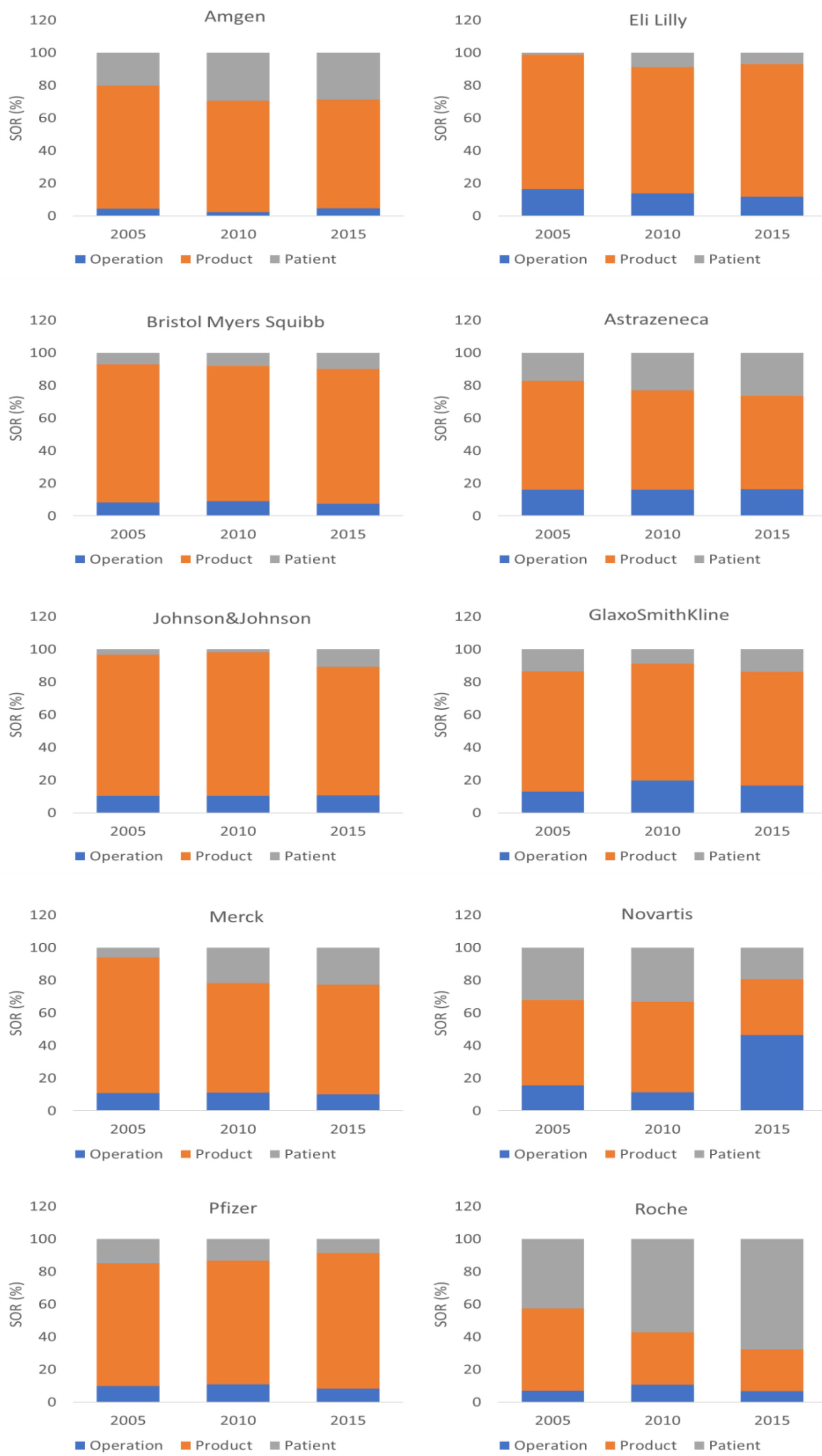


Figure 8. Roche shifts from product centricity to patient centricity.

In addition to uncovering the Roche's differentiated patient-centric strategy, three additional trends were also noted. First, companies including Amgen, Bristol Myer Squibb, AstraZeneca, Johnson & Johnson, Merck, Eli Lilly are also increasingly reporting their patient-related efforts in their 10-K although the percentage of increase remains relatively small. Second, out of the 10 firms, Pfizer is the only firm increases its focus on product centricity. Three, Novartis showed a dramatic shift towards Operation Centricity in 2015. This signal is consistent with a recent publication by Dreamer and Niewiarowski (2013, p145-152), who provided explanations behind this approach:

> Novartis Pharma began its Operational Excellence….. achieving tremendous results in productivity, cycle time reduction, and working capital optimization. Much of these achievements have been sustained since the inception of the Innovation Quality & Productivity program.

It is also worth noting that out of these 10 pharmaceutical companies, Novartis is the only firm that owns a generic division, Sandoz, and control the majority of the global generic marker share. Taken together, these findings suggest that only one out of the ten firms maintains patient centricity as its strategic orientation. For the other nine companies, their strategic focus remains on the products.

As indicated in Figure 9 below, there is an observable trend that patient centricity is indeed on the rise over the past 10 years. This appears to be the first empirical evidence of the existence of patient centricity in the pharmaceutical industry. The application of the Strategic Orientation Ratio (SOR) to the strategy sections of firm 10K reports enables objective measurement of the level and change in patient centricity. For example, it allows us to see that patient centricity in the pharmaceutical industry increased from 15% to 21%

between 2005 and 2015. Although the overall change within the industry is small, the evidence of Roche's strategic orientation strongly indicates that patient centricity is a genuine differentiated strategy that is fully embedded in their business and not a PR ploy. This finding leads to an important question, 'Is patient centricity profitable?', which will be addressed in Chapter 3 of this research.

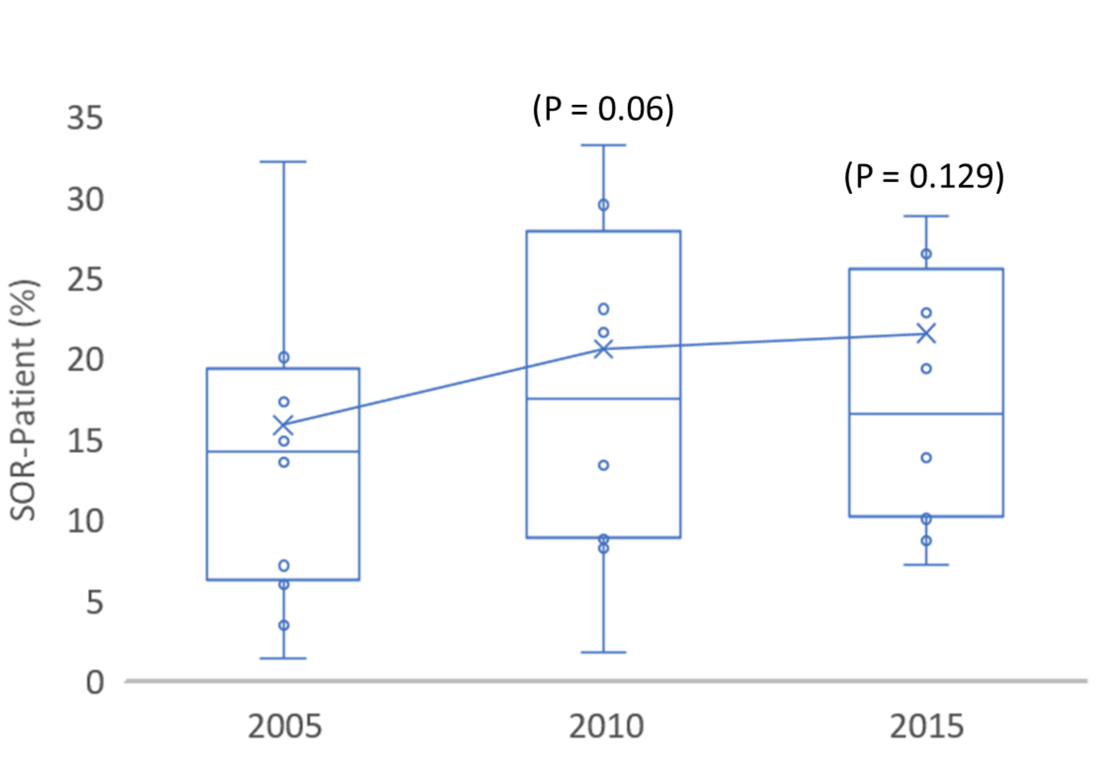


Figure 9. The rise of patient centricity in the 10 pharmaceutical firms.

Conclusion

Patient centricity—a new buzzword rising in the pharmaceutical industry—is a difficult term to define. As such, the rise of patient centricity in the pharmaceutical industry remains an ambiguous and potentially cynical move in the public's eyes as there is no industry-accepted definition and no research that delineates patient centricity, however, it is defined, affects firm performance.

Within this context, I structured this research with two objectives. The first was to develop a measurement capable of quantifying the existence and extent of patient centricity or orientation in the pharmaceutical companies. The second objective was to examine the relationship between patient centricity and firm performance.

In Chapter 2, several important contributions were made. First, building upon the existing strategic management theories, particularly Porter (1980) and Treacy and Wiersema (1995), a simple and intuitive measurement of strategic orientation ratio (SOR) was developed to analyze and classify corporate strategic orientations. Second, the Strategic Orientation Ratio (SOR) was successfully validated against 9 non-pharmaceutical companies across industries, including Walmart, American Airlines, Waste Management, Apple, Nike, P&G, Amazon, Nordstrom, and Salesforce. Third, the same Strategic Orientation Ratio (SOR) was applied to analyze ten multi-national pharmaceutical companies to determine their strategic orientations.

The findings suggest that the pharmaceutical industry overall still predominantly emphasizes product centricity despite the increased talk of patient centricity. Notably, we found evidence that patient centricity as a strategic orientation exists in the pharmaceutical business. Although the industry average of patient centricity (SOR-Patient) is still relatively low, there is an observable trend that many pharmaceutical companies are increasing their efforts toward patients. Among those, Roche by far is the most patient-centric firm. Evidently, Roche's SOR-Patient is dramatically differentiated from all of its peers and it has embedded patient centricity in its core business over a decade. This finding suggests that the traditional blockbuster model is not the only viable strategy for pharmaceutical executives to consider. Firms that embed patient centricity and focus on personalized medicine to meet the needs of niche markets could be an effective strategic alternative.

CHAPTER 3

THE RELATIONSHIP BETWEEN PATIENT CENTRICITY AND FIRM PERFORMANCE

Introduction

In the dynamic and competitive pharmaceutical marketplace, firms continue to look for advantages over their peers. Although the strategic focus of the pharmaceutical industry predominantly centers on products, patient centricity has been gaining traction. As demonstrated in Chapter 2, there is empirical evidence that a strategic orientation of patient centricity exists, and has been increasing in the last 10 years. By quantifying the emphasis of the top 10 pharmaceutical firms on patient-related efforts in their 10-K annual reports, the level and rise of patient centricity were objectively measured at the industry level, and a few firms were also found to have increased their patient-related efforts for over a decade. Hence, patient centricity is more than a buzzword. It is a new strategic trend rising in the pharma industry. However, as was evident in Chapter 2, the adoption of patient centricity has been slow, and one of the barriers may be the missing link between patient centricity and the firm's financial performance.

Since there is variance in the degree to which companies are centered around patient-related efforts, this leads to an important question: have these patient-centric efforts contributed to firms' performance? In other words, is there empirical evidence that can validate patient centricity as a viable business strategy? This question is important since the pharmaceutical industry overall is still very product-centric. Until there is empirical evidence demonstrating that patient centricity has an impact on a firm's financial performance, the "right thing to do" mantra may never become a legitimate, mainstream strategy.

An empirical examination of the relationship between patient centricity and firm performance has the potential to provide insights that are meaningful for the development of the pharmaceutical firm strategy. This Chapter reviews the key concepts relating to pharmaceutical firm performance in the traditional product-centric model and the newly proposed patient-centric model. The key constructs of a patient-centric pharma model are developed, and the firms' financial performance, including market cap and return on assets (ROA), are evaluated across the 10 pharmaceutical companies using descriptive analyses. Once the variables are defined, the relationship between patient centricity and firm performance are further examined using statistical analyses, so that the question, "does patient centricity impact firm performance?" may be concluded.

Conceptual Foundation

Firm Performance

Traditionally, researchers have used the term firm performance as the key indicator of the functional fit of a firm within a competitive environment (Venkatraman, 1984; Hansen, 1989). There are two streams of research on the determinants of firm performance. One emphasizes the importance of external economic factors such as market condition, political environment, or regulations on success and explains why profitability differs across industries. The other sees organizational factors such as top management, organization structure, climate, process, and people, the key determinants of success. The modern evolutionary economic theory sums up these two schools of research well and suggests that the firm performance is the result of the complex dynamics between external and internal factors working in tandem (Nelson & Winter, 1982; Zajac, 2000). Drawing from Charles Darwin's theory of evolution consisting of a three-step process: (1) variation, (2) selection, and (3) retention, evolutionary theorists propose that the same 'survival of the fittest' mechanism can be applied to the world of economics, and that firms' performance are the outcome of this selection process.

To further refine the evolutionary economic theory, Foster (1997) noted a distinct feature of biological evolution where randomly occurring mutations are considered the sources of variation. However, in "economic evolution", if firms are the analog of organisms/species, variation in products and services do not occur randomly by mutation. In other words, human creations typically are designed to solve problems and/or delight potential users. Therefore, according to economic evolution, variation is teleological—a purpose-guided invention fostered by organizational structure, climate, process, and people, through which variation in products and services are produced. Therefore, Foster (1997) proposed that it was through the self-organization process that randomness may be introduced and that firms employ human ingenuity i.e. creativity and imagination to produce a whole host of novelties on the market. These novelties then undergo the market selection process, i.e., the forces of buyers/customers, and the retention then is signaled through the growth of market shares. From this point of view, a firm that can effectively detect the external buyers/customers-demands and respond accordingly would likely be the fittest and thus would exhibit the best firm performance.

The Product-Centric Model (Blockbuster Model)

In the 1970s, the first billion-dollar drug, Cimetidine (Tagamet) ushered in the so-called blockbuster era into the pharmaceutical industry. Since then, the blockbuster model has been the cornerstone of many successful pharmaceutical firms such as Pfizer (Lipitor, Viagra), GlaxoSmithKline (Advair) and Abbott/Abbvie (Humira). Part of the success of these billion-dollar drugs is that they target chronic diseases of large populations. With patent exclusivity and limited treatment options, these drugs can command high premium prices and generate tremendous profit.

Upon further examining how these blockbuster drugs were cultivated from a corporate strategy perspective, Hannigan and Mudambi (2013) found that the vast majority of blockbuster drugs developed in the past three decades were discovered by one firm and commercialized by another. They argue that R&D alone is not enough to create a blockbuster because the origins of many blockbusters can come from a variety of sources, large and small. They suggested that pharmaceutical performance such as blockbuster earnings hinge upon not only the innovative medicine itself but also the firm's ability to commercialize the drug. The prior belief that large firms benefit from economies of scale in R&D turns out not to be a significant factor in driving firm performance (Cockburn, 2001). Rather, firms must have the ability to commercialize the drug and obtain market access (*aka* reimbursement) in order to maximize gains from their innovations (Paniz, 2010). Essentially, while many firms are capable of discovering and developing new drugs, only those that are capable of obtaining market access through government payers like NHS or formularies of hospitals can succeed in the blockbuster model.

Based on the above, two factors can be constructed to represent the traditional product-centric pharma model—namely, the capabilities of product innovation and market access. The model is synthesized below to illustrate the relationship between the firm performance and the two capabilities: (1) product innovation, measured by the number of innovative products, and (2) market access, measured by the pharmaceutical sales which are the paid access to the medicine (aka reimbursement). These two factors work hand-in-hand to drive the success of the pharmaceutical business.

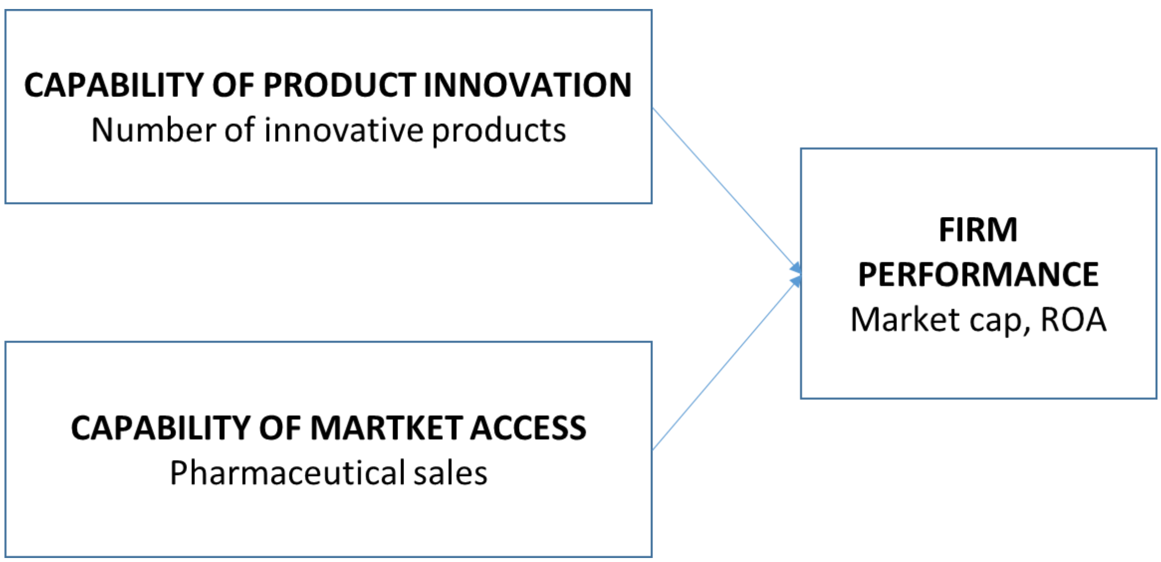


Figure 10. The Traditional Product-Centric Pharma Model

The Niche Buster Model

For decades, the highly profitable pharmaceutical companies have competed on the blockbuster model and devoted little attention in the rare disease areas (the FDA defines the rare or orphan disease as the disease affecting fewer than 200,000 people in the US). However, as the blockbuster model appear to lose its edge, a new niche buster model is emerging (Dolgin, 2010). The key feature of the niche buster model is that it focuses on well-defined disease-causing mutations, which often means it’s developing personalized medicine (aka precision medicine) for a small patient population. This model is the result of the advancement of molecular diagnostics and the passing of the Orphan Drug Act (ODA) signed by President Reagan in 1983. As part of the government effort to encourage orphan drug development and meet unmet needs in rare diseases, the ODA provides economic incentives, including 7-year of market exclusivity, tax credits for R&D, and a waiver for FDA fees. Many biotech and pharmaceutical companies jump on those opportunities which led to significant increases in orphan drugs and oncology product approvals in recent years (Phillips, 2013).

Patient Centricity Model at Roche

Although the ‘Big Pharma’ overall may be slow to follow, as shown in Chapter 2, Roche may be an early adopter, which already shifted their product innovation from the blockbuster model to the new niche buster model focusing on the development of personalized medicine. To more understand fully what specific patient centricity model implemented at Roche, a deeper analysis of the content of the 2015 Roche annual report was conducted. By using a free online word cloud generator (Davies, 2018), the high-frequency words are visualized (Figure 11).

Figure 11. Roche's patient-related descriptions displayed by word-cloud (2015).

From the total 226 phrases containing patient(s), several repeated themes appeared. These included: engaging patients, incorporating patient input throughout the drug development process and partnering with patient advocacy organizations to deepen the understanding of unmet medical needs. In addition, identifying patients, genomic mapping, monitoring patient response to treatment, and matching the right patient with the right treatment to achieve the optimal benefits for the patient were also described extensively. These themes particularly appeared throughout the cancer therapies discussion and essentially illustrated the definition and approach of personalized medicine from the National Cancer Institute (2019):

> ***Personalized medicine (aka precision medicine)***
> a form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease. In cancer, personalized medicine uses specific information about a person's tumor to help diagnose, plan treatment, find out how well treatment is working, or

> make a prognosis. Examples of personalized medicine include using targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose cancer.

This personalized medicine stands in stark contrast to the pharmaceutical industry's traditional pursuit of the blockbuster drug that offers a 'one-size-fits-all' solution. Instead of targeting broad market access by general disease diagnosis, Roche applied the genomic research that guides the precision treatment in a well-defined patient population. Although the population size may be small, by implementing companion diagnostics and patient assess program(s), these precision medicine has the potential to reach all qualified patients across the globe and receive reimbursement.

Therefore, the patient centricity at Roche can be illustrated as follows where patient centricity is the strategic orientation that functions like the 'glue' which forms a tight alignment between strategy and operation (Figure 12).

Patient Centricity = **Patient needs** X **Personalized Medicine** X **Patient Access**

The Patient Centricity as a Strategic Orientation

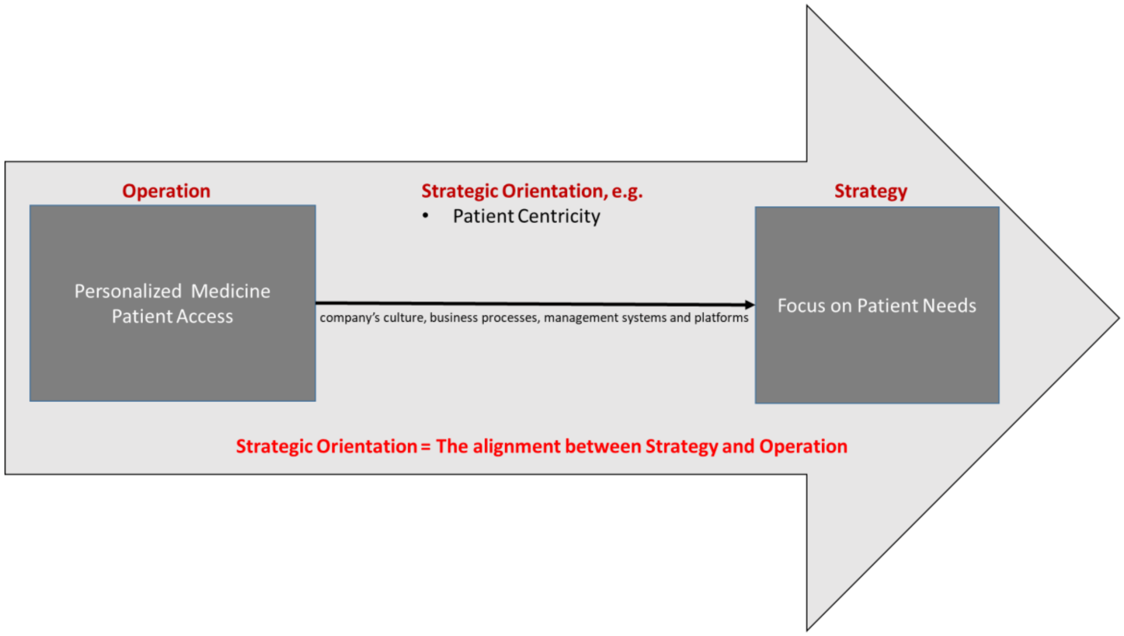
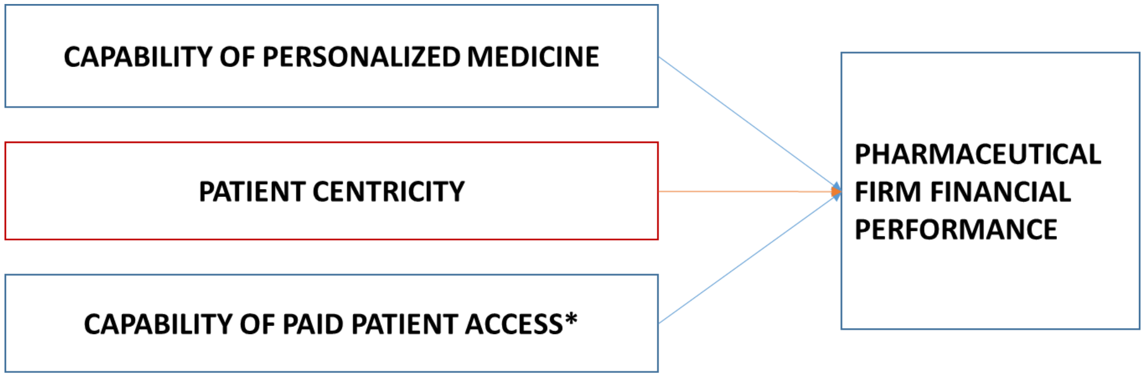


Figure 12. The Patient Centricity as a Strategic Orientation

Taken together, a new definition of patient centricity is proposed as the following:

Patient Centricity *is a strategic orientation to meet patient needs at the individual or specific population levels, by developing personalized medicine(s) that deliver the best experience and outcomes, and by ensuring patient access to those personalized products.*

In line with the definition, a patient-centric pharma not only sets the competitive strategy of focus (on patient needs), but also aligns their operation to develop personalized medicine and provide patient access to those personalized products. Hence, an ideal patient-centric model can be conceptualized as follows:



* Paid Patient Access – aka. Reimbursement

Figure 13. The Patient-Centric Conceptual Model for Pharma

Notably, this conceptual model is currently limited by the lack of availability of data for model testing, i.e. there is no official classification of personalized medicine issued by FDA, and the total reimbursement from the exact units of the personalized medicine sold to the right patients are proprietary and not available. Subsequently, a patient centricity research model for pharma is developed below so that the variables and hypotheses can be tested.

In this research model (Figure 14), the focus on patient, not product, created a drastically differentiated strategy that it potentially gives the firm an edge because of their deep understanding of patient's needs. From the organizational psychology perspective, focus on the patient may also create a noble purpose for the firm, allowing management to engage and motivate employees at a deeper level. Further, having a strategic orientation on patients gives a 'glue effect' that it creates a coherent alignment across functions and drives product and commercial strategy, thereby reducing fragmentation, which often is a problem in the product-centric environment. Patient centricity (SOR-Patient) is the strategic glue that enhances pharma performance, and may also may have a direct effect on pharmaceutical firm performance. This leads to:

H1: The degree of patient centricity (SOR-Patient) and has a direct and positive effect on pharmaceutical firm performance.

Second, as mentioned earlier, patient centricity starts with a deep understanding of individual patients' needs. Because every patient is uniquely different in their biological, physiological, emotional, and environmental makeup, the personalized medicine is thus the best approach to deliver the best experience and treatment outcome. Currently, there is no official designation from FDA to classify products as personalized medicine. Since the approval of Herceptin in 1998, the pharma industry has entered the personalized medicine era and the oncology research has been leading the development of personalized medicine. As such, a firm's capability to develop personalized medicine such as oncology product represents its sophistication to compete in the patient-centric personalized medicine model, and it may directly contribute to firm performance. This leads to an expectation of a relationship between the number of oncology products and pharmaceutical firm performance. Therefore, it follows:

H2: The number of oncology products has a direct and positive effect on pharmaceutical firm performance.

Third, finding the right patients and providing them access to personalized medicine is another key area of focus at Roche. There are two types of medicine access that pharmaceutical companies offer, simply, the paid versus unpaid access (Paniz, 2010). The paid access, also known as reimbursement, is typically managed through patient's health insurance, private or public. According to Hannigan and Mudambi (2013), the firm's ability to commercialize the products significantly contribute to the drug's financial performance. The commercialization is not about running million-dollar TV advertisements but to gain successful market access and obtain reimbursement. A patient-centric firm must have the ability to find the right patient, provide access to medicine and obtain reimbursement. Essentially, the best available proxy measure for reimbursement is pharmaceutical sales. Therefore, we hypothesize:

H3: Pharmaceutical sales has a direct and positive effect on pharmaceutical firm performance.

Taken together, the realistic patient-centric pharma research model is illustrated in Figure 14, including the three hypothesized relationships, as follows:

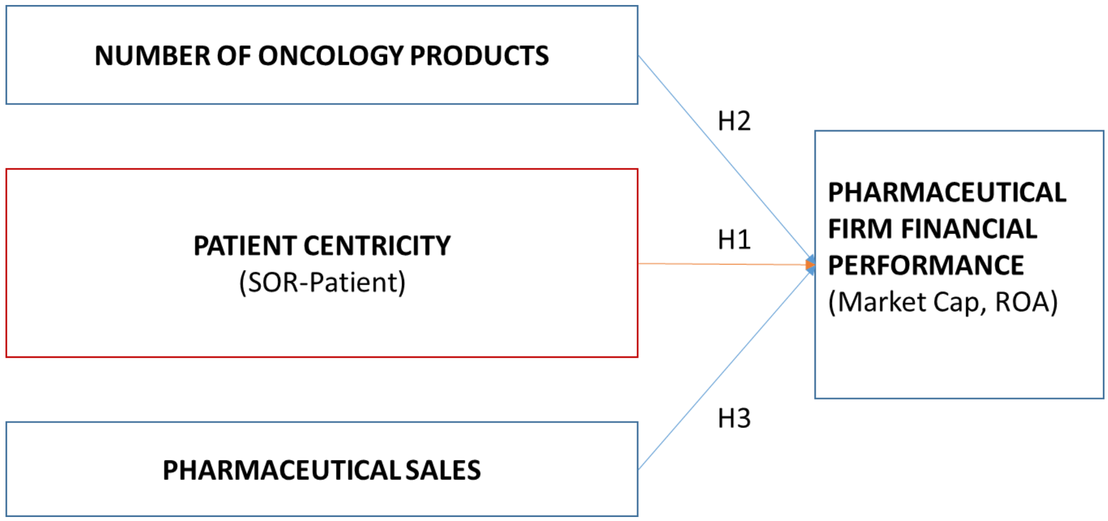


Figure 14. The Patient Centricity Research Model for Pharma.

Methodology

The methodology was developed to test the hypotheses. In the following section, the sample, data, variables, and analytical approach are discussed and explained.

Sample

The same 10 global pharmaceutical firms selected in Chapter 2 are included in this part of the research. They include Amgen, AstraZeneca, Bristol Myer Squids, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The characteristics of the 10 firms are summarized in the table below. As of 2015, these 10 firms jointly account for $1.6 trillion of Market Cap and represent 35% of the total global pharmaceutical market shares. Collectively, their total revenue reached $377 billion at the end of 2015. From a market cap perspective, Johnson & Johnson is the largest with a size of $283B while AstraZeneca ranks number ten within this sample set. By taking the employee numbers into account, Amgen has the highest market cap per capita of $6.5M while GlaxoSmithKline has the lowest value of $0.97M per capita. In 2005, Pfizer owns the largest market share of 8.5%. However, with the increasing competition from the branded and generic products, many companies suffered the loss of market shares and Johnson & Johnson become the market share leader retaining 6.6% of total market share in 2015.

From strategic orientation perspective, product centricity (SOR-Product) dominated the industry in 2005. Yet, within the past 10 years, the strategic emphasis has diverged, as shown in Table 6. Some companies, including Amgen, AstraZeneca, Bristol Myers Squibb, Johnson & Johnson, Eli Lilly, Merck, and Roche, increased their focus towards patients. Meanwhile, Pfizer further increased product centricity, Novartis shifted significantly toward operation centricity, and GlaxoSmithKline remains no change in general but with slight increases in operation centricity.

Table 6. Descriptive Statistics of the 10 pharmaceutical companies.

Ticker Symbol	Company Name	Firm Origin	Founded	Year	Market Cap ($M)	Employee (x1000)	Market Share (%)	SOR-Operation (%)	SOR-Product (%)	SOR-Patient (%)
AMGN	Amgen	American	1980	2005	96525	17	2.1	4	76	20
				2015	122397	18	2	5	66	29
AZN	AstraZeneca	British	1999*	2005	76837	65	4.0	16	67	17
				2015	85834	62	2.3	16	57	26
BMY	Bristol Myers Squibb	American	1887	2005	44972	43	3.2	8	85	7
				2015	114811	25	1.6	8	82	10
GSK	GlaxoSmithKline	British	2000*	2005	142673	100	6.3	13	73	14
				2015	97647	101	3.4	17	69	14
JNJ	Johnson&Johnson	American	1886	2005	178766	116	8.4	10	86	3
				2015	283010	127	6.6	11	79	11
LLY	Eli Lilly	American	1876	2005	61691	43	2.4	16	82	1
				2015	88917	41	1.9	12	81	7
MRK	Merck	American	1891	2005	69407	62	3.7	11	83	6
				2015	146899	68	3.7	10	67	23
NVS	Novartis	Swiss	1996*	2005	122589	91	5.4	15	52	32
				2015	204250	119	4.6	46	34	19
PFE	Pfizer	American	1849	2005	171659	106	8.5	10	75	15
				2015	199329	98	4.6	8	83	9
RHHBY	Roche	Swiss	1896	2005	125914	68	4.7	7	50	43
				2015	235267	92	4.7	7	26	68

Data source: Compustate (2015). *Merger formation of the current entity.

Data

The financial statement data of the 10 pharmaceutical companies were collected from the Compustat Global fundamental datasets provided by Wharton Research Data Services (WRDS). The data include Market Cap, Total Assets, Net Income, Return on Assets (ROA), Market Share, R&D expenditures, employee numbers. The data range covers the fiscal year from 2005 to 2015. In doing so, this provides a longitudinal view of the firms and also increases our analyzable sample size to N=110 for statistical analysis.

As described in Chapter 2, the firm's Strategic Orientation Ratio (SOR) is calculated based on the firm's annual filings (see method development in Chapter 2). The 10-K filings or annual reports of the 10 pharmaceutical firms were downloaded from the SEC or companies' websites and cover the same time period (2005-2015) as their financial performance data.

The total numbers of novel molecular entities (NME) approved during 2005-2015 and the oncology products (used as a proxy for personalized medicine.) were retrieved from the FDA database.

Variables

Dependent Variable – Financial Performance

Business executives use a variety of indicators to assess progress against their strategic objectives and monitor their business performance against competitions. Due to differences among varying types of industries, e.g. R&D intensity, regulations, risks, many industries have developed specific performance indicators. Despite some differences, total revenue (sales) is a widely used performance indicator by business managers and investors (Hansen, 1989; Hall, 2002; Lin, 2006). Further, although the pharmaceutical industry is a century-old industry, it lacks standardized performance measures. Researchers have looked at various dimensions of firm performance, including sales, patent approvals, and new product launches (Hall, 2002; Lin, 2006).

To answer the research question of whether patient centricity is a profitable strategy, I will focus on firms' financial performance and use the two widely accepted accounting measures, market cap and return on assets (ROA), to gauge performances across firms because they reflect the outcome of firm's strategy, execution, and profitability. Additionally, Market Share and Tobin's Q, which provide different perspectives of firm performance, will be explored briefly in the descriptive analysis.

Market Capitalization (Market Cap)

Wall Street investors and analysts often use Market Capitalization (Market cap) as an indicator of a firm's financial strength and performance. By using firm mortality as the outcome measure, Queen and Roll (1987) found that firm size (as measured by Market Capitalization in their research) was the best predictor of the firm's survival over both the short and long terms.

Market Cap is calculated as the result of a stock price per share multiplied by the total number of outstanding shares. Because the stock price is reflective of the optimism of the investors in the company's future, it represents the prospective value of the company. Typically, a firm that has strong profitability in its quarterly report will drive up the stock price as the investors celebrate the growth. In some cases, if investors are confident in a firm's long-term strategy and capabilities, the stock price can soar even in the absence of profit (e.g., Amazon).

Besides firm factors, individual stock price may be affected by the economic environment. Incidents like the 2000s dotcom bubble, the 9/11 terrorist attack, and the 2008 financial crisis all had a significant impact on global market growth. Despite various global events between 1950 and 2019, the average market cap value of S&P 500 companies remains positive and has increased around 10% on an annual basis.

Within the pharmaceutical industry, the company's stock price is highly influenced by the quality of its pipeline, regulatory approvals, and firm strategy. If a firm has many blockbuster products (>$B per annual sales), the value of its stock price will likely increase. Conversely, patent expiration on any blockbuster product will reduce investors' confidence, and therefore drive down the stock price. Taken together, the market cap is a performance indicator that encompasses the overall quality of the firm's strategy, products and execution performance.

Return on Assets (ROA)

Return on Assets (ROA) is a widely accepted accounting measure and have been frequently employed by researchers to evaluate performance differences among firms (Hawawini, 2003).

Business analysts often gauge a firm's financial health by several parameters, including liquidity, liability, operational efficiency, and profitability. Liquidity and liability are particularly important in the start-up phase as they must survive in the short-term before they can prosper in the long-term. Cash flow and equity/debt ratio may determine a firm's ability to manage its debt obligations and maintain operation at the float. However, the most important parameter remains the firm's bottom line, the profitability. By definition, return on assets (ROA) takes the return (net income) and the total assets into account and essentially represents how well a firm utilizes its assets to generate profit. Therefore, it is regarded as a key indicator of a company's profitability (Al-Matari, 2014).

Within the pharmaceutical industry, many factors influence ROA, including Merger & Acquisition (M&A), R&D expenditure, management, sales, market competition, regulatory environment, etc. As many researchers have reported that the cost of medicine development has reached 2B (100-fold increases since 1950) yet the financial return on these products has dropped to its lowest levels of 3.2% in 2017, it suggests that the pharma industry is facing unprecedented pressure to transform (Scannell, 2012; Smietana, 2015; Tollman, 2016; DiMasi, 2016; Felice, 2017). This profit decline may be attributed to the generic competition and the governmental control of healthcare cost. According to the Generic Pharmaceutical Association annual report (Herist, 2013), the use of generic drugs saves the US healthcare system for more than half a billion per day. As a result, the generic fulfillment of prescriptions in the US has risen from 17% in 1980 to 80% in 2010. In response to intensified competition from both brand name and generic companies and the pressure to fill the pipeline, many pharmaceutical companies went through a series of unprecedented large-scale merger and acquisition (M&A) in the past decade. So far the results of M&A showed mixed effects on the firms' ROA (Demirbag, 2007; Szücs, 2014). Despite such a turbulent environment if a firm is capable of demonstrating ROA above the industry average, it would suggest a strong management performance that delivers profitability.

Market Share

A firm's market share is defined as the percentage it accounts for an industry's total market. It is calculated by taking the firm's sales and dividing it by the total sales of the industry over the same period. Researchers have found that a firm's market share is determined by many factors, including product quality, competition, advertising, pricing, and user expectation (Bridges, 1995; Bahadir, 2009). This indicator provides a general idea of how competitive a firm's products or services are in relation to its total market and competitors. A firm that maintains its market share must grow its sales at the same rate as the total market. In other words, a firm that has above (or below) industry performance would imply its growth rate is higher (or lower) than the market growth rate.

Clay Christiansen (2016) described a concept that the reason why customers buy a drill bit is that they want a hole. Therefore, studying the functional, social and emotional needs of customers will provide product developers with deeper insights than simply getting user feedback on the product itself. In the context of healthcare and pharmaceutical industry, when patients, doctors and insurance payers 'hire' the medicine, the 'job' they want the medicine to do is for patients to get well. Therefore, the best 'qualified' medicine should be hired to do the job. A medicine's performance as measured by safety, efficacy, and health outcomes are critical ways to defend the price and market share. If a medicine only produces a marginal benefit or worse, 'not doing the job' (non-responsive / wrong population), the medicine will likely be 'fired' and lose its market share because of the pressure of market selection (Nelson and Winter, 1982). For this reason, market share is a useful indicator that represents a firm's ability to sense market demand and produce competitive products, thereby defending its market share and growth.

Tobin's Q

Tobin's Q is a well-established indicator that gauges the firm's value. By definition, Tobin's Q is the ratio between the market value and the replacement cost of a firm. Many investors use this Q ratio to determine whether an individual company is over- or under-valued, therefore decide to buy or sell.

Industry analysts also use Tobin's Q to predict M&A activities. For example, Andrade (2001) report that High-Q firms buy low-Q firms in two-thirds of all M&A since 1973. Danzon (2007) studied the M&A activities in the pharmaceutical industry and found that for large firms, mergers are a response to combat patent expirations and gaps in a firm's product pipeline. Whereas in small firms, mergers are primarily an exit strategy in response to financial trouble.

Lang (1994) found that diversified firms tend to be poor performers with a lower Q ratio than their comparable pure-play peers. Chang (2007) further indicated that related products have positive effects on firm performance but un-related products (diversification) significantly and negatively impact firm performance with a robust signal in the service and manufacturing industries.

In summary, the four performance indicators in Table 7 provide different perspectives on firm performance and serve a good starting point for this research.

Table 7. Performance Indicators and their perspectives.

		Definition	Perspectives
Primarily	Market Cap	Stock price x Outstanding Shares	It represents investors' confidence in the firm's strategy, products, and performance in the present and future.
	Return on Assets (ROA)	Net income / total assets	It is a profitability index and indicator of management effectiveness.
Exploratory	Market Share	Net sales / industry revenue	It represents the relative competitiveness of the firm's products/services, and a barometer of market selection pressure.
	Tobin's Q	Market value / replacement value	It is a valuation index indicating over- or under-value of a firm. Diversification tends to predict poor performance and lower Tobin's Q.

Independent Variables

Based on the definition of patient centricity (see below), the conceptual model, and the hypotheses proposed above, the three constructs, namely patient centricity, personalized medicine, and patient access are defined as independent variables for the regression analyses.

> 'Patient Centricity is a strategic orientation to meet patient's needs at the individual or specific population levels, by developing personalized medicine(s) that deliver the best experience and outcomes, and by ensuring patient access to these personalized products.'

Patient Centricity (SOR-Patient)

As mentioned above, patient centricity is a unique differentiation strategy implemented by Roche. The emphasis and special attention on the users, not the products, potentially gives Roche an edge in its product strategy because of the deep understanding of patient's needs. In addition, patient centricity provides a noble calling, which may engage and motivate employees better than product centricity. Patient centricity gives a coherent alignment to all of a firm's functions, keeping them from fragmenting, which happens more often in the product-centric environment. Therefore, it is possible that the degree of patient centricity (SOR-Patient) may impact directly firm performance.

As described in the method of Chapter 2, each firm's strategic orientation ratio (SOR) is calculated based on the word frequency found in the 10-K Item 1 filings. The degree of patient centricity (SOR-Patient) within each firm between 2005 and 2015 is used to predict firm performance.

Oncology Products

As mentioned earlier, personalized medicine is a form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease. Oncology has been at the forefront of personalized medicine. Due to the fact that there is no official designation of personalized medicine issued by the FDA. Therefore, in this analysis, the oncology products are used as a proxy to measure a firm's capabilities of developing personalized medicine.

Pharmaceutical Sales

Many pharmaceutical companies two types of medicine access, namely paid and unpaid access (Paniz, 2010). The unpaid access includes free or low-cost medication through patient assistance programs for people with low-income or does not have insurance. The paid access, also called reimbursement, is managed through patient's health insurance, private or public. Giving that the paid access is essentially the pharmaceutical sales, therefore, the net sales data are used as a proxy to measure a firm's capability to provide patient access to the products and obtain reimbursement.

R&D Expenditure

Prior research suggests that R&D expenditure is a significant factor in predicting firm performance. Schumpeter (1942) suggests that big pharma has the advantage of economies of scale, and can cycle a significant portion of their large revenues back into R&D o increase productivity. Large R&D budgets are one of the major barriers to entry according to Porter's Five Forces theory (Porter, 1979), thereby reducing competition in the pharmaceutical industry. However, recent work by Cockburn (2001) and Demirel (2012) suggest that R&D investment often fails to boost growth in large firms, and instead has a negative effect on performance. As R&D expenditure is a well-known factor associated with firm performance, it is included in the regression model as a control variable.

Firm Dummy

A dummy variable for the pharma firms is included to control for firm fixed effects. Pfizer is used as the base since it has been the firm with the largest market cap.

Analyses

The general trend, growth rate (slope and ratio) of market cap, return on assets, market share, and Tobin's Q of the 10 big pharmaceutical companies are evaluated using descriptive analysis. To control the firm size effect, which may influence firm's growth rate in market cap, return on assets, market share and Tobin's Q, and each firm's growth rate over the 10-year period (slope and ratio) is normalized to its own baseline at 2005 prior to the cross-firm comparison. The Pearson Bivariate Correlation is also performed to inspect the relationships amongst all the variables. In addition, the multivariate linear regression model is applied to test the hypotheses and the predictors in the research model. Furthermore, the dummy variables for the firm and the use of MANOVA are explored.

Table 8. Summary of the variables.

Variables	Measures	Data Source
Dependent Variables		
Market Cap ($M)	Share price x total outstanding shares	Compustat
Return on Assets (ROA)	Net Income / Total Assets	Compustat
Independent Variables		
Patient Centricity (SOR-Patient)	Word counts of Patient/T* %	10-K Item 1
Oncology Products	Number of oncology products introduced	FDA
Pharmaceutical Sales	Net sales	Compustat
Control Variable		
R&D Expenditure	R&D expense	Compustat
Firm Dummy		

T* = Sum of three wordcounts in the 10-K, Item 1

Results

Descriptive Analyses - Comparison of 10 Firms' Performance

The four performance indicators, including the market cap ($M), ROA, market share (%), and Tobin's Q, are compared across the 10 firms in figure panel below (Figure 15). As mentioned, a firm's stock price and the growth of its market cap size are primarily driven by investors' confidence in the firm's strategy, products, and operation performance. However, the global economic environment may also provide the context for trend prediction. For instance, between 2000 and 2019, the economy encountered the dot.com bubble, 9/11 terrorists attack, the 2008 financial meltdown, and the 2016 Brexit impact, yet, the overall market growth remains positive and the S&P 500 index grew nearly 8-10% per year between 2005 and 2015. Consistent with the bullish market trend, the 10 big pharmaceutical companies also exhibit positive growth in their market caps, suggesting a general optimism of the investors in these companies' performance.

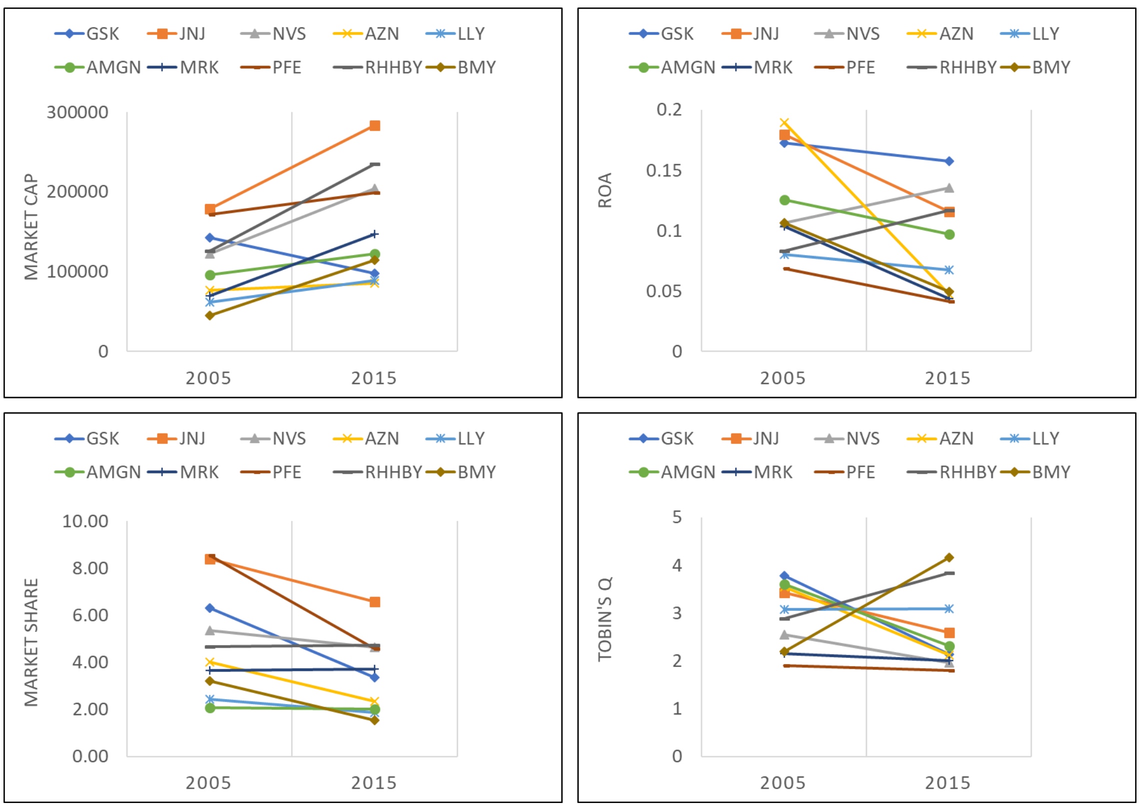


Figure 15. Firm performance across the 10 pharmaceutical firms.

Besides the market influence, the volatility of the pharma stock price is frequently impacted by the trial results and the regulatory approvals. Between 2005–2015, approximately 130 pharmaceutical companies jointly contributed to the total of 313 novel molecule entities (NMEs) approval by the FDA. The 10 pharmaceutical companies represented in this research accounted for over one-third of the total NMEs approvals (114/313, 36%). During this 10-year period, the total NMEs produced by the industry as a whole and the new oncology products exhibit an upward trend suggesting that the productivity of the pharmaceutical industry and personalized medicine may be slightly improving. However, as shown in Figure 16, a decline of ROA was observed across the 10 firms despite the uptick of total NMEs and oncology drugs approval. This is consistent with Munos (2009) and others who reported an industry-wide productivity decline over the past six decades.

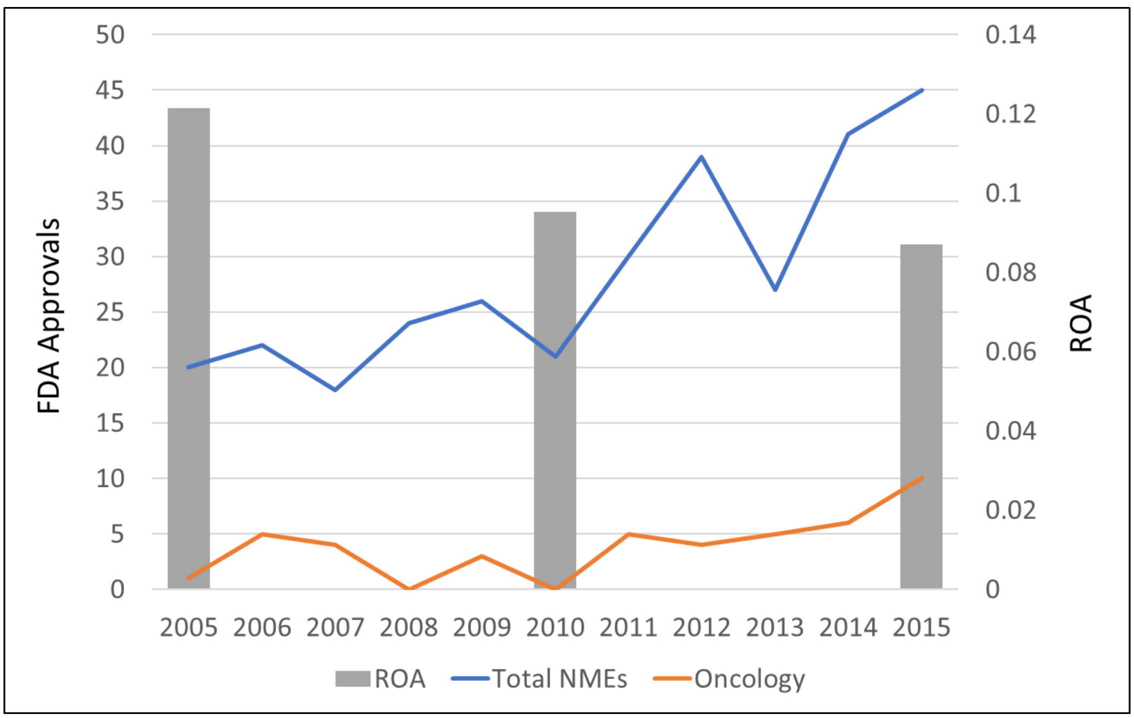


Figure 16. The ROA decline despite the increasing approvals of NMEs.

Indeed, as shown in Figure 16, in contrast to the bullish trend of market caps, 5 out of the 10 firms suffered negative growth in their Return on Assets (ROA), Market Share and Tobin's Q. During 2005-2015, the total revenue of the global pharmaceutical industry market share grew from $600B to over $1Trillion. In order for firms to maintain their market share, the firm must increase their market share at the same rate as the total market. As seen in Figure 16, it appears many firms were losing their market share, and this may be due to the intensified brand and generic competitions.

Owing to the fact that it is difficult to compare the firm performance based on the figures above, the 10-year growth rate and the growth ratio relative to 2005 (see formulas below) were calculated to standardize the comparison and to determine who the top performers are.

10-year growth rate (slope) = Δ (Performance of 2015-Performance of 2005) / 10

10-year growth ratio = Performance of 2015 / Performance of 2005

By comparing each firm's 10-year growth rate using the slope and ratio, the top performers emerged. As indicated in Figure 17 below, despite this challenging period, Roche not only was the most patient-centric firm but also had the largest market cap growth, the most increases in Return on Assets (ROA), and maintained its market share over the past 10 years period. This result provides the first evidence that patient centricity and top firm performance are not mutually exclusive as previously assumed. Although it is only one company, this data proves that it is possible to be patient-centric and profitable.

Figure 17. Growth rate comparison across the 10 pharmaceutical firms.

Correlation Analyses

As described in Chapter 2, there is a significant increase of patient centricity, which was measured by the SOR-Patient (%) from the 10-K filings across the 10 pharmaceutical firms in the period of 2005-2015. By Pearson correlation analysis, the increases of patient centricity are positively correlated with the market cap, the growth of ROA, and market share ($0.1<r<0.5$, see Table 9 below). Meanwhile, product centricity (SOR-Product) is negatively associated with several firm performance indicators.

Table 9. Correlation between Strategic Orientation and Firm Performance.

Correlations

		SOR-Operation	SOR-Product	SOR-Patient	Market Cap ($M)	Market Cap Growth (2015/2005)	ROA	ROA Growth (2015/2005)	% Market Share	Market share growth (2015/2005)	Tobin's Q	Q Growth (2015/2005)
SOR-Operation	Pearson Correlation	1	-.281**	-.203*	.058	-.080	.079	-.014	.147	-.089	-.124	-.162
	Sig. (2-tailed)		.003	.034	.550	.408	.415	.884	.126	.354	.196	.091
	N	110	110	110	110	110	110	110	110	110	110	110
SOR-Product	Pearson Correlation	-.281**	1	-.883**	-.213*	-.113	-.079	-.193*	-.114	-.382**	-.086	.011
	Sig. (2-tailed)	.003		.000	.025	.240	.414	.043	.236	.000	.370	.911
	N	110	110	110	110	110	110	110	110	110	110	110
SOR-Patient	Pearson Correlation	-.203*	-.883**	1	.190*	.154	.042	.204*	.045	.434**	.149	.068
	Sig. (2-tailed)	.034	.000		.047	.108	.665	.032	.644	.000	.121	.478
	N	110	110	110	110	110	110	110	110	110	110	110
Market Cap ($M)	Pearson Correlation	.058	-.213*	.190*	1	.466**	-.004	.021	.739**	.077	.190*	.210*
	Sig. (2-tailed)	.550	.025	.047		.000	.965	.832	.000	.425	.047	.028
	N	110	110	110	110	110	110	110	110	110	110	110
Market Cap Growth (2015/2005)	Pearson Correlation	-.080	-.113	.154	.466**	1	-.192*	-.057	.031	.084	.340**	.646**
	Sig. (2-tailed)	.408	.240	.108	.000		.045	.553	.749	.382	.000	.000
	N	110	110	110	110	110	110	110	110	110	110	110
ROA	Pearson Correlation	.079	-.079	.042	-.004	-.192*	1	.757**	.136	.128	.262**	.012
	Sig. (2-tailed)	.415	.414	.665	.965	.045		.000	.156	.184	.006	.901
	N	110	110	110	110	110	110	110	110	110	110	110
ROA Growth (2015/2005)	Pearson Correlation	-.014	-.193*	.204*	.021	-.057	.757**	1	.046	.193*	.148	.231*
	Sig. (2-tailed)	.884	.043	.032	.832	.553	.000		.635	.043	.122	.015
	N	110	110	110	110	110	110	110	110	110	110	110
% Market Share	Pearson Correlation	.147	-.114	.045	.739**	.031	.136	.046	1	.280**	-.007	-.023
	Sig. (2-tailed)	.126	.236	.644	.000	.749	.156	.635		.003	.945	.809
	N	110	110	110	110	110	110	110	110	110	110	110
Market share growth (2015/2005)	Pearson Correlation	-.089	-.382**	.434**	.077	.084	.128	.193*	.280**	1	.078	-.031
	Sig. (2-tailed)	.354	.000	.000	.425	.382	.184	.043	.003		.419	.751
	N	110	110	110	110	110	110	110	110	110	110	110
Tobin's Q	Pearson Correlation	-.124	-.086	.149	.190*	.340**	.262**	.148	-.007	.078	1	.690**
	Sig. (2-tailed)	.196	.370	.121	.047	.000	.006	.122	.945	.419		.000
	N	110	110	110	110	110	110	110	110	110	110	110
Q Growth (2015/2005)	Pearson Correlation	-.162	.011	.068	.210*	.646**	.012	.231*	-.023	-.031	.690**	1
	Sig. (2-tailed)	.091	.911	.478	.028	.000	.901	.015	.809	.751	.000	
	N	110	110	110	110	110	110	110	110	110	110	110

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Regression Analyses - Hypotheses Testing

To examine whether the correlations identified above actually predict firm performance, multiple regression analyses were performed to test the hypotheses below:

H1: The degree of patient centricity (SOR-Patient) has a direct and positive effect on pharmaceutical firm performance.

H2: The number of oncology products has a direct and positive effect on pharmaceutical firm performance.

H3: Pharmaceutical sales has a direct and positive effect on pharmaceutical firm performance.

First, the descriptive statistics of the three strategic orientations were analyzed using the 10-K Item I of the 10 pharmaceutical firms from 2005 to 2015 (N=110).

Table 10. Descriptive Statistics of Patient Centricity across all observations.

Descriptive Statistics

	Mean	Std. Deviation	N
SOR-Operation	12.17025449	7.295184597	110
SOR-Product	68.67855002	15.20598533	110
SOR-Patient	19.15119549	14.90185256	110

Based on the MANOVA analysis, the group mean of each SOR is significantly different from one another despite how each group has a large standard deviation. As shown in Figure 18 below, product centricity (SOR-Product) is the dominant strategic orientation across all observations, followed by patient centricity (SOR-Patient) and operation centricity (SOR-Operation). This result is as expected and reflective of the current landscape.

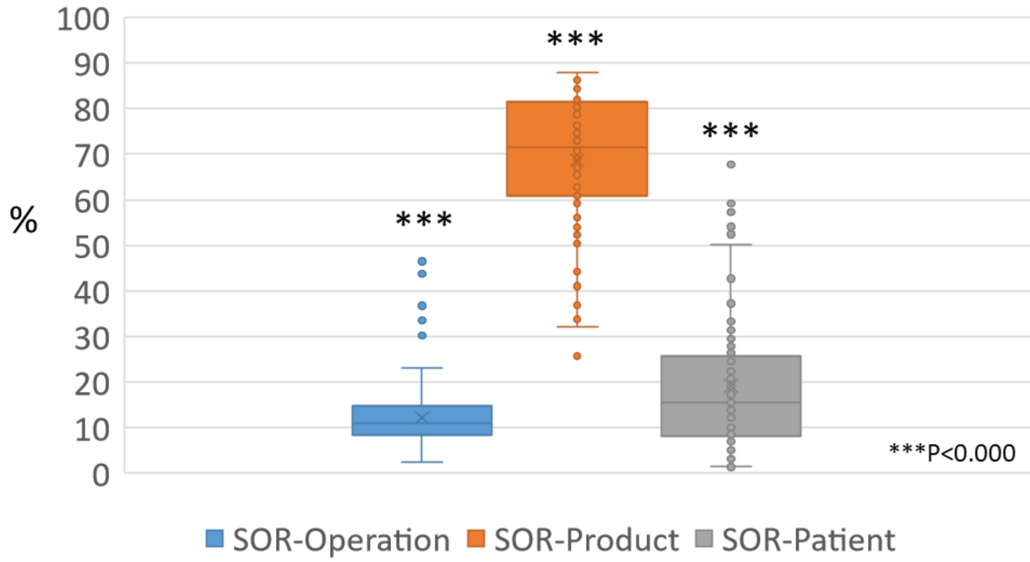


Figure 18. Group means analysis by MANOVA

Effect of Patient Centricity, Oncology Products, and Sales on Market Cap

Market cap reflects investors' confidence in the firm's strategy, products, and operation performance. By defining the market cap as the dependent variable in the linear regression model, the three independent variables, namely SOR-Patient, the capability of producing personalized medicine (measured by the numbers of oncology products), and the capability of providing patient access (measured by total sales), were found to be statistically significant predictors of market cap performance. As expected, the beta value indicated the effect size being: sales > oncology products > SOR-Patient, respectively. The model suggests that by increasing 1 % of SOR-Patient, the market cap increases by $370M. Further, for each oncology product approval, the market cap increases by $17B.

Furthermore, for each $1M in sales increases, the market cap increases by $3M. The overall model, including the R&D expenditure as the control variable, is capable of explaining 74.4 % of the variance of the market cap performance, with adjusted R square = 0.744, F=80.123, and p=0.000, respectively. The tests for multicollinearity suggest a very low level of multicollinearity is present with VIF <2 for all three predictors. Taken together, this result supports the research model that the combination of patient centricity (SOR-Patient), the ability to produce personalized medicine (oncology products) and the ability to provide patient access (sales) are the three critical predictors of market cap performance. As such, the hypotheses H1, H2, and H3 are supported, with the market cap as the measure of firm performance. Beta coefficients for the three predictors and their t-test statistics are indicated in the table below.

Table 11. Coefficients and Statistics for Market Cap Prediction

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics: R Square Change	F Change	df1	df2	Sig. F Change
1	.868[a]	.753	.744	29336.02105	.753	80.123	4	105	.000

a. Predictors: (Constant), RnD Exp ($M), Oncology Products, SOR-Patient, Sales ($M)

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Coefficients Beta	t	Sig.	Collinearity Statistics Tolerance	Collinearity Statistics VIF
1	(Constant)	2894.672	8543.351		.339	.735		
	SOR-Patient	368.424	212.197	.095	1.736	.085	.790	1.266
	Oncology Products	17051.927	4670.637	.183	3.651	.000	.935	1.069
	Sales ($M)	2.883	.353	.821	8.172	.000	.233	4.291
	RnD Exp ($M)	-.705	2.763	-.027	-.255	.799	.210	4.764

a. Dependent Variable: Market Cap ($M)

X_1 = SOR-Patient;

X_2 = Oncology Products;

X_3 = Sales ($M)

X_4 = R&D Expenditure

$$Market\ Cap\ \omega = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \varepsilon$$

Effect of Patient Centricity, Oncology Products, and Sales on ROA

Return on Assets (ROA) is a profitability indicator. By definition, it is the ratio of net income over total assets. Because the net income is the function of revenue minus expenditure, we expect that out of the three proposed predictors, including SOR-Patient, the capability of producing personalized medicine (measured by the numbers of oncology products), and the capability of providing patient access (measured by product sales), at minimal, sales should have a direct effect on ROA performance. In addition, R&D expenditure and the prior year ROA are known predictors of ROA (Danielson, 2005). Therefore, they are included as control variables in the regression analysis.

As shown in the table below, SOR-Patient, sales, R&D expenditure, and the prior year ROA are statistically significant predictors of ROA. As expected, the prior year ROA positively predicts current year ROA performance. By increasing 1 % of patient centricity, a firm can expect to increase ROA by 0.1%. For every $1M of sales increases, the ROA increases by 0.0002%. However, for every $1M of R&D expenditure increases, it decreases ROA by 0.002%. This finding is consistent with many prior studies where R&D investment does not always translate positively into firms' growth (Demirel & Mazzucato, 2012; Cohen & Klepper, 1996). Demirel and Mazzucato (2012) reported that particularly in large firms, R&D investment fails to boost growth, instead, has a negative effect on the firms' performance. Surprisingly, oncology products do not predict the ROA performance, therefore only the hypotheses H1 and H3 are supported in this case. Taken together, patient centricity, sales, R&D expenditure, and the prior year ROA are statistically significant predictors of ROA with overall adjusted R = 0.223, F = 7.194, and p<0.000, respectively.

Table 12. Coefficients and Statistics for ROA Prediction.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics: R Square Change	F Change	df1	df2	Sig. F Change
1	.509[a]	.259	.223	.0444621155	.259	7.194	5	103	.000

a. Predictors: (Constant), RnD Exp ($M), LAGS(ROA,1), Oncology Products, SOR-Patient, Sales ($M)

Model		Unstandardized Coefficients B	Std. Error	Standardized Coefficients Beta	t	Sig.	Collinearity Statistics Tolerance	VIF
1	(Constant)	.095	.016		5.936	.000		
	SOR-Patient	.001	.000	.199	2.079	.040	.783	1.278
	Oncology Products	.007	.007	.085	.967	.336	.930	1.075
	Sales ($M)	2.005E-6	.000	.656	3.712	.000	.231	4.337
	RnD Exp ($M)	-1.800E-5	.000	-.792	-4.255	.000	.208	4.817
	LAGS(ROA,1)	.319	.086	.319	3.722	.000	.980	1.020

a. Dependent Variable: ROA

X_1 = SOR-Patient

X_2 = Oncology Products

X_3 = Sales ($M)

X_4 = R&D Expenditure ($M)

X_5 = ROA_{n-1}

$$ROA\ \hat{y} = \beta_0 + \beta_1 X_1 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \varepsilon$$

To further explore possible relationships and explanations in the data, a series of additional analyses were conducted with a dependent variable of Tobin's Q, and with several interactions. Briefly, in the Tobin's Q model, out of the three predictors, both oncology products and sales are statistically significant while SOR-Patient is not. In addition, R&D expenditure exhibited a negative effect, suggesting that for every $1M of R&D spent, it decreases Tobin's Q value by 0.00015. The Tobin's Q model overall supported the hypotheses H2 and H3. By further evaluating the interactions between SOR-Patient and oncology products or sales, both of them were found to be statistically significant, suggesting that patient centricity although is not a predictor of Tobin's Q, it plays a moderator role indirectly affecting Tobin's Q performance. The results of these analyses are presented in Appendix A.

Conclusion

In this Chapter, we set out to answer one question—does patient centricity have a positive effect on firm performance? Through the development of a novel methodology, the Strategic Orientation Ratio (SOR), I uncovered that there was an increase in patient centricity being implemented across the 10 pharmaceutical firms at various degrees. In Chapter 2, Roche was found to exercise a differentiated strategic orientation, patient centricity, compared to its peers since 2005. In this Chapter, I explored four performance indicators that represent different aspects of firm performance and conducted statistical and non-statistical analysis to examine the relationships between patient centricity and firm performance. By applying the performance metrics across the 10 pharmaceutical firms and measuring them head-to-head against one another, the top performers emerged. Roche, previously identified as the most patient-centric firm in Chapter 2, was found to be one of the top performers, suggesting that patient centricity and high firm performance can co-exist.

To further delineate the relationship between patient centricity and firm performance, a conceptual research model was developed as follows. First, the key constructs were extracted from the customer centricity research, the patient centricity literature, and the annual reports of Roche. From those, I developed a new definition of patient centricity in the context of pharmaceutical industry and proposed a conceptual model where, patient centricity (SOR-Patient), personalized medicine and patient access are the three key components of a patient-centric pharma model. In this model, the entire firm is tightly aligned, from strategy to operation, to produce personalized medicine (measured by oncology products) and ensure patient access (measured by sales). This alignment not only represents a coherent competitive strategy but is also well-aligned to external market demands. Because the purpose of medicine is to treat disease, the best experience and outcome is likely achieved by the personalized approach. Any other ways would be deviated from the optimal and considered substandard.

By correlation analyses, patient centricity is positively associated with several performance indicators while product centricity has the opposite effect. By performing multiple regression analyses, the results indicated that patient centricity (SOR-Patient) indeed predicts market cap and ROA performance. In addition, patient centricity (SOR-Patient) also plays a moderator role in the ROA and Tobin’s Q performance.

Taken together, this Chapter provides the empirical evidence that patient centricity has a positive impact on firm performance and supports the notion that patient centricity if operationalize coherently as a strategic orientation, it is not only the ‘right thing to do’ but also a viable competitive strategy.

CHAPTER 4.

CONCLUSION AND EXPECTED CONTRIBUTION

The rise of patient centricity in the healthcare system has become a global movement in the 21st century. A growing body of evidence demonstrates that patients who are more actively engaged in their healthcare experience better outcomes and incur lower healthcare costs (Fenton, 2012; Hibbard, 2013). As a result, many states and policymakers have rolled out public policies to promote patient-centric care. In contrast, the rise of patient centricity in the pharmaceutical industry did not seem to link to a clear cause. It occurred at the peak of the industry-wide productivity crisis and the low point of negative reputation (Scannell, 2012; Kessel, 2014). Consequently, there is a lot of skepticism as to whether patient centricity is an actual shift in strategic orientation to repair the reputation and productivity, or simply a public relations (PR) buzzword.

There is a general assumption in business that customer centricity is about customizing products and services to satisfy customers, therefore it can be a very expensive way to operate and can lead to reduced profitability. Within Pharma, given the high costs and long timeline to bring a product to market, many pharmaceutical executives also hold the belief that patient centricity is not a suitable strategy and is not profitable. However, these assumptions have not been empirically supported by data or research.

After a decade of prominent efforts led by the Food and Drug Administration (FDA) and the Patient-Centered Outcome Research Institute (PCORI), the adoption of patient centricity in the pharmaceutical industry remains limited. Until there is a well-defined business model with empirical proof that patient centricity is profitable, it will be difficult for patient centricity to become the mainstream practice in the pharmaceutical industry.

To address the evidence gap, this research took a unique approach that integrated business and medical literature by drawing from well-established frameworks, namely Porter's Generic Competitive Strategy (Porter, 1980) of Cost Leadership, Differentiation and Focus, and Treacy and Wiersema's three value disciplines (1995) of operational excellence, product leadership, and customer intimacy. An expressed typology of *strategic orientation*, namely Operation Centricity, Product Centricity, and Customer Centricity was developed. Firms may express all three strategic orientations. However, from a resource perspective, to focus energy for competitiveness, a firm should master one discipline that is aligned to its strategy while maintaining the other two disciplines at a competent level. The strategic orientation is therefore defined as the result of the alignment between strategy and operation. To apply this framework, a novel measurement is established. The Strategic Orientation Ratio (SOR) was developed and first validated for customer centricity for 9 non-pharmaceutical companies. Subsequently, the SOR is extended from customer centricity to patient centricity, and the extent of patient centricity in 10 pharmaceutical firms was measured.

To further delineate the relationship between the level of patient centricity and firm financial performance, an explicit patient centricity strategy and its actionable components were proposed in a research model. Patient centricity is defined as *a strategic orientation to meet patients' needs at the individual or specific population levels, by developing personalized medicine(s) that deliver the best experience and outcomes, and by ensuring patient access to these personalized products.* From this definition emerges a conceptual model and testable hypotheses that examine the effect of the patient centricity components on pharmaceutical firm financial performance.

Four performance metrics, including market cap, return on assets (ROA), market share, and Tobin's Q were analyzed across the 10 pharmaceutical firms and the top performers emerged. Roche was identified as not only the most patient-centric firm but also one of the top performers. Although only N of 1, this finding suggests that patient centricity and profitability do co-exist, and the previous assumption of patient centricity not being a profitable model is not true.

By analyzing the correlation metrics between patient centricity and firm performance, the results indicated that patient centricity is positively and significantly associated with market cap, ROA and market share, while product centricity has the opposite effect. Further, the extent of patient centricity (SOR-Patient) is a significant predictor of market cap and ROA performance, which reflects the firm's strategy, products, operation performance, and profitability. Furthermore, patient centricity also plays a moderator role in ROA and Tobin's Q performance.

In summary, this research contributed several important elements to patient centricity research. First, I developed a novel methodology, the Strategic Orientation Ratio (SOR) that quantifies firms' strategic orientation, thereby the extent of patient centricity in the pharmaceutical companies can be objectively measured for the first time. Second, from a small sample set (N=10), I uncovered one firm which has been implementing patient centricity as a competitive strategy for over a decade. Importantly, that firm's performance was superior to many of its peers, suggesting that patient centricity and profitability are not mutually exclusive, as previously assumed. Third, I also provided a definition, an actionable model and the empirical evidence supporting the idea that the combination of patient centricity, personalized medicine, and the patient access through sales all contribute to firm performance. To my knowledge, this is the first demonstration of patient centricity as an alternative strategy linking to its product types and impact on firm performance. This research provides evidence supporting the concept that patient centricity is not just a 'right thing to do' mantra but if executed coherently and supported by product types and sales, it is a viable competitive model.

Limitation & Discussion

Strategic Orientation Ratio (SOR)

This research established a novel methodology, the Strategic Orientation Ratio (SOR), to quantify firms' strategic orientation by using their public 10-K reports. Owing to the fact that the calculation of Strategic Orientation Ratio (SOR) is strictly based on the relative ratio of the three keywords, namely, 'operation', 'product', and 'patient', a potential unintended consequence which we don't wish to see is companies starting to re-write their 10-K reports and mislead the public. We would caution firms to neither view the Strategic Orientation Ratio (SOR) as merely a word-number games nor to use 10-K as a PR ploy because it is not only a violation of SEC rules but also a misuse of this research.. We would caution firms not to view the Strategic Orientation Ratio (SOR) as merely a word-number game or use 10-K as a PR ploy because it is not only a violation of SEC rules but also a misuse of this research. In fact, our model suggests that the strategic orientation plays a moderate role explaining approximately 10% variance of firm performance. Further, it needs to be backed up by the firms' ability to produce oncology products and reach patients by sales, both of which have much more predictive power. Therefore, we would highly encourage firms to first make a clear decision regarding which strategic orientation they will choose to best compete and to review their future reports to ensure that what they strategize and operate is truthfully reflected in the documents, so that these accurate reports can be used and trusted by the public.

Sample Size

As described in the introduction of this research, the buzzword ‘patient centricity’ appeared to rise in the midst of industry-wide productivity and reputational crisis around 2010. I asked the question whether the rise of patient centricity is a PR ploy relating to the scandals or a genuine strategy to improve the industry performance. For that reason, the sample selection in this research was mainly based on two articles, Munos (2009) and Kessel (2014), with additional consideration of M&A and their data availabilities. Total 10 firms and 11 years (2005-2015) of longitudinal data were collected resulting in N = 110 data points covering the firms and time period of interest. Although not ideal, by assuming all data points as independent observations, the Pearson Correlation, and multiple regression analyses can be performed.

To address concerns regarding a sample size effect and the likelihood of a Type II error skewing the results, I estimated the sample size required for multiple regression based on the rules described by Green (1991):

1) To estimate a minimal sample size for testing the overall model fit:

$$\mathrm{N1} = 50 + 8\kappa;\ \kappa \text{ is the number of predictors}$$

2) To estimate the Beta of the model:

$$N2 = 104 + \kappa; \ \kappa \text{ is the number of predictors}$$

In this research, the numbers of predictors were 3, namely SOR-patient, Oncology Products, and Sales. Therefore, my total observations of 110 are sufficiently greater than the two estimates, N1 = 74 and N2 = 107, respectively.

Although the independent observations of N = 110 enable statistical analyses, it is a limitation of this research and understandably there might be some outliers and unknown been introduced into the models. For future research, a larger sample size that includes as many as pharmaceutical firms would be recommended.

Lagging Effects

This research evaluates three predictors, namely the firm's strategic orientation, products, and sales, and their effect on firm performance. Considering that some performance indicator such as market cap is highly volatile and reflective of real-time drug approval events, others like the Return on Assets (ROA) and Tobin's Q may be lagging behind product launch. To ensure that the models established in this research have been optimized, I tested the ROA and Tobin's Q with 1, 3 and 5 years lag of oncology products and re-run the regression models. The results indicated little or no improvement of model predictions with the lag adjustment, suggesting that the overall ability to produce oncology product impacts the firm performance at all time without lagging effect.

Table 13. Evaluation of Lagging Effects

	Predictor	Predictor p-value	Model Adjusted R square
ROA	Oncology Products	0.24	0.243
	Oncology Products_1y Lag	0.467	0.237
	Oncology Products_3y Lag	0.842	0.233
	Oncology Products_5y Lag	0.804	0.232
Tobin's Q	Oncology Products	0.03	0.174
	Oncology Products_1y Lag	0.008	0.192
	Oncology Products_3y Lag	0.583	0.137
	Oncology Products_5y Lag	0.381	0.14

Managerial Implications and Recommendations

This research was set out to demystify the concept of patient centricity and provide empirical evidence as well as an actionable model for pharma executives to consider. The example of Roche demonstrated the feasibility and profitability of patient centricity as a viable alternative model. In addition, the new definition of patient centricity suggests that the heart of patient centricity is personalized medicine and patient access, which is more in line with industry trends and market demand.

Clay Christiansen (2016) in his book, Jobs to Be Done, explains why developers ought to focus on the customer's jobs to be done in order to compete for market share. Taking medicine as an example, the purpose of medicine is to treat disease, therefore only the most 'qualified' medicine (that delivers the best experience and outcome) should be 'hired' to do the job. Conversely, if the medicine is accessed by the wrong patient population, and consequently produces a marginal benefit or worse, 'not doing the job' (drug not working), the medicine will be 'fired' and lose its market share. This whole concept is consistent with the evolutionary economic theory (Nelson & Winter, 1982) where the market permits a variety of products to be present but only the fittest products will survive in the long run and grow under the selection pressure. Because the best experience and outcome can only be achieved by the personalized medicine model, any other ways would be considered suboptimal. Therefore, if a pharmaceutical firm desires to compete for market leadership, they must acquire capabilities to operate the patient-centric model to be the fittest.

The patient-centric model will require significant changes in organizational structure, operation, culture, and technical capabilities. Three capabilities, including data analytics, biomarkers, and digital measurements are discussed below for consideration. Accordingly, employees' up-skills and talent development in those areas will be critical for success.

Data Analytics

Prior to the human genome era, pharmaceutical companies were primarily competing on the blockbuster model and paid little attention to rare diseases. Due to the lack of predictive biomarkers and deep understanding of the disease model, the drug targets often were selected based on the pathology of the masses, e.g. L-Dopa, chemotherapies, etc. This approach led to a wave of successful medicine development and the one-size-fits-all model has yielded many drug approvals. However, as discussed earlier, the one-size-fits-all blockbuster model is losing its edge and may no longer meet the regulators' and market's demands. It's now time to break down data silos and leverage modern data analytics to solve complex disease models.

Take Alzheimer's Disease (AD) and Parkinson's Disease (PD) as examples. Clifford (2013) used an aggregated dataset from Alzheimer's disease (AD) patients and developed the temporal evolution of AD biomarkers in relation to each other and to the onset and progression of clinical symptoms. Such a model provides a valuable framework for AD research and enables better trial design for medicine development. With continued and varied new data input, this disease model will evolve and refine over time to achieve better accuracy.

Parkinson's Disease is a common neurodegenerative disorder involving a range of motor and non-motor symptoms. The existing approved therapy L-Dopa ameliorates the motor symptoms. However, most PD patients suffer the dopamine non-responsive symptoms (Vu, 2012), e.g., freezing of gait (FoG). A team of data scientists from the University of Michigan and Tel Aviv Medical Center recently took a multidisciplinary approach to investigate falls in Parkinson's Disease using model-based and model-free analytical methods (Gao, 2018). They found that the model-free machine learning based techniques like Random Forest, AdaBoost, Support Vector Machines, Neural Network, and SuperLearner, outperform the traditional logistic regression model and predict more reliable clinical outcomes for forecasting of falls in PD patients.

These works exemplify the importance of two capabilities involving data. First, the firm should take a collaborative approach to connect disparate data sources that are currently siloed in various healthcare and research entities and establish a data management team to develop a protocol of aggregating complex, multisource data. Second, the firm must also establish a data science team skilled in the model-based and model-free machine learning techniques to optimize predictive analytics.

Biomarkers

The value of biomarkers in the drug development process has been well documented (Kraus, 2018). Researchers have found that biomarker-guided drug development programs have a success rate of 3-fold or higher than the non-guided ones (Falconi, 2014). In addition, by having a companion diagnostic biomarker, the drug is tested in the likely responsive population, thereby the efficacy signal can be enriched and the clear benefits to patients can be achieved.

The FDA details a rigorous pathway for the development of biomarkers in their Biomarker Qualification Program (BQP). Under the BQP, seven biomarker categories were defined, including susceptibility/risk, diagnostic, monitoring, prognostic, predictive, response, and safety. A list of approved biomarkers has been made available to the public and may be used in multiple drug development programs across different sponsors.

The development of a biomarker is a collaborative process that may involve many stakeholders, e.g., regulators, healthcare providers, payers, diagnostic companies, academic researchers, and pharmaceutical companies. Since biomarkers play a critical role in the patient-centric model -- not only can they be used to accelerate drug development programs but also support to future commercialization effort -- a patient-centric firm must establish a biomarker team that is multi-disciplinary and can collaborate effectively with all stakeholders.

To create a world-class biomarker capability, Roche has recently acquired its strategic partner Foundation Medicine's cancer platform and declared its commitment to precision oncology efforts (Sheridan, 2018). In addition, Roche Diagnostics is also developing biomarker registries to propel the development of personalized medicine beyond oncology. This practice could potentially drive the whole post-marketing value chain, including proper prescriptions, reimbursement, and better health outcomes for patients in the real world.

Objective Measurements

Historically, we have succeeded in medicine development in the areas where the objective measurements of the effect were possible. For instance, viral suppression was measured as the efficacy endpoint for the anti-viral HIV regimens. Blood pressure (BP), heart rate (HR), and electrocardiogram (ECG) were used to develop many drugs for cardiovascular diseases. The spirometry test measures the endpoint of respiratory diseases such as COPD and Asthma, and the disease-free-survival (DFS) was the clinical gold standard for oncology. In contrast, pharma struggles the most with diseases like Alzheimer's disease (AD) and Parkinson's disease (PD), where we lack disease models, biomarkers, and objective measures. Until we can establish those, it will be challenging to develop breakthrough therapies for AD, PD and other complex diseases.

The good news is that we have entered the 4^{th} industrial revolution era, according to the world economic forum. This means that we have unprecedented capability to use digital technology to improve personal health, which we did not have in the previous era. Sensors that measure physiological performance, such as glucose, sleep, heart rate, seizures, movement, and breathing offer unique opportunities of continuous monitoring, potentially provide early detection of safety and efficacy signals, and a more complete understanding of drug effects, drug dosing, and pharmacodynamics than was previously possible (Munos, 2016; Kim, 2019). Based on their potential value, many pharmaceutical and device companies have invested significant efforts to develop digital measurements. Similar to the Biomarker Qualification Program (BQP), the development of the New Digital Biomarker (NDB) and Novel Digital Endpoint (NDE) require a multidiscipline, regulatory-guided pathway to achieve validation and acceptance. To date, drug approvals have not utilized NDE as a primary clinical outcome measure, due to the current lack of validated NDEs accepted by the regulatory agency. Significant efforts are underway to improve disease models, predictive analytics and biomarker registries for Oncology, AD and PD. Firms that are interested in developing personalized medicine in these diseases should establish a measurement science team with expertise in biomarker, engineering and clinical outcome assessment (COA). The cross-functional collaboration and knowledge sharing between data, biomarker, and measurement science teams are an integral part of the patient-centric firm.

Clinical Trial Design

In the patient-centric nichebuster model, trial design will be very different from traditional studies. For instance, the CREATE trial (NCT 01524926) uses Bucket trial design to evaluate the effectiveness of crizotinib, based on its mechanism of action (MOA) in a variety of cancer types (Dugger, 2017). Conversely, the ALCHEMIST trial (NCT02194738) uses the so-called Umbrella trial design to test the effectiveness of a variety of therapies in NSCLC patients. The most personalized approach is the N of 1 design, which aims to treat each patient individually, in a controlled manner. Columbia University is currently running a study to evaluate the master regulator effect in 260 patients with various tumor types. Each individual patient's tumor genome and transcriptome will be analyzed, and the personalized best-match treatment will follow. Such a personalized treatment model will not only support hypotheses testing in a small trial size but also allow possibilities to optimize the experience and outcomes.

The FDA has been very supportive of patient centricity and clinical trial transformation. Since 2016, it has partnered with consortia such as Clinical Trial Transformation Initiatives (CTTI) to provide recommendations for various transformation projects. Most recently, an innovation office was created in January 2019 to accelerate drug development. As technology is evolving, the regulations are too. A modern patient-centric firm should assign its clinical development team and regulatory team to pay close attention to the new regulations and formulate or adjust its development strategy according.

New Entrants into Healthcare

Besides the suggestions described above, pharma executives should also seek a new business model to prepare for the turbulent environment ahead. In the theories of Disruptive Innovation and Innovator's Dilemma (Christiansen, 2013; 2015), Clay Christiansen described the phenomena of how cheaper products and services can bring down large companies like US Steel, Kodak and Digital Equipment. In those cases, the large, established incumbents were gradually disrupted by the new entrants who competed for the lower margin markets. This is because the large firms tended to focus on the higher profit margin markets, which caused them to voluntarily surrender their market shares bit by bit to the disruptors. Eventually, the entire industry was taken over by the new entrants, who benefited from the advancement of technology and the commoditization of innovation.

There are signs of disruption. First, researchers have reported that the pharma industry's financial returns dropped to their lowest levels of 3.2% in 2017 (De Felice, 2017). This profit decline has been attributed to generic competition and governmental control of healthcare cost. According to the Generic Pharmaceutical Association's annual report (Herist, 2013), the use of generic drugs saves the US healthcare system for more than half a billion per day. As a result, the generic fulfillment of prescriptions in the US has risen from 17% in 1980 to 80% in 2010. This generic takeover phenomenon seems to be explained by the theories of Disruptive Innovation and Innovator's Dilemma. Meaning, in response to the intensified competition from both the branded and generic companies and the pressure to fill the pipeline gap, pharmaceutical executives will choose to pursue the high-profit margin products and let go of the lower profit ones. Over time, through such a dynamic of disruption, the industry may eventually cllapse. Second, during this disruption process, the industry may encounter increasing activities of large-scale merger and acquisition (M&A) and consolidation. Interestingly, at the start of 2019, following the announcements of GlaxoSmithKline acquiring Tesaro, Bristol-Myers Squibb acquiring Celgene, and Eli Lilly buying Loxo, many industry analysts already predicted an increase in M&A this year. Additionally, it's important to note that, beyond M&A, Novartis is the only major pharmaceutical firm that seems to take on a Walmart-like operation centricity and has branded, generics, and digital therapeutics in their pipeline while Roche strictly focuses on patient centricity and personalized health. It would be important to monitor the long term outcome of these two different approaches.

With the advancement of information technology (IT) in the past 50 years, technologies such as human genetics, biomarkers, electronic health record, Internet of

Things (IoT), big data, Artificial Intelligence (AI), and deep learning have all made the personalization affordable, and many firms are leveraging data analytics to increase product effectiveness, user experience, trust and customer lifetime value (CLV). A 21st century Pharma should consider becoming the health solution provider and offer personalized products because the industry's new entrants like Amazon, Google, and Digital Therapeutics companies are all equipped with technical capabilities to tackle disease model, data analytics, and digital measurements. It likely won't take long for these companies to use AI to personalize their products and services, as well as to gain insight into life science and disrupt the drug discovery process. If we believe the future of healthcare is personalized health and disease prevention, pharma must arm themselves with the capability to achieve personalization.

It's my hope that this research will not only fill the literature gaps but also serve as a necessary catalyst that will encourage more companies to shift their strategic focus towards patients. Then the transformation of the pharma industry to become genuinely patient-centric will finally be possible.

Recommendations for Future Research

This research took a unique approach that integrated business and medical literature and offered not only a new method for examining the firms' strategic orientation but also introducing many academic theories to solve a real-world business challenge. This approach, if well accepted in medical research, could open the door for many new streams of work that apply theories in business applications. For instance, one may study the Strategic Orientation Raito (SOR) and business performance in other industries and investigate how these orientations interplay and evolve over time, and examine whether customer centricity and patient centricity are the essential ‘DNA’ of the fittest firms in the 21st century.

The textual analysis which was introduced in Chapter 2 is a useful technique that can be further utilized to investigate other important business questions. The Strategic Orientation Raito (SOR), if adopted widely, could be used to study firms that lack a single strategic orientation as an indicator of lack of focus and evaluate their performance against firms that have a single fully aligned strategic orientation. Essentially, if the lack of focus predicts poor performance, this SOR measurement can not only be used as a firm’s typology but also a functional predictor of a firm’s short- and long-term performance.

I also mentioned that in the patient-centric model, ideally, one should measure precisely the number of personalized medicines produced under the strategy of patient centricity and the actual units sold to the right patients. Unfortunately, these data are not presently available, owing to the fact that there is no official designation of personalized medicine issued by the FDA and the prescription sales data linking to the ‘right’ patients are strictly proprietary information. Therefore, in this research model, the oncology products and total sales data were used as a proxy to measure a firm’s abilities to produce personalized medicine and to reach patients and provide them access to the products. In the future, if the ideal data become available, the model may be re-visited, and if all pharma and biotech firms will be reporting their strategic orientations accurately in their 10-Ks, the relationship between patient centricity and firm performance may be further explored in a larger sample set, and the causal effect may also be explored.

REFERENCES CITED

Al-Matari, E. M., Al-Swidi, A. K., & Fadzil, F. H. B. (2014). The measurements of firm performance's dimensions. *Asian Journal of Finance & Accounting*, *6*(1), 24-49.

Andrade, G., Mitchell, M., & Stafford, E. (2001). New evidence and perspectives on mergers. *Journal of Economic Perspectives*, *15*(2), 103-120.

Bahadir, S. C., Bharadwaj, S., & Parzen, M. (2009). A meta-analysis of the determinants of organic sales growth. *International Journal of Research in Marketing*, *26*(4), 263-275.

Banker, R., Liang, Y., & Ma, X. (2016). A textual measure of strategy. *Working Paper*

Beiske, B. (2002). Research methods. Uses and limitations of questionnaires, interviews, and case studies. Retrieved from: https://books.google.com/books?id=kCEV2tLnBvEC&printsec=frontcover&dq=inauthor:%22Ben+Beiske%22&hl=en&sa=X&ved=0ahUKEwiv_p-5ptDhAhUErVkKHVu0ACYQuwUIKzAA#v=onepage&q&f=false

Boyer, K. K., & McDermott, C. (1999). The strategic consensus in operations strategy. *Journal of Operations Management*, *17*(3), 289-305.

Bridges, E., Yim, C. K., & Briesch, R. A. (1995). A high-tech product market share model with customer expectations. *Marketing Science*, *14*(1), 61-81.

Chang, S. C., & Wang, C. F. (2007). The effect of product diversification strategies on the relationship between international diversification and firm performance. *Journal of World Business*, *42*(1), 61-79.

Christensen, C. M., Hall, T., Dillon, K., & Duncan, D. S. (2016). Know your customers'" jobs to be done". *Harvard Business Review*, *94*(9), 14.

Christensen, C. (2013). *The innovator's dilemma: when new technologies cause great firms to fail*. Harvard Business Review Press.

Christensen, C. M., Raynor, M. E., & McDonald, R. (2015). What is disruptive innovation. *Harvard Business Review*, *93*(12), 44-53.

Cockburn, I. M., & Henderson, R. M. (2001). Scale and scope in drug development: unpacking the advantages of size in pharmaceutical research. *Journal of Health Economics*, *20*(6), 1033-1057.

Cohen, W. M., & Klepper, S. (1996). Firm size and the nature of innovation within industries: the case of process and product R&D. *The Review of Economics and Statistics*, 232-243.

Cohen, F. J. (2005). Macro trends in pharmaceutical innovation. *Nature Reviews Drug Discovery*, *4*(1), 78.

Comanor, W. S., & Scherer, F. M. (2013). Mergers and innovation in the pharmaceutical industry. *Journal of Health Economics*, *32*(1), 106-113.

Cool, K. O., & Schendel, D. (1987). Strategic group formation and performance: The case of the US pharmaceutical industry, 1963–1982. *Management Science*, *33*(9), 1102-1124.

Cool, K., & Dierickx, I. (1993). Rivalry, strategic groups, and firm profitability. *Strategic Management Journal*, *14*(1), 47-59.

Danielson, M. G., & Press, E. (2005). When does R&D expense distort profitability estimates?. *Journal of Applied Finance*, *15*(2).

Danzon, P. M., Epstein, A., & Nicholson, S. (2007). Mergers and acquisitions in the pharmaceutical and biotech industries. *Managerial and Decision Economics*, *28*(4-5), 307-328.

Davies (2018). *Word Cloud Generator* https://www.jasondavies.com/wordcloud/

De Felice, D. (2017). How Pharma can fix its reputation and its business at the same time. *Harvard Business Review*.

Demirbag, M., Ng, C. K., & Tatoglu, E. (2007). Performance of mergers and acquisitions in the pharmaceutical industry: a comparative perspective. *Multinational Business Review*, *15*(2), 41-62.

Demirel, P., & Mazzucato, M. (2012). Innovation and firm growth: Is R&D worth it?. *Industry and Innovation*, *19*(1), 45-62.

DeSarbo, W. S., Anthony Di Benedetto, C., Song, M., & Sinha, I. (2005). Revisiting the Miles and Snow strategic framework: uncovering interrelationships between strategic types, capabilities, environmental uncertainty, and firm performance. *Strategic Management Journal*, *26*(1), 47-74.

DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, *22*(2), 151-185.

DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics*, *47*, 20-33.

Dolgin, E. (2010). Big pharma moves from'blockbusters' to'niche busters'. *Nature Medicine, 16 (8),* 837.

Dreamer, S., & Niewiarowski, P. (2013). Lean in Novartis Pharma: sustainability through a five step deployment methodology. In *Leading Pharmaceutical Operational*

Excellence (pp. 145-152). Springer, Berlin, Heidelberg.

du Plessis, D., Sake, J. K., Halling, K., Morgan, J., Georgieva, A., & Bertelsen, N. (2017). Patient Centricity and Pharmaceutical Companies: Is It Feasible? *Therapeutic Innovation & Regulatory Science*, *51*(4), 460-467.

Dunlap-Hinkler, D., Kotabe, M., & Mudambi, R. (2010). A story of breakthrough versus incremental innovation: Corporate entrepreneurship in the global pharmaceutical industry. *Strategic Entrepreneurship Journal*, *4*(2), 106-127.

Dyer, T., Lang, M., & Stice-Lawrence, L. (2017). The evolution of 10-K textual disclosure: Evidence from Latent Dirichlet Allocation. *Journal of Accounting and Economics*, *64*(2-3), 221-245.

Falconi, A., Lopes, G., & Parker, J. L. (2014). Biomarkers and receptor targeted therapies reduce clinical trial risk in non–small-cell lung cancer. *Journal of Thoracic Oncology*, *9*(2), 163-169.

Fenton, J. J., Jerant, A. F., Bertakis, K. D., & Franks, P. (2012). The cost of satisfaction: a national study of patient satisfaction, health care utilization, expenditures, and mortality. *Archives of Internal Medicine*, *172*(5), 405-411.

Foster, J. (1997). The analytical foundations of evolutionary economics: From biological analogy to economic self-organization. *Structural Change and Economic Dynamics*, *8*(4), 427-451.

Fox, N. J., Ward, K. J., & O'Rourke, A. J. (2005). The 'expert patient': empowerment or medical dominance? The case of weight loss, pharmaceutical drugs and the Internet. *Social Science & Medicine*, *60*(6), 1299-1309.

Getz, K. A. (2015). Establishing return-on-investment expectations for patient-centric initiatives. *Therapeutic Innovation & Regulatory Science*, *49*(5), 745-749.

Ghemawat, P., Cassiman, B., Collis, D. J., & Rivkin, J. W. (2010). *Strategy and the Business Landscape*. Upper Saddle River, NJ: Pearson.

Green, S. B. (1991). How many subjects does it take to do a regression analysis. *Multivariate Behavioral Research*, *26*(3), 499-510.

Hannigan, T., Mudambi, R., & Sfekas, A. (2013). A longitudinal analysis of blockbuster pharmaceutical drugs. *DRUID Academy*.

Hall, L. A., & Bagchi-Sen, S. (2002). A study of R&D, innovation, and business performance in the Canadian biotechnology industry. *Technovation*, *22*(4), 231-244.

Hansen, G. S., & Wernerfelt, B. (1989). Determinants of firm performance: The relative importance of economic and organizational factors. *Strategic Management Journal*, *10*(5), 399-411.

Hawawini, G., Subramanian, V., & Verdin, P. (2003). Is performance driven by industry-or firm-specific factors? A new look at the evidence. *Strategic Management Journal*, *24*(1), 1-16.

Herist, K. N., Bootman, J. L., & Maine, L. L. (2013). 2013 American Association of Colleges of Pharmacy annual report. *American Journal of Pharmaceutical Education*, *77*(10).

Hibbard, J. H., & Greene, J. (2013). What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Affairs*, *32*(2), 207-214.

Hill, C. W., & Snell, S. A. (1988). External control, corporate strategy, and firm performance in research-intensive industries. *Strategic Management Journal*, *9*(6), 577-590.

How to read a 10-K. (2011). Retrieved from https://www.investor.gov/news-alerts/investor-bulletins/how-read-10-k

Howley, M. J., & Malamis, P. (2016). Preventing patient centricity from becoming a fad. *Applied Clinical Trials*, *25*(2/3), 14.

Hsieh, H. F., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research*, *15*(9), 1277-1288.

Joshi, M. P., Kathuria, R., & Porth, S. J. (2003). Alignment of strategic priorities and performance: an integration of operaations and strategic management perspectives. *Journal of Operations Management*, *21*(3), 353-369.

Kessel, M. (2014). Restoring the pharmaceutical industry's reputation. *Nature Biotechnology*, *32*(10), 983.

Lang, L. H., & Stulz, R. M. (1994). Tobin's q, corporate diversification, and firm performance. *Journal of Political Economy*, *102*(6), 1248-1280.

Li, F. (2010). Survey of the Literature. *Journal of Accounting Literature*, *29*, 143-165.

Li, F., Lundholm, R., & Minnis, M. (2013). A measure of competition based on 10K filings. *Journal of Accounting Research*, *51*(2), 399-436.

Lin, B. W., Lee, Y., & Hung, S. C. (2006). R&D intensity and commercialization orientation effects on financial performance. *Journal of Business Research*, *59*(6), 679-685.

Loughran, T., & McDonald, B. (2011). When is a liability not a liability? Textual analysis, dictionaries, and 10Ks. *The Journal of Finance*, *66*(1), 35-65.

McKee, A. (2003). *Textual Analysis: A Beginner's Guide*. Sage.

Miles, R. E., & Snow, C. C. (1994). *Organizational Strategy, Structure and Process*. New York, Mc Graw–Hill.

Mills, J., & Bourne, M. (2002). *Strategy and Performance* (Vol. 2). Cambridge University Press.

Mudambi, R. (2002). Knowledge management in multinational firms. *Journal of Iinternational Management*, *8*(1), 1-9.

Munos, B. (2009). Lessons from 60 years of pharmaceutical innovation. *Nature Reviews Drug Discovery*, *8*(12), 959.

National Cancer Institute. 2019. Retrieved from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/personalized-medicine

Nelson, R., & Winter, S. (1982). An evolutionary theory of economic growth. *Belknap-Harvard, Cambridge, MA*.

Paniz, V. M. V., Fassa, A. G., Maria de Fatima, S. M., Domingues, M. R., & Bertoldi, A. D. (2010). Measuring access to medicines: a review of quantitative methods used in household surveys. *BMC Health Services Research*, *10*(1), 146.

Petrova, E. (2014). Innovation in the pharmaceutical industry: The process of drug discovery and development. In *Innovation and Marketing in the Pharmaceutical Industry* (pp. 19-81). New York, NY: Springer.

Phillips, M. I. (2013). Big Pharma's new model in orphan drugs and rare diseases. *Expert Opinion on Orphan Drugs, 1(1),* 1-3.

Porter, M. E. (1979) *How competitive forces shape strategy. Harvard Business Review*, 57(2), 137-145.

Porter, M. E. (1980). Industry structure and competitive strategy: Keys to profitability. *Financial Analysts Journal*, *36*(4), 30-41.

Porter, M.E. (1985). *Competitive Advantage: Creating and Sustaining Superior Performance*. New York: Free Press.

Queen, M., & Roll, R. (1987). Firm mortality: Using market indicators to predict survival. *Financial Analysts Journal*, *43*(3), 9-26.

Robbins, D. A., Curro, F. A., & Fox, C. H. (2013). Defining patient-centricity: opportunities, challenges, and implications for clinical care and research. *Therapeutic Innovation & Regulatory Science*, *47*(3), 349-355.

Roberts, P. W. (1999). Product innovation, product–market competition and persistent profitability in the US pharmaceutical industry. *Strategic Management Journal*, *20*(7), 655-670.

Sally (2016). *Nordstrom's Customer Service Is The Definition of Above & Beyond.* Retrieved from https://sharpencx.com/blog/nordstrom-customer-service/

Scannell, J. W., Blanckley, A., Boldon, H., & Warrington, B. (2012). Diagnosing the decline in pharmaceutical R&D efficiency. *Nature Reviews Drug discovery*, *11*(3), 191.

Scherer, F. M. (2001). The link between gross profitability and pharmaceutical R&D spending. *Health Affairs*, *20*(5), 216-220.

Smietana, K., Ekstrom, L., Jeffery, B., & Møller, M. (2015). Improving R&D productivity. *Nature Reviews Drug Discovery*, *14*(7), 455.

Spector, R., & McCarthy, P. D. (2012). *The Nordstrom Way to Customer Service Excellence: The Handbook for Becoming the" Nordstrom" of Your Industry*. Hoboken, NJ: John Wiley & Sons.

Spotts, G. (2005). *Wal-Mart: The High Cost of Low Price*. New York: The Disinformation Company.

Stegemann, S., Ternik, R. L., Onder, G., Khan, M. A., & van Riet-Nales, D. A. (2016). Defining patient centric pharmaceutical drug product design. *The AAPS Journal*, *18*(5), 1047-1055.

Szücs, F. (2014). M&A and R&D: Asymmetric effects on acquirers and targets?. *Research Policy*, *43*(7), 1264-1273.

Tollman, P., Panier, V., Dosik, D., Biondi, P., & Cuss, F. (2016). Organizational effectiveness: a key to R&D productivity. *Nature Reviews Drug Discovery*, *15*(7), 441.

Treacy, M., & Wiersema, F. (1995). *The Discipline of Market Leaders: Choose Your Customers, Narrow Your Focus, Dominate Your Market*. New York: Basic Books.

Yeoh, P. L., & Roth, K. (1999). An empirical analysis of sustained advantage in the US pharmohaceutical industry: Impact of firm resources and capabilities. *Strategic Management Journal*, *20*(7), 637-653.

Yeoman, G., Furlong, P., Seres, M., Binder, H., Chung, H., Garzya, V., & Jones, R. R. (2017). Defining patient centricity with patients for patients and caregivers: a collaborative endeavour. *BMJ Innovations*, *3*(2), 76-83.

Venkatraman, N., & Camillus, J. C. (1984). Exploring the concept of “fit” in strategic management. *Academy of Management Review*, *9*(3), 513-525.

Zajac, E. J., Kraatz, M. S., & Bresser, R. K. (2000). Modeling the dynamics of strategic fit: A normative approach to strategic change. *Strategic Management Journal*, *21*(4), 429-453.

APPENDIX

Expansion of Analyses

Moderator (interaction) effect of Patient Centricity

Based on the analyses above, the patient centricity was found to be a statistically significant predictor of market cap and ROA performance, it is possible that patient centricity may also have a moderator effect driving the development of personalized medicine and patient access. Therefore, additional exploratory analyses to examine the interaction between patient centricity and oncology products or sales were performed and the hypotheses H4a and H4b are proposed as follow.

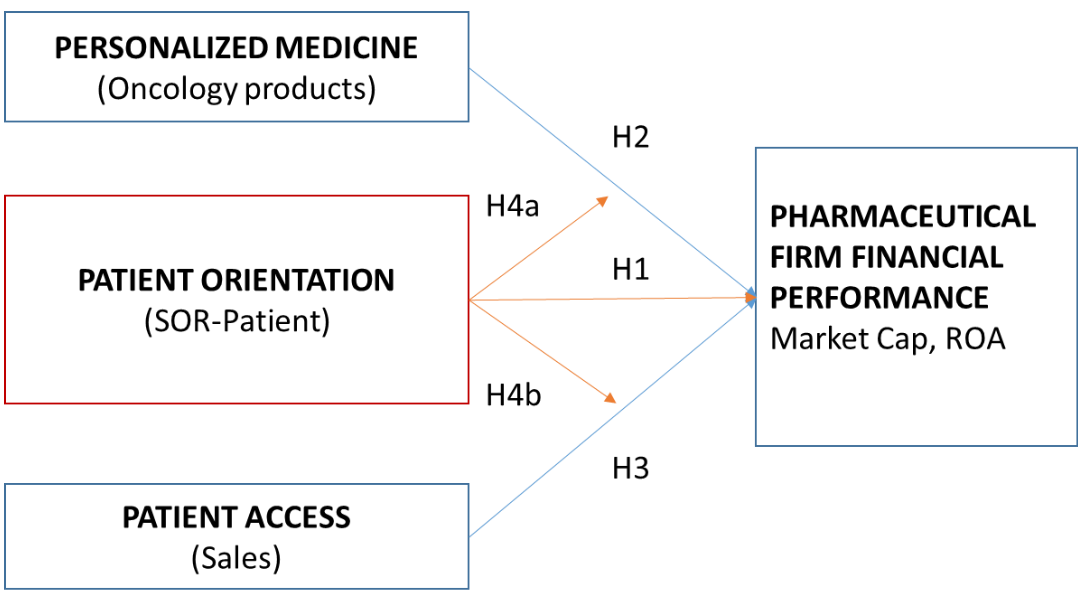


Figure 19. Conceptual Model of Patient Centricity as a Mediator and Moderator.

H4a and H4b: The degree of patient centricity (SOR-Patient) moderates the effect of H1 and H2 on firm performance.

Moderator Effect of Patient Centricity on Market Cap

To evaluate the indirect effect of patient centricity (SOR-Patient) as a moderator, i.e. the interaction between SOR-Patient and oncology products or sales, each variable was standardized by Z-scores prior to the regression analysis. As shown in the table below, the addition of patient centricity (SOR-Patient) as a moderator only improves the model minimally. The interaction between SOR-Patient and oncology products was not statistically significant, which suggests that H4a is not supported. Similarly, the interaction between SOR-Patient and sales is also not statistically significant, suggesting H4b is not supported.

Table 14. Patient Centricity is not a Moderator in Market Cap.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.872[a]	.761	.747	29162.31250	.761	54.596	6	103	.000

a. Predictors: (Constant), SORP x Sales, RnD Exp ($M), Oncology Products, SORP x Onco, SOR-Patient, Sales ($M)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
		B	Std. Error	Beta			Tolerance	VIF
1	(Constant)	2606.885	8635.015		.302	.763		
	SOR-Patient	397.873	218.576	.102	1.820	.072	.735	1.360
	Oncology Products	16162.688	4744.067	.173	3.407	.001	.896	1.117
	Sales ($M)	2.482	.451	.707	5.505	.000	.141	7.092
	RnD Exp ($M)	1.703	3.258	.065	.523	.602	.149	6.703
	SORP x Onco	3084.556	2292.927	.071	1.345	.181	.834	1.200
	SORP x Sales	-6417.156	4275.901	-.105	-1.501	.136	.478	2.093

a. Dependent Variable: Market Cap ($M)

X_1 = SOR-Patient;

X_2 = Oncology Products;

X_3 = Sales ($M)

X_4 = R&D Expenditure

X_1X_2 = SOR-Patient x Oncology Products

X_1X_3 = SOR-Patient x Sales

$$Market\ Cap\ (\omega') = Markek\ Cap\ (\omega) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \varepsilon$$

Moderator Effect of Patient Centricity on ROA

To evaluate the interaction between SOR-Patient and oncology products or sales, each variable was standardized by Z-scores prior to the regression analysis. The table below summarizes the overall model with adjusted R square = 0.294, F = 7.425, 0<0.000, respectively. The interaction between SOR-Patient and oncology products was not statistically significant but the interaction between SOR-Patient and sales is significant, which suggests that H4a is not supported but H4b is.

This model essentially suggests that besides for sales, R&D expenditure, and prior year ROA being the predictors of ROA, patient centricity has an indirect effect, moderating ROA through sales. For every unit of that interaction, it increases ROA by 2 cents per dollar.

Table 15. Patient Centricity is a Moderator in ROA.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics: R Square Change	F Change	df1	df2	Sig. F Change
1	.583[a]	.340	.294	.0423777125	.340	7.425	7	101	.000

a. Predictors: (Constant), SORP x Sales, LAGS(ROA,1), RnD Exp ($M), Oncology Products, SORP x Onco, SOR-Patient, Sales ($M)

Model		Unstandardized Coefficients B	Std. Error	Standardized Coefficients Beta	t	Sig.	Collinearity Statistics Tolerance	VIF
1	(Constant)	.107	.016		6.802	.000		
	SOR-Patient	.000	.000	.116	1.229	.222	.733	1.364
	Oncology Products	.004	.007	.045	.527	.599	.887	1.127
	Sales ($M)	3.313E-6	.000	1.084	4.994	.000	.139	7.204
	RnD Exp ($M)	-2.628E-5	.000	-1.157	-5.479	.000	.147	6.817
	LAGS(ROA,1)	.283	.083	.283	3.434	.001	.959	1.042
	SORP x Onco	.004	.003	.102	1.142	.256	.823	1.216
	SORP x Sales	.018	.006	.346	2.953	.004	.476	2.101

a. Dependent Variable: ROA

Tobin's Q

Tobin's Q is an indicator of the market valuation of the firm over its replacement value. Similar to the market cap, investors evaluate a firm's value based on its strategy, product pipeline, and operational performance. In addition, Tobin's Q was found to be associated with the firm's diversification (Lang, 1994). As such, by mimicking the market cap data model above, the effects of the direct and indirect predictors are analyzed. In the Tobin's Q model below, out of the three main predictors, both oncology products and sales are statistically significant while SOR-Patient is not. In addition, R&D expenditure exhibited a negative effect, suggesting that for every $M of R&D spent, it decreases Tobin's Q value by 0.00015. This result supported the hypotheses H2 and H3. By further evaluating the interactions between SOR-Patient and oncology products or sales, both of them were found to be statistically significant, suggesting that patient centricity, although not a predictor of Tobin's Q, plays a moderator role indirectly affecting Tobin's Q performance. As such, the hypothesis H4a and H4b are supported in this case.

Overall, this model implies that a firm that focuses on oncology products and sales can increase its Tobin's Q ratio. In addition, patient centricity (SOR-Patient) indirectly moderates Tobin's Q by strengthening both capabilities of producing oncology products and ensuring patient access through sales with a total adjusted R square = 0.205, F = 5.671, and p<0.000, respectively.

Table 16. Patient Centricity is a Mediator and Moderator in Tobin's Q

Model Summary

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	.498[a]	.248	.205	.5709110114	.248	5.671	6	103	.000

a. Predictors: (Constant), SORP x Sales, RnD Exp ($M), Oncology Products, SORP x Onco, SOR-Patient, Sales ($M)

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Standardized Coefficients Beta	t	Sig.	Collinearity Statistics Tolerance	Collinearity Statistics VIF
1	(Constant)	2.565	.169		15.154	.000		
	SOR-Patient	.001	.004	.033	.329	.743	.728	1.374
	Oncology Products	.219	.093	.212	2.354	.020	.895	1.117
	Sales ($M)	1.457E-5	.000	.376	1.737	.085	.156	6.410
	RnD Exp ($M)	.000	.000	-.516	-2.407	.018	.159	6.303
	SORP x Onco	.085	.045	.176	1.888	.062	.836	1.196
	SORP x Sales	.273	.081	.401	3.382	.001	.520	1.922

a. Dependent Variable: Tobin's Q

X_1 = SOR-Patient;

X_2 = Oncology Products;

X_3 = Sales ($M);

X_4 = R&D Expenditure;

X_1X_2 = SOR-Patient x Oncology Products;

X_1X_3 = SOR-Patient x Sales ($M)

$$Tobin's\ Q = \beta_0 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_1 X_2 + \beta_6 X_1 X_3 + \varepsilon$$

Tobin's Q was reported to be associated with the firm's diversification (Lang, 1994). The figure below illustrates that the number of therapeutic areas (TA) represented per firm (X-axis) and the 10-year average of Tobin's Q per firm (Y-axis) appear to have an inverse U relationship. Meaning, when firms possess an overly low- or high-diverse portfolio, it may lead to a lower Tobin's Q (10-year average per firm).

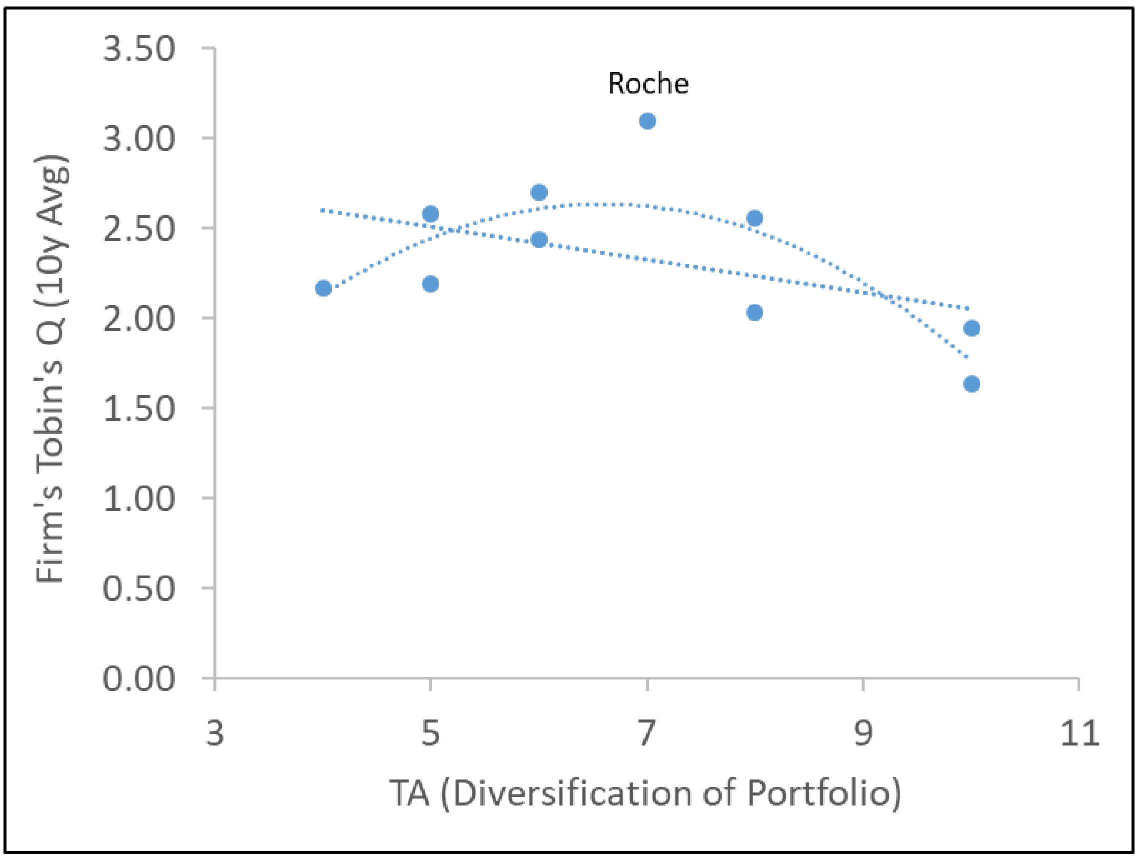


Figure 20. The relationship between portfolio diversification and Tobin's Q.