2018

Successful Marketing Strategies for Promoting Clinical Diagnostic Instrument Validation Packages

Hsiao-Ching Teng
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Hsiao-Ching Teng

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Chad Sines, Committee Chairperson, Doctor of Business Administration Faculty

Dr. Daniel Smith, Committee Member, Doctor of Business Administration Faculty

Dr. Peter Anthony, University Reviewer, Doctor of Business Administration Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2018

Abstract

Successful Marketing Strategies for Promoting Clinical Diagnostic Instrument Validation Packages

by

Hsiao-Ching Teng

MBA, Brandman University, 2015

BS, Boston University, 2009

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

Walden University

August 2018

Abstract

Successful marketing strategies for clinical validation packages not only help laboratories increase the accuracy and efficiency of testing, but also facilitate clinical quality awareness and collaboration. False diagnosis and inefficiency in healthcare can be costly, and managers in diagnostic instrument manufacturing organizations need strategies to promote validation packages to help laboratories reduce errors leading to inappropriate treatment. The purpose of this single case study was to explore strategies business development managers use to integrate dynamic capabilities for marketing instrument validation packages aimed to increase clinical laboratory quality and test accuracy. The conceptual framework was Teece's concept of dynamic capabilities. The data collection process involved semistructured interviews with 4 business development managers from a diagnostic instrument manufacturing organization in the western United States who had successfully marketed validation packages. Analysis of the audio recordings, notes from the interviews, and marketing flyers yielded 1 overarching theme, collaboration of cross-functional teams, and 4 subthemes: integration, effectiveness, partnership, and profitability. The results suggested dynamic capabilities created value for validation packages, differentiated the products and services from those from the competitors, and increased customer satisfaction and profitability. The implications for positive social change include the potential to promote validation packages to clinical laboratories and raise awareness of laboratory quality, leading to improved healthcare outcomes.

Successful Marketing Strategies for Promoting Clinical Diagnostic Instrument Validation Packages

by

Hsiao-Ching Teng

MBA, Brandman University, 2015

BS, Boston University, 2009

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

Walden University

October 2018

Dedication

I dedicate this doctoral study to my best friend and the love of my life, Prashob Vadakoot, for enduring my long nights of research and writing, and his unconditional love and support.

Acknowledgements

The advancement of this study would not be possible without the help and support of many individuals. I would like to thank my parents, Ying-Nan Teng and Feng-Chu Tiao, for raising me to believe that I can accomplish great things. I would like to thank my brother, Hsiao-Hsiang Teng, for teaching me the patience in life. I would like to thank my canine son, Hamper Vadakoot, for providing me with emotional support and comfort. I would like to thank my work mentors, Minh Dang, Gary Hand, and Bruno Gsell, for their inspiration. I would like to extend heartfelt thanks to my Chair, Dr. Chad Sines, for his mentorship and encouragement. I would also like to thank Dr. Daniel Smith and Dr. Peter Anthony for their support and guidance.

Table of Contents

Section 1: Foundation of the Study

Americans spent more than one-third of their large annual healthcare expenditure of over $3 trillion in 2012 on outpatient laboratory tests (Hicks, 2015). The costs associated with the tests, ordering of the incorrect tests, misuse of the tests, and poor quality of the tests not only can be financially burdensome to patients (Hicks, 2015; Luga & McGuire, 2014), but also can lead to delayed or incorrect treatments (Freeman, 2015). Accurate and high-quality diagnostic processes have the potential to minimize overuse in healthcare spending and improve care delivery.

In changing environments, dynamic capabilities allow organizations to integrate, build, and reconfigure internal and external resources to gain a competitive advantage (Teece, 2012). The scrutiny on laboratory quality has increased, and the compliance demands from clinical regulatory agencies have impacted the diagnostic laboratory industry (McMillan, 2016). Because regulatory environments are constantly changing to address new technologies and quality demands, organizations in the healthcare industry can use dynamic capabilities to gain productivity and profits.

The next generation sequencing (NGS) market is relatively new in the clinical diagnostic industry (Cummings, Peters, Lacroix, Andre, & Lackner, 2016). Many NGS diagnostic instrument manufacturing organizations offer instrument validation packages to their customers in clinical laboratories to help them improve and maintain laboratory quality and regulatory compliance. To increase competitive advantage and profitability, business development managers should explore good strategies for integrating dynamic capabilities when developing and marketing NGS instrument validation packages. In this

study, my goal was to contribute insight about the strategies business development managers used to integrate dynamic capabilities in marketing. My focus was NGS instrument manufacturing organizations in the western United States that offered validation packages to their clinical customers to improve laboratory quality.

Background of the Problem

The total national health expenditure in the United States was $3 trillion in 2014 (Centers for Disease Control and Prevention, 2015). The high expenditure on healthcare resources and the progress in medical diagnostics innovation has led to scrutiny by governing authorities and healthcare agencies (Chen & Scheld, 2014; Panagiotou, 2013). However, in clinical and laboratory testing, there are mandatory standards and regulations for the procedures and documentation to account for the quality assurance (Lester, Harr, Rishniw, & Pion, 2013). Many diagnostic instrument manufacturing organizations offer instrument validation packages designed to help laboratories maintain quality records.

Over-diagnosis or incorrect diagnosis of cancer in the United States can lead patients into unnecessary treatments. Unnecessary treatments have cost $100 billion a year in chemotherapy revenues (Esserman, Thompson, & Reid, 2013). Laboratory staff applying quality assurance methods such as analytical validations, a type of compliance services, are more likely to avoid incorrect diagnoses (Fitzgibbons et al., 2014); however, there is a lack of studies on how to market validation services aimed to increase laboratory quality in the United States (Smith, 2010). In this single case study, I explored how a diagnostic instrument manufacturing organization marketed the validation

packages aimed to increase laboratory quality assurance and minimize incorrect diagnoses. The study included interviews with four business development managers currently employed in an NGS oncology diagnostic instrument manufacturing organization located in the western United States. The purpose of this qualitative single case study was to explore strategies business development managers used to integrate dynamic capabilities for marketing instrument validation packages aimed to increase clinical laboratory quality and test accuracy.

Problem Statement

The inconsistent quality of oncology diagnostic laboratories can cause systematic incorrect diagnoses of cancer, leading patients into unnecessary treatments that cost $210 billion a year in chemotherapy in the United States (Hicks, 2015). Problems with diagnostic tests accounted for 47.4% of diagnostic errors in primary care settings, resulting in false positive and false negative outcomes (Plebani, 2017). The general business problem was that incorrect diagnosis of cancer frequently happens in the United States, especially when the clinical laboratories do not meet the standards of regulatory compliance. The specific business problem was that some managers in oncology diagnostic instrument manufacturing organizations lacked marketing strategies to promote instrument validation packages for increasing the accuracy of oncology laboratory test results.

Purpose Statement

The purpose of this qualitative single case study was to explore what marketing strategies successful managers in a diagnostic instrument manufacturing organization

used to promote sales of validation packages for increasing the accuracy of oncology laboratory test results. The targeted population consisted of managers in an NGS instrument manufacturing organization located in the western United States who had successfully marketed validation packages. The population was appropriate for this study because research suggested compliance services lead to resource-efficient diagnoses (Gagan & Van Allen, 2015) and most in vitro diagnostics had been certified based on the manufacturers' assessment (Enzmann, Meyer, & Broich, 2016). The reduction of testing errors and decrease in inappropriate treatment would enhance the quality of healthcare for patients (Long-Mira, Washetine, & Hofman, 2016). The implication for positive social change includes positive improvement for patient care.

Nature of the Study

The design for this qualitative single case study involved interviews with business development managers in an NGS instrument manufacturer located in the western United States who had successfully marketed validation packages. I considered three methods for this research study: qualitative, quantitative, and mixed methods. The qualitative research method allows researchers to gain insights into why people engage certain behaviors (Rosenthal, 2016), which is the most common method of data collection used in healthcare research (Leung, 2015). I chose the qualitative method for this study because it was most suitable for exploring narratives, meanings, and behaviors. The quantitative method was not appropriate for this study because this approach involves numerical data and statistical analysis (Hafford-Letchfield, 2014), and the purpose of this study did not require numerical data design or hypothesis testing. The mixed method

approach involves both a qualitative and quantitative component (Creswell & Poth, 2017), but because there was no quantitative component to the study, mixed methods was not appropriate.

I considered four qualitative research designs: narrative research, phenomenology, ethnography, and case study. Narrative design begins with the experiences of individuals that are expressed in lived or told stories and provides a means to analyze the stories (Lewis, 2015); phenomenology includes the explanation of the meaning of common lived experiences for research participants (Yin, 2014); and ethnography includes the description and interpretation of the shared and learned patterns of values, behaviors, beliefs, and language of a culture-sharing group (Creswell & Poth, 2017). However, these approaches were not suitable for this study for identifying and exploring strategies to promote products. A case study is used to explore an issue through analysis and in-depth description of a bounded system (Creswell & Poth, 2017). The case study is the most appropriate design for a study looking to define strategies to address a problem. I selected the single case study method because the focus of this research was to understand successful marketing elements. The study allowed me to explore the marketing strategies in instrument validation packages for increasing oncology laboratory testing accuracy.

Research Question

What marketing strategies do managers in oncology diagnostic instrument manufacturing organizations use to promote instrument validation packages for increasing the accuracy of oncology laboratory test results?

Interview Questions

1. Describe the validation packages that you offer for your NGS platforms.
2. Describe the target customer base for the compliance products that you offer.
3. What are your marketing strategies for the compliance products?
4. What elements of the validation package provide a competitive advantage to your company?
5. How often does your organization revise the compliance service package to reflect customer needs and attract target market?
6. How does your organization evaluate the distribution channels for the validation packages?
7. How does your organization determine the effectiveness of your marketing strategies?
8. What additional information can you share regarding marketing strategies for promoting sales of instrument validation products?

Conceptual Framework

The objective of this study was to explore some managers' lack of marketing strategies to promote instrument validation packages aimed to increase oncology laboratory quality in oncology diagnostic instrument manufacturing organizations. It is crucial to understand the regulatory needs in clinical laboratory to create and market a product that is valuable to the customers for businesses that desire to improve sales and create a positive brand reputation (Dwesar & Rao, 2014). The dynamic capabilities theory (Teece, Pisano, & Shuen, 1997) was the conceptual framework for this study

because dynamic capabilities determine organizations' ability to build, integrate, and realign internal and external resources to address changing business environments (Teece, 2010).

Dynamic capabilities refer to organizations' capability to succeed as a result of using accessible resources during rapidly changing environments (Teece, 2010). These capabilities determine the speed and degree to which organizations align or realign their resources to meet the changing requirements and opportunities (Teece et al., 1990, 1997). Due to the expansion of global clinical networks and rapid competitive responses, business owners need to develop and maintain asset alignment capabilities and collaborate with others to combine resources to deliver value to customers (Teece, 2012). I used the dynamic capabilities theory to help understand how successful managers in oncology diagnostic instrument manufacturing organizations market products and services for adding value to their compliance services in response to constantly changing regulatory environments. These organizations' ability to succeed was dependent on their ability to adapt to a changing environment and meeting new demands.

Operational Definitions

Analytical qualification: Analytical qualification is a documented verification, which includes an accuracy study to evaluate concordance between results obtained by the newly designed assay and analyzed by another method or laboratory (Grosu et al., 2014).

In vitro diagnostic products: In vitro diagnostics are reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a

determination of the state of health to cure, mitigate, treat, or prevent disease (U.S. Food and Drug Administration, 2014).

Installation qualification: Installation qualification is a documented performance test to show that the equipment is correctly installed and operates in accordance with established specifications (Sandhya et al., 2015).

Next generation sequencing (NGS): NGS is the technology to sequence millions of short fragments of DNA in parallel instead of one DNA fragment at a time (Aziz et al., 2015).

Operational qualification: Operational qualification is a documented verification to show that the system or subsystem performs as intended (Sandhya et al., 2015).

Performance qualification: Performance qualification is a documented verification that the system consistently operates within predetermined acceptance criteria (Sandhya et al., 2015).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions are beliefs that the researcher takes to be true without proof (Marshall & Rossman, 2016). Interviewing is one of the most common methods of gathering qualitative data in research and the findings from the interviews are dependent on truthfulness (Bullock, 2016). The validity of qualitative studies often depends on the participants' truthfulness, credibility, and trustworthiness (Twining, 2017). I anticipated that the managers who participated in this doctoral study answered honestly. In addition,

I assumed that the participants understood the scope of this study and were willing to provide information necessary to contribute to this research.

Limitations

Limitations are constraints beyond the researcher's control that can impact the study outcome (Marshall & Rossman, 2016). It is important to clarify the limitations in qualitative case studies. Many case studies have been performed within a specific context, which contributes to a misconception about applications in other research areas (Sangster-Gormley, 2013). The primary limitation of the study was what effects the relationship between the clinical laboratory and the compliance performance had on the success or failure of an accreditation or audit. If the laboratory managers opted to have the instrument manufacturers to perform compliance services, the results and documentation quality would rely on the manufacturer representative who performed the tests. However, a testing representative could skew the audit and accreditation results by poorly performing tests, and there was not a known methodology to screen for representatives' ability to perform instrument qualifications and analytical validations during this study. This concern was noted during the interview; therefore, the discrepancy in representatives' competence was included in this study. Future research should be done to determine if the instrument manufacturer's representative's ability to execute compliance services will impact the compliance package value.

In addition to the relationship between clinical laboratories and the instrument manufacturing organization, there were two other limitations. First, the number of four participants was small. Second, business development managers participating in this

study were limited to the area of the western United States and only those who had demonstrated success in addressing strategies for marketing NGS compliance packages.

Delimitations

Delimitations are boundaries that the researcher institutes in the study to keep it manageable (Bhat, Gijo, & Jnanesh, 2014). The researcher sets the boundaries or delimitations for an exploratory single case study (Bouzon, Miguel, & Rodriguez, 2014). Local regulatory guidance and clinical requirements can vary (Vis & Huisman, 2016), but this study was performed on one NGS instrument manufacturer located in the western United States. The research effort included in-depth interviews with managers who had successfully marketed compliance services. For this study, the compliance services provided by the NGS instrument manufacturers referred to instrument installation qualification, operational qualification, performance qualification, and analytical validation. Having the three qualifications completed on clinical instruments not only keeps the laboratory in compliance but also improves the overall knowledge of the process (Agnihotri, Kaur, Kumar, & Chahal, 2013), while analytical validation guarantees that each step and activity throughout the total testing process is correctly performed to provide valuable results for medical decisions and effective patient care (Giuseppe et al., 2013).

Significance of the Study

The inconsistent quality of oncology diagnostic laboratories' technicians can cause systematic incorrect diagnoses of cancer, leading patients into unnecessary treatments that cost $210 billion a year in chemotherapy in the United States (Hicks,

2015). Scholars have shown that good laboratory compliance can help avoid false diagnoses (Fitzgibbons et al., 2014). By adding value to these services, more laboratories' owners could market the compliance packages aimed to increase laboratory quality.

Contribution to Business Practice

Equipment validation compliance assures that the workflow is developed, maintained, and operated as designed (Agnihotri et al., 2013). Through understanding the value proposition, managers at diagnostic instrument manufacturers can channel marketing resources that add value to instrument validation packages and ultimately increase sales. The growing scrutiny on diagnostic laboratory quality has increased the demand for testing instrument performance under their intended use (Ravell & Chandramohan, 2014). The contents, quality, price, and execution efficiency for the instrument validation packages are critical issues influencing sales. Dynamic capabilities allow organizations to integrate, build, and reconfigure resources to address the changing business environments (Teece, 2012). Through continuous integration and reconfiguration of internal and external resources, managers in NGS instrument manufacturers can offer best in class validation packages in response to the rapidly changing clinical regulatory environments while achieving sales goals.

Implications for Social Change

Diagnostic laboratory results are required for making a large portion of medical decisions (Peter et al., 2010). Studies, like one conducted in Canadian laboratories on the relationship between laboratory quality and patient safety, have shown that laboratories with a solid foundation in quality enhanced patient safety by preventing several care

issues (Allen, 2013). Accreditation and validation have the potential to improve the quality of healthcare for patients through the reduction of testing errors and decreases in inappropriate treatment (Peter et al., 2010). When instrument manufacturers proactively provide compliance assistance to clinical laboratories, staff are more likely to accept and follow through with meeting regulatory requirements. As a result, the quality of patient care should improve, and healthcare resources can be allocated more accurately and efficiently.

A Review of the Professional and Academic Literature

The goal of this study was to explore marketing strategies that successful managers used to promote oncology diagnostic instrument validation packages. These compliance packages included the production of documented verification to help clinical laboratories achieve accreditation and maintain quality practices (Acuna, Collino, & Chiabrando, 2015). Dwesar and Rao (2014) stated that to effectively design and market a product that is valuable to the customers, managers must have the desire to improve. The dynamic capabilities theory is the conceptual framework for this study because dynamic capabilities help determine organizations' ability to build, integrate, and realign internal and external resources to address changing business environments (Teece, 2010). I used this theory to understand how successful managers in oncology diagnostic instrument manufacturing organizations marketed products and services to add value to their compliance services in response to constantly changing regulatory environments.

I organized the literature review according to the following six themes: (a) healthcare spending, (b) diagnostic laboratory quality, (c) accreditation and regulations,

(d) instrument manufacturing organizations' role, (e) dynamic capabilities and value in third-party validation services, and (f) resource-based theory. This review of literature consists of scholarly resources including peer-reviewed articles, books, and government reports. The roster includes 89 total references: 76 (85.4%) have a publishing date within 5 years of 2018, the expected year of CAO approval; 85 (95.5%) of which are peer-reviewed. I used the following databases to search for peer-reviewed articles applicable for my study: Google Scholar, Walden University Library, Science Direct, Emerald Management Journals, Management and Organizational Studies, EBSCOhost, and ProQuest. Within this study, I used the following search themes and terms: *clinical diagnostic instruments, diagnostic laboratory quality, total quality system, healthcare spending, CLIA inspection, instrument qualification, NGS diagnostics, laboratory-developed tests, medical device manufacturer, laboratory accreditation, dynamic capabilities,* and *resource-based view*.

Healthcare Spending

Healthcare expenditure in the United States has been a large portion of the annual spending in gross domestic products. More than one-third of the U.S. annual expenditure was spent on outpatient laboratory tests such as routine diagnostic tests and oncology screening (Hicks, 2015); however, not all laboratory tests result in the patients' best interests. The costs associated with the tests, ordering of incorrect tests, misuse of tests, and poor quality of tests not only can be financially burdensome to the patients (Hicks, 2015; Luga & McGuire, 2014), but also can lead to delayed or incorrect treatments

(Freeman, 2015). Accurate and high-quality diagnostic processes have the potential to minimize unnecessary healthcare spending and improve care delivery.

In 2010 the cost of healthcare in the United States exceeded $2.7 trillion, and up to 30% of spending was identified as wasteful (Luga & McGuire, 2014). Additionally, roughly one-third of the $2 trillion spent in the U.S. healthcare system has been linked to fraud, waste, and abuse (Thornto, Brinkhuis, Amrit, & Aly, 2015). Finally, the annual healthcare expenditure in the United States for laboratory tests was estimated at $65 billion in 2012, with approximately $6.8 billion in unnecessary laboratory testing and procedures that did not improve patient care (Freedman, 2015). NGS sequencing has been incorporated rapidly to clinical laboratory testing, including detection of germline variants in inherited diseases and somatic variants in cancers (Lyon et al., 2015). The annual cost of cancer healthcare in the United States is expected to reach $158 billion in 2020 (Young, 2015). Physicians are often unaware of the cost of tests and treatments, making it difficult to account for the financial impact (Hicks, 2015). Promoting laboratory quality to ensure that diagnostic tests are performed as efficiently as possible is a practical route to minimize healthcare cost and wasteful treatments.

As healthcare expenditures continue to rise, the efficacy and efficiency associated with the costs are under scrutiny (Vijayasree et al., 2017). Laboratory managers face challenges in testing, including the ability to accurately, efficiently, and safely order and interpret diagnostic tests. To improve current laboratory testing situation, each laboratory test must be appropriately ordered, properly conducted, reported in a timely manner, correctly interpreted, and affect a decision for treatment of the patient. Human error by

technicians such as incorrect tests ordered by the physicians, failure of guideline implementation, and inappropriate laboratory use can contribute to poor testing (Freedman, 2015).

There is a need for new strategies to address these challenges in laboratory quality. Manufacturers, regulatory agencies, and laboratories should all be involved in striving for laboratory quality measures that will lead to more cost- and resource-efficient testing (Zehnbauer et al., 2017). Additionally, Hicks (2015) stipulated that 78% of the physicians in the United States thought treatments should be solely devoted to patients' best interests, regardless of the costs. This implies that strategies to curb overuse that are driven by a financial imperative are unlikely to result in meaningful changes. By focusing on laboratory quality measures, all stakeholders can improve care delivery while reducing unintended overuse (Hicks, 2015). For instance, Luga and McGuire (2014) suggested that to contain costs by reducing waste, it is necessary to improve the effectiveness of care delivered. The NGS instrument manufacturers designed helps the systems to meet diagnostic needs and address their intended use. Validating the system using the manufacturers' established standards will ensure that the system is performing according to specifications and laboratory members are adhering to the clinical guidelines (Sandhya et al., 2015). Validating diagnostic instruments reduces the rate of poor test results from inconsistent instrument performance (Sandhya et al., 2015), which is helpful in minimizing retests and spending associated with subsequent actions. By focusing on laboratory quality measures, stakeholders can improve care delivery while reducing unintended overuse.

Diagnostic Laboratory Quality

Laboratory medicine plays a pivotal role in the provision of healthcare. The healthcare costs, treatment, and patient care are determined by the associated diagnosis from the interpretation of the clinical laboratory results. Although there are notable advances in laboratory diagnostics, a number of errors still exist that can lead to erroneous patient diagnosis and treatment. These errors are challenging to address because the scope of the testing process from accurate test ordering, appropriate sample handling, properly conducted protocols, timely result delivery, to correct interpretations (Freedman, 2015) leads to a complicated pathway that is prone to errors. Negative factors influencing test ordering by physicians, failure of guideline implementation, and inappropriate laboratory use can all contribute to poor testing. The rapid adoption of NGS in clinical testing complicates the matter as clinical NGS testing involves complex analytic wet bench processes and intensive bioinformatics analyses (Aziz et al., 2015). Ensuring all tests are conducted efficiently can not only reduce the processing costs, but also lead to meaningful results that will help deliver proper treatments to patients.

Medical errors concerning diagnosis and clinical decision-making can contribute to poor outcomes, including delayed or missed diagnoses, mortality, and excessive costs. For example, Tehrani et al. (2013) performed a study on diagnosis-related claims from the National Practitioner Data Bank from 1986 to 2010 and found that the diagnostic errors reached 28.6% and accounted for the highest proportion of total payments at 35.2%, with outcomes including death and permanent injury over 350,706 paid claims. Most error claims came from outpatient laboratory testing at 68.8%, and the sum of

diagnosis related payments was $38.8 billion (Tehrani et al., 2013). The findings from the study suggest that the public health burden of diagnostic errors is significant, and healthcare stakeholders should consider diagnostic safety an important health policy issue and a potential avenue to reduce annual spending.

Other studies have also shown that healthcare overuse can cause financial harm, and quality measures to improve care delivery can be the solution for money saving (Hicks, 2015). The efficiency of appropriate test use on patient outcomes and on cost effectiveness across the whole patient pathway is the key to improve healthcare (Freedman, 2015). Lippi, Plebani, and Graber (2016) argued that quality in laboratory medicine should guarantee that each step and activity throughout the total testing process is correctly performed to provide valuable results for medical decisions and effective patient care. Scientists have observed a 10-fold reduction in the analytical error rate after laboratories undergoing improvements in both reliability and standardization of analytical techniques, reagents, and instrumentation (Giuseppe et al., 2013). Furthermore, advancement in information technology, quality control, and quality assurance methods can also help reduce diagnostic errors (Lippi et al., 2016). Clinical instrument validation packages targeting the improvement in laboratory quality have the potential to reduce errors, minimize retests, and increase healthcare cost savings (Vijayasree et al., 2017).

Although diagnostic tests are often defined by their sensitivity, specificity, and ease of use, the actual clinical impact of such tests also depends on their availability and price (Schroeder, Elbireer, Jackson, & Amukele, 2015). This impact is especially obvious in resource-limited regions (Schroeder et al., 2015). For instance, a study conducted in

clinical laboratories in Kampala to measure the diagnostic test availability, test volumes, and pricing suggested that 50% of overall test availability was provided through private laboratories while only 36% from public laboratories (Schroeder et al., 2015). In addition, the price of the test was dependent on the test availability. The more common the diagnostic test is, the cheaper the average price (Schroeder et al., 2015). The test availability hinged upon whether the laboratory passed the regulatory inspection and obtained the authorization to perform the diagnostic test. This suggests that the overall laboratory quality can impact test prices.

Singh, Meyer, and Thomas (2014) argued that diagnostic errors pose a threat to healthcare quality and safety, including outpatient diagnostic errors. There are many reasons why diagnostic errors are difficult to monitor: varying error definitions, the need to review data across multiple healthcare providers, and the need to review care settings over time (Singh et al., 2014). From monitoring unusual patterns of return visits and the lack of follow-up of abnormal clinical findings related to cancer, diagnostic errors can be confirmed through chart review (Singh et al., 2014). Singh et al. (2014) revealed in their study an annual rate of outpatient diagnostic errors of 5.08%, indicating that approximately 12 million adults in the United States encountered diagnostic errors every year. The costs associated with these diagnostic errors are significant and cause unnecessary financial burden (Hicks, 2015).

The reduction of diagnostic testing errors and the improvement of laboratory quality contribute to not only cost-saving benefits, but also laboratory operating efficiency and advanced patient care. Abdallah (2014) argued that quality initiatives have

shown success in many healthcare organizations. Elbireer et al. (2013) also recognized the importance in clinical laboratory quality and the laboratories' function in addressing the high rates of diseases and emphasized the benefits of using a standard baseline measure of quality such as the World Health Organization (WHO) Laboratory Strengthening Checklist. Elbireer et al. showed that although laboratories with higher testing volumes tended to be of higher quality compared to low volume laboratories, there is significant room for improvement in clinical laboratories in general. Elbireer et al. recommended three areas in which focused interventions could significantly improve laboratory quality at low or no additional cost: having work conducted only by clinically qualified staff, only accepting test volumes high enough to support staff competency, and obtaining accreditations to abide by clearly-defined quality standards. The improved laboratory quality should reduce the risk of error and harm (Lippi et al., 2016).

Although many healthcare organizations that have recognized the significance in quality and patient care had success in quality initiative, some have continued to struggle in initiative implementation. Understanding drivers and challenges in quality initiative implementation from literature reviews and comparing them to current healthcare processes can help with proposing a framework that could lead to best implementation results (Abdallah, 2014; Al-Mutairi et al., 2016). The diagnostic testing laboratory's ability to provide reliable results and operational logistics are often the focal points of clinical laboratory operation (Acuna et al., 2015). By obtaining laboratory accreditation, management ensures compliance and minimized instances of error. Additionally, Acuna et al. (2015) argued that technological developments and the modular installation of

automated equipment and robotics requires adaptation and new tools for designing and implementing internal and external quality control as well as quality assurance. Because the instrument manufacturers have designed and optimized the diagnostic equipment, it can be beneficial for laboratories to use their instrument validation offerings. Marketing strategies often improve the delivery of products (Kaleka & Morgan, 2017), which can be used to enable instrument manufacturing organizations to deliver valuable products aimed to enhance the quality in clinical laboratory operation.

Diagnostic errors lead to missed opportunities to make a correct and timely diagnosis, causing patients harm. Therefore, it is important for clinical laboratories to focus on the quality of the entire testing process instead of just the analytical portion. The total testing process pertains to a number of phases of laboratory testing, from preexamination, examination, and postexamination activities (Adcock, Favaloro, & Lippi, 2016). Most laboratory errors occur in the preexamination phase, preventing clinical laboratories from delivering accurate and meaningful laboratory results (Adcock et al., 2016; Zaini, Dahlawi, & Siddiqi, 2016). In addition, extra-laboratory factors often cause a multitude of errors in the preexamination phase (Plebani et al., 2014; Sciacovelli, Aita, & Plebani, 2017). The preexamination phase activities are sample collection, handling, transportation, processing, and storage, which are often outside the control of the laboratories that performed the actual tests (Adcock et al., 2016). Having a clear and standardized quality system and using external quality assessment can help improve quality in the total testing process (Giuseppe et al., 2013).

Although striving for quality over the total testing process can minimize diagnostic errors, physicians' interpretation of the test results can contribute to inaccuracies as well, leading to missed opportunities to make a correct and timely diagnosis (Al-Mutairi et al., 2016). Bari, Khan, and Rathore (2016) showed in their study that although 98.5% of the medical practitioners described some form of error, only 11% disclosed the error to the patients' family. Even though the disclosure of error rate was low, many medical practitioners showed a positive change in their behavior and became more careful (Bari et al., 2016). Many of the instrument manufacturer-provided validation packages include customer trainings. Considering the often severe consequences caused by medical errors, the indirect value in these validation packages can be significant.

The rapid development of new cancer treatments has shifted the focus of tumor evaluation in pathology toward molecular analysis. Diagnostic molecular pathology, which determines the molecular aberrations present in tumors for diagnostic, prognostic, or predictive purposes, has faced technological challenges due to the shifted focus. Laboratory staff members have to meet the needs of comprehensive molecular testing using only limited amount of tissue; therefore, staff members must make choices for analytical methods that lead to accurate, reliable, and cost-effective results (Dubbink et al., 2014). Because the validation of the test procedures and results are critical, participation and good performance in internal and external quality assurance schemes should be mandatory (Dubbink et al., 2014). For validation of comprehensive molecular assays, laboratories should consider test conditions, including the input of DNA, setup of

standard operating procedures, determination of coverage needed, and testing software applications prior to implementing new technology in the laboratory (Dubbink et al., 2014). Revell and Chandramohan (2014) argued that validation should provide objective evidence that the total testing process is fit for the particular diagnostic purpose and meets the regulatory requirements for intended use. For laboratories residing in areas with no local consensus for validation of NGS tests, pathology laboratories should collaborate with specially trained clinical scientists in molecular pathology who are educated in design, analysis, and evaluation of molecular pathology tests and have knowledge on basic pathology (Nkengasong & Birx, 2014). Commercially available pre-designed reference standards are tools to help disease detection accuracy and parallel testing (Dubbink et al., 2014). Diagnostic instrument manufacturers often design the reference materials and have the resources to connect with various laboratories. It can be a cost-effective approach for managers in the clinical laboratories to subscribe to the validation packages that are commercially available.

Laboratory operations can affect patient results. Phillips, Njau, Li, and Kachur's study (2015) on malaria showed that accuracy in diagnostic results directly impacted treatment effectiveness. Freedman (2015) argued that the staff's ability to ensure that a test is appropriately ordered, properly conducted, reported in a timely manner, and correctly interpreted directly impacts the decision for patient treatment. Negative factors influencing test ordering by physicians, failure of guideline implementation, and inappropriate laboratory utilization could contribute to poor testing (Freedman, 2015), resulting in a delay in treatment and worsen patient condition (Hicks, 2015).

Harmonizing common testing practice can address the inconsistencies in test quality and improve patient outcomes across the whole patient pathway (Freedman, 2015).

There has been an increase in funding for global health suggesting that efficient and reliable laboratory services and networks were necessary for high quality patient care, prevention, disease surveillance, and outbreak investigations (Gershy-Damet et al., 2010). Recognizing the importance of laboratory quality globally, WHO has established a step-wise approach to help laboratories in developing countries. For example, sub-Saharan Africa improves quality by acknowledging their current status, supporting them with a series of evaluations to demonstrate improvement, and recognizing their progress (Gershy-Damet et al., 2010), so patients across the globe can receive quality treatment. Dubbink et al. (2014) suggested laboratories residing in areas where accreditation and clinical testing standards are fully established collaborate to improve quality. The involvement of WHO in diagnostic laboratories located in developing countries not only motivates laboratories to drive quality initiatives, but also infers the impact of such quality in patient care.

The diagnostic error can harm patients in many ways. For example, medical care could lead to financial harm to patients and families. In addition to financial harm, the amount of time spent on overuse could lead to a delay in effective treatment. Anxiety that medical tests trigger and the harm of social stigma could also worsen patients' condition (Hicks, 2015). The ability to measure the incidence of diagnostic errors is critical to perform research on this subject and to initiate quality improvement projects aimed to reduce the risk of error as breakdowns in the diagnostic process can lead to staggering

toll of harm on patients (Hicks, 2015; Lippi et al., 2016). The laboratory tests' turnaround time for emergency situations is often critical to patient care. Imoh et al. (2016) argued that by minimizing the quality of tests, there is potential to reduce turnaround time and improve patient survival in emergency care. This suggests that laboratory quality not only affects routine diagnostics but also emergency treatments.

There are negative effects of false diagnostic tests beyond measurable patient care, and the improved quality of tests has the potential to reduce the undesirable outcomes. Incorrect diagnoses are associated with increased patient anxiety with no measurable health utility decrement. The United States Preventative Task Force was evaluating the harm caused by false-positive mammograms due to their common occurrence and their impact on the quality of life (Tosteson et al., 2014). The findings from measuring personal anxiety, health utility, and attitudes towards future screening of 1226 participants showed that anxiety was significantly higher for women with false-positive mammograms with similar health utility scores (Tosteson et al., 2014). In addition, data from the study by Tosteson et al. (2014) suggested that future screening intentions differed by groups where 25.7% of women with false-positive results intended to obtain future screening compared to 14.2% with negative results.

Accurate and high-quality clinical support services are essential in the diagnostic process and treatment of patients. Plebani (2017) argued that in the past 50 years the need to control and improve quality in clinical laboratories had not only grown but was developed to expand along with technological developments. The introduction and monitoring of quality indicators, such as the analytical performance specifications, helped

reduce analytical errors drastically over time (Acuna et al., 2015; Plabani, 2017). To assure the most appropriate clinical outcomes, laboratory professionals should actively be involved as partners in the diagnostic team to improve upon clinical pathways and patient results. Although traditional laboratory quality efforts focus on the analytical phase, the quality of total testing process provides a more complete caliber and better insights for testing conditions.

With increasing requests in target therapies and immunotherapies, there are growing demands in good pathology laboratory practice to ensure quality of care (Washetine et al., 2017). Although there are networks which support both diagnostic and clinical inpatient and outpatient care, there is a continuous flow of information to review regarding the quality assurance strategies (Hashjin, 2015; Pandey, Pabinger, Kriegner, & Weinhausel, 2016). Hashjin et al. (2015) performed a descriptive cross-sectional study in Iran among 84 hospitals to explore their quality approach. The results showed that the average reported application rate for the quality assurance strategies ranged from 57% to 94% in the sampled population. Most frequent strategies were checking drug expiration dates (94%), pharmacopoeia availability (92%), equipment calibration (87%), and identifying staff responsibilities (86%). Hashjin et al. (2015) suggested that clinical chemistry and microbiology laboratories held the highest quality standards, and private-for-profit hospitals valued quality more than governmental hospitals as there was room for improvement in general. Accurate and high-quality clinical support services are essential in the diagnostic process and treatment of patients and both private-for-profit and governmental hospitals should reassess their quality assurance strategies frequently.

Good laboratory practices not only enhance test quality and efficiency but also improve laboratories' technical processes, competitive advantage, and market share (Manickam & Ankanagarl, 2015). Since quality has become a critical measure of performance and customer satisfaction, accreditation becomes an opportunity for laboratories to reassure their customers (Manickam & Ankanagarl, 2015). Marques, de Figueiredo, and de Gutierrez (2015) performed a study in Brazil and found poor health services contributed to poor patient care and unmet patient needs. The effectiveness in breast cancer screening in Brazil was low and customer satisfaction was below expectation, leading to more than 13,000 annual deaths in 2012 (Cecilio et al., 2015). The study in Brazil showed the importance of good laboratory practices and how it directly affected laboratories' commercial operations and mortality.

Laboratory medicine plays a pivotal role in the provision of healthcare; however, human errors have compromised clinical laboratory test accuracy (Li et al., 2016; Vecellio, Maley, Toouli, Georgiou, & Westbrook, 2015). To help reduce errors, Li et al. (2016) investigated possible causes and interventions by examining disqualified samples. Five error interventions were introduced: the integration of quality management system of samples in the pre-analytical phase into clinical information system, the application of standardized procedure on patients' preparation, the standardization of sample collection process, the establishment of green channel for sample delivery, and the implementation of double-signing confirmatory system (Li et al., 2016). The findings showed that after 1-year's intervention, the incidence of pre-analytical errors decreased from 1.36% to 0.94%

(Li et al., 2016). This indicates that intervention measures can be effective, and human errors impact not only laboratory quality but also patient care.

Accreditation and Regulations

The scrutiny on laboratory quality has increased over the years, and the compliance demands from clinical regulatory agencies have impacted the diagnostic laboratory industry. The FDA advanced two guidance drafts in 2014 for laboratory-developed tests to set a regulatory framework for next-generation sequencing (Evans, Burke, & Jarvik, 2015). This initiative has kindled debates not only about the legal authority of the FDA for genomic testing but also the potential impact this regulation had on discovery and innovation. Typically, after the next-generation sequencing and other genomic tests identified a genetic variant, clinical validity would speak to its effect on health (Evans et al., 2015). There are significant challenges for clinical validity in laboratory-developed tests because the FDA only recognizes 76,606 unique variants with clinical interpretations, leaving millions of variants for which the FDA would require premarket studies to demonstrate clinical validity (Evans et al., 2015). The costs and delays to comply with premarket studies could deter many laboratories from providing anything beyond variant calls, driving laboratories in the United States out of the global business of genomic interpretation and diminishing the safety of American consumers.

Due to the recognized importance in laboratory quality, there has been an increase in development funding for global health, suggesting that efficient and reliable laboratory services and networks are necessary for high-quality patient care, prevention, disease surveillance, and outbreak investigations (Gershy-Damet et al., 2010). Breakthrough of

the health status and disease detection required new strategies to control the processes (Acuna et al., 2015). WHO has established a step-wise approach to help laboratories in developing countries to improve quality by acknowledging their current stand, supporting them with a series of evaluations to demonstrate improvement, and recognizing their progress (Gershy-Damet et al., 2010). The lack of accreditation suggested that fulfilling the requirements of international and regional laboratory accreditation schemes was not commonly perceived as immediately feasible due to the current state of the laboratories. Factors that affect accreditation feasibility include the lack of trained laboratory experts, weak quality management systems, and the high cost associated with participation in international accreditation schemes (Gershy-Damet et al., 2010). The accessibility, affordability, scalability, and sustainability of quality programs in laboratories located in developing countries are the determining factors for enrollment (Gershy-Damet et al., 2010). Affordable validation services performed by trusted instrument manufacturing organizations can be a solution for these laboratories.

The increasing scrutiny for laboratory quality is a global phenomenon. For developed countries, such as the United States, the regulatory agencies continue to improve their efforts in assisting laboratories to strive for better quality. Both Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) Laboratory Accreditation Program require clinical laboratories to verify performance characteristics, especially when introducing an unmodified approved test system, such as a medical diagnostic instrument. To comply with these requirements, periodic calibration and calibration verification should be performed (Killeen et al.,

2014). Complying with clinical requirements helps make good medical decisions, and there is value in having periodic calibration and verification performed on diagnostic instruments.

For developing counties, such as most African countries, it is challenging to achieve laboratory quality standards set up by developed countries (Mbah et al., 2014; Nkengasong & Birx, 2014). Nigeria has adopted WHO's improvement process towards accreditation in 2010, and the quality effort implemented resulted in measurable and positive impact on the laboratories in Nigeria (Mbah et al., 2014). To compete with global laboratories, managers in health laboratories in Nigeria continue to implement further improvements toward formal international accreditations (Mbah et al., 2014). The increased scrutiny in laboratory quality is observed not only in developed countries but also in developing countries and there is a demand for services designed to streamline the quality initiatives.

The current status of laboratory quality requirements may not be sufficient to ensure good quality, leading to potential compromises on patient care. Plebani, Sciacovelli, Aita, Padoan, and Chiozza (2014) argued that current laboratory accreditation recognizes the need to evaluate, monitor, and improve all the procedures and processes in the initial phase of the testing cycle but grouped pre-analytical errors into identification and sample problems. Lippi et al. (2016) argued that most of the approaches to improve diagnostic error rate have limitations. To provide valuable laboratory services, accreditation agencies should establish quality indicators, which allow the identification of errors and nonconformities, that can occur in all steps of the

pre-analytical phase (Plebani et al., 2014). Continuous updates and sustainable quality initiatives can minimize preventable patient harm.

The need for assurance in quality, cost reduction, and government regulation compliance has brought increased focus on validation in clinical diagnostic and pharmaceutical industry (Vijayasree et al., 2017). Three types of process validation according to the requirements stipulated by the United States Food and Drug Administration (FDA): prospective process validation, concurrent process validation, and retrospective process validation (Vijayasree et al., 2017). These process validations differ in the stage where documented evidence was established. Regarding the phases of process validation, phase 1 covers the pre-validation phase or the qualification phase, phase 2 covers the process validation phase, and phase 3 covers the validation maintenance phase (Vijayasree et al., 2017). There are four elements of validation: design qualification, installation qualification, operational qualification, and performance qualification. For each element, it is important that good manufacturing practices are observed to ensure reliability and efficiency (Vijayasree et al., 2017). Quality must be consistent at every step of the process, and performing a quality check only at the end of each product cycle is not sufficient to meet the stringent quality requirements stipulated by the United States FDA (Vijayasree et al., 2017).

Official regulatory requirements for laboratories are getting more stringent. As a result, good laboratory practice, good automated laboratory practice, and good manufacturing practice carry increased values; however, with the required stringent validation of analytical equipment and methods, the analysis costs increase significantly

(McMillan, 2016). Diagnostic instrument manufacturing organizations design and develop clinical diagnostic systems and are often equipped with resources to assist their customers in complying regulatory requirements. McMillan (2016) recommends that clinical laboratories use instrument hardware validated by manufacturers to gain efficiency in method development.

Next-generation sequencing (NGS) and its applications have been growing in clinical industry and public health laboratories. The complexities of these next-generation sequencing assays called for a new set of standards to ensure testing quality as old established standards might not be applicable (Gargis, Kalman, & Lubin, 2016; Lyon et al., 2015). Targeted therapy is the current standard of practice for patients with hematologic malignancies (Kanagal-Shamanna et al., 2016). This type of therapy includes NGS-based analysis performed in clinical laboratories. The technology is fairly new and complex, leading to substantially different validation and test implementation between laboratories. There are three stages in the testing process: test development, test validation, and quality management (Kanagal-Shamanna et al., 2016). The test development phase includes sample preparation, target enrichment, sequencing, and analysis (Quail et al., 2012). General assay conditions, coverage, sample pooling, and analysis setting are all factors impacting the entire workflow in this phase (Kanagal-Shamanna et al., 2016). For the test validation phase, laboratory staff should validate the entire test using established conditions, including known sensitivity, specificity, robustness, and reproducibility (Kanagal-Shamanna et al., 2016). In the quality management phase, laboratories should implement quality control in every sequencing

run and periodically perform staff proficiency tests (Kanagal-Shamanna et al., 2016). NGS applications have challenged validation, quality control, and data interpretation beyond what clinical laboratories previously encountered (Lyon et al., 2015), and clinical regulatory agencies are revising quality requirements rapidly to ensure these new applications are properly conducted.

Given the rapid growth in the numbers of laboratory-developed tests, the FDA has become concerned that the absence of its oversight could compromise patient safety (Evans et al., 2015; Sidawy, 2015). As a result, the FDA outlines the laboratory requirements for reporting laboratory-developed tests and adverse events related to testing. The recent published FDA oversight ensured both analytical validity and clinical validity through its premarket review or approval process before a test was offered for clinical use (Caliendo & Hanson, 2016; Sidawy, 2015). When a laboratory made a significant change to the test, the test would be considered a new test and a notification should be provided before offering the modified laboratory-developed test. This FDA oversight for laboratory-developed tests has the potential to strike a balance that ensures patient safety without limiting beneficial and innovative test offerings. The oversight development shows that there is increasing quality scrutiny even for newly developed technology, such as the laboratory-developed tests.

The laboratory-developed tests can be approved for clinical use under CLIA in the United States (Ferreira-Gonzalez et al., 2014). The FDA considers these laboratory-developed tests to be medical devices under their regulatory jurisdiction; therefore, these tests are subject to regulatory scrutiny. Since CLIA allows clinical laboratories to modify

FDA-approved tests to develop their own tests as long as the laboratories follow the requirements to validate the performance characteristics of the laboratory-developed tests, the development of such tests has flourished, particularly when a medically-needed diagnostic is not available in an FDA-approved version (Genzen, Mohlman, Lynch, Squires, & Weiss, 2017). Contrary to the FDA's regulatory jurisdiction, most clinical laboratories do not agree that laboratory-developed tests are a medical device, but a medical service (Ferreira-Gonzalez et al., 2014). As a result, most laboratory managers focused their validation process on analytic validity through accuracy and reliability as recommended by CLIA guidelines instead of FDA's guidelines for good manufacturer practice. Ferreira-Gonzalez et al. (2014) reasoned that there is a need for an enhanced regulatory framework for these laboratory-developed tests because they pose risks to patient care and well-being. A good enhanced framework should come with the best features of CLIA's regulatory framework for clinical laboratories with attention to the FDA's approach for certain diagnostic medical devices. In addition, there is a need for a standardized validation process and such a standard should be developed and maintained with the assistance of an objective third-party body of experts to ensure independent review.

The accreditation and regulation demands increased as the clinical biochemistry professional worked continuously to provide reliable results and optimize operational logistics (Acuna et al., 2015). Through obtaining laboratory accreditation, the laboratories ensure quality compliance while minimizing instances of error (Acuna et al., 2015; Manickam & Ankanagarl, 2015). There are new challenges in obtaining accreditation as

technological developments, the modular installation of automated equipment, and robotics require adaptations and new tools for designing and implementation of internal and external quality control as well as quality assurance. Additionally, breakthrough of health status and disease detection required new strategies to control the processes. The clinical accreditation should be considered mandatory in clinical laboratories because data have shown accreditation increased compliance in analytical quality management system (Acuna et al., 2015). For many countries, the voluntary clinical laboratory accreditation drives the costs of obtaining accreditation (Acuna et al., 2015). To drive a culture of total and continuous clinical quality assurance, a network of partnerships should be in place to gather resources and achieve affordable quality initiatives (Evans et al., 2015).

The rapid adoption of NGS in clinical testing called for the development of new laboratory standards to regulate this technology. Aziz et al. (2015) suggested that a checklist for clinical NGS testing that set standards for the analytic wet bench process and for bioinformatics analyses could help set quality standards. The newly-added quality requirements by CLIA committee are used to address documentation, validation, quality assurance, confirmatory testing, exception logs, monitoring of upgrades, variant interpretation and reporting, incidental findings, data storage, version traceability, and data transfer confidentiality (Aziz et al., 2015). These new additions will standardize laboratory quality and should be adopted quickly by diagnostic laboratories to prevent gaps in patient care.

The development of new cancer treatments has shifted the focus of tumor evaluation in pathology towards molecular analysis (Cummings et al., 2016). Diagnostic molecular pathology, which determines the molecular aberrations present in tumors for diagnostic, prognostic, or predictive purposes, has faced with tissue and technological challenges due to the shifted focus (Dubbink et al., 2014). The laboratories have to meet the need of comprehensive molecular testing using only limited amounts of tissue, so choices must be made for analytical methods that lead to accurate, reliable, and cost-effective results. The validation of the test procedures and results are critical. Participation and good performance in internal and external quality assurance schemes is mandatory (Dubbink et al., 2014).

For validation of comprehensive molecular assays, Dubbink et al. (2014) suggested laboratories consider test conditions, including DNA-input, setup of standard operating procedures, determination of coverage needed, and testing software applications prior to implementing of new technology in the laboratory. For laboratories residing in areas with no local consensus for validation of NGS tests, collaboration amongst clinical scientists or using commercially-available pre-designed reference standards is critical for detection accuracy (Dubbink et al., 2014). Poor laboratory performance can lead to closure of the laboratory. It is in the best interest of laboratories to improve quality and testing reliability.

Although obtaining accreditation seems to be a pathway to good laboratory quality and improved patient care, it is up to debate whether or not the quality standards are maintained after the laboratories receive accreditation. Dekaran and O'Farrell (2014)

performed a study to find out whether accredited hospitals and laboratories maintained quality and patient safety standards over the accreditation life cycle. Four phases of the accreditation life cycle were established: The initiation phase, the pre-survey phase, the post-accreditation phase, and the stagnation phase (Dekaran & O'Farrell, 2014). The initiation phase involved laying the foundation for achieving compliance with quality standards. The pre-survey phase occurred within 3 to 5 months of the accreditation survey, including a mock survey that identified existing quality gaps. The post-accreditation phase referred to the period immediately after the accreditation survey. In the post-accreditation phase, most hospitals fell back towards pre-accreditation levels immediately because the staff no longer felt the pressure to perform optimally (Dekaran & O'Farrell, 2014). Dekaran and O'Farrell (2014) also reported a stagnation phase, following the post-accreditation slump, in which hospitals and laboratories operated with no new initiatives to drive further improvements. The findings from Dekaran and O'Farrell's study (2014) suggested a reduction in compliance immediately after the accreditation survey. The lack of subsequent fading in quality performance was assuring to stakeholders as accredited hospitals and laboratories overall provided services of better quality than those that were not accredited.

Good laboratory practices not only enhance test quality and efficiency but also improve laboratories' technical processes, competitive advantage, and market share. Manickam and Ankanagarl (2015) argued that accreditation is the process that ensures good laboratory practices are implemented. To get accredited, laboratories should implement a successful laboratory management system. Manickam and Ankanagarl

(2015) showed that the size of the laboratory was irrelevant in its decision to implement a quality system; however, there were differences in the safety aspect: small laboratories carried lower safety index compared to larger facilities in the sample population. In addition, Manickam and Ankanagarl's study (2015) showed the quality system management implementation process was not generally practiced effectively as there was a lack of quality measures for series of inter-related steps involving the use of instruments, reagents, staff, and related resources, which caused inefficiency in test results. There is a business opportunity for instrument manufacturing organizations to sell validation services that can address the quality gaps involving the use of instruments, reagents, and staff.

Clinical audit is a process that provides opportunities for continual improvement. Since laboratory efficiency is directly connected to test result turnaround time, the clinical improvements in emergency tests are critical to patient care (Imoh, Mutale, Parker, Erasmus, & Zemlin, 2016). Imoh et al. (2016) administered a 6-month retrospective audit to determine the root cause of non-conformities and assess the effectiveness of changes made. Of the total of 1505 cerebrospinal fluid chemistry requests, the study found most delays occur during the transport of samples to the laboratory, especially during after regular work hours (Imoh et al., 2016). The findings offered an insight that drove changes to pre-analytical practices in the laboratory that would help improve test turnaround time and customer satisfaction. This study presented the advantages of clinical audits in addition to ensuring laboratory compliance such as patient health and customer satisfaction.

Tzankov and Tornillo (2016) argued that accreditation of clinical laboratories is a matter of course in the industrialized world. Early studies suggested that auditing laboratories apply standards established by trial-and-error, book knowledge, other evidence, or tradition. This led to a 55% accreditation rate and 10% fail rate while the other 35% required significant efforts to meet accreditation requirements (Tzankov & Tornillo, 2016). Although accreditation provided a hallmark of performance and competence, it could not substitute for professional competence (Tzankov & Tornillo, 2016). Some laboratory errors still occurred in accredited laboratories, suggesting that accreditation could not prevent all mistakes. Furthermore, according to the ISO accreditation guidelines, all processes, procedures, and examinations related to pathologic diagnostics must be documented as standard operating procedures that are current and accessible to the laboratory staff, providing practical advantages (Tzankov & Tornillo, 2016). Tzankov and Tornillo's experience (2016) showed that accreditation provided practical advantage by standardization, helped eliminate waste, reduced unnecessary interfaces and intermediate steps, improved processes and procedures, and decreased the number of technical errors. The caveats for laboratory accreditation were that it should be meant to improve the end results for patients. Processes often had limited influence on results and introduced bureaucracy. Tzankov and Tornillo (2016) argued that although there are proven advantages of accreditation, the excessive multiplication of written documents demanded is unnecessary. Purchasing already standardized documented validation packages, such as the instrument installation qualification, operational qualification, and analytical validation, can reduce the burden of producing written

documents for clinical laboratories and allow laboratory members to focus on helping patients.

Not everyone agrees that laboratory accreditation can improve clinical quality. Wilson, Smye, and Wallace (2016) argued that ISO accreditation arose from factory inspection during World War II, which can be obsolete. Wilson et al. (2016) reviewed data from 14 years of internal and external laboratory audits that checked compliance with ISO 17025 in a public health laboratory and found that most non-compliance came from clauses in the standard that would not affect patient results. Because fewer than 1% of non-compliances were likely to produce poor quality of laboratory service, Wilson et al. (2016) recommended that management obtain positive proof before using the standards to deliver the efficacy, effectiveness, and value required of modern healthcare interventions. Contrary to Wilson et al. (2016), Zehnbauer et al. (2017) argued that well-developed formal evaluation including reference samples and standardization are necessary. It is in patients, providers, payers, manufacturers, regulatory agencies, and laboratories' best interest to strive for not only consistent and accurate testing results but also transparent and comparable outcomes with quality measures implemented across test platforms.

Obtaining accreditation and abiding by regulatory requirements is not just a quality initiative for clinical laboratories. Physicians are the primary customers of the clinical laboratory (McCall et al., 2016). Both the College of American Pathologists (CAPs) Laboratory Accreditation Program and the Joint Commission recognize the importance of customer satisfaction as part of their respective accreditation programs

(McCall et al., 2016). In addition to monitoring laboratories' communication processes, the efficiency in information transfer, completeness of test requisition, timeliness of reporting results, and report accuracy are all included in the customer satisfaction evaluation (McCall et al., 2016). McCall et al. (2016) concluded that high physician satisfaction and loyalty with clinical laboratory services helped laboratories remain accredited. Clinical laboratories looking to retain customers should consider laboratory accreditation as not only a quality indicator but also part of customer satisfaction assessment.

Instrument Manufacturing Organizations' Role

Diagnostic instrument manufacturing organizations are not just providers for the equipment but also facilitators in research, healthcare, and quality management. Fleming performed a study in 2015 to show the relationship between medical device funding and innovation. In the early stage of the device development, device safety and effectiveness play an important role (Fleming, 2015). In the midstage, stability, regulatory standards, and clinical trial plans become crucial to funding decisions (Fleming, 2015). Throughout the innovation process, regulatory and reimbursement policies have a profound impact on the amount of capital in laboratories (Fleming, 2015). Using data from quarterly investment statistics submitted by the venture capital industry since 1995, Fleming (2015) compared the four quarters of 2009 to 2014 and found the amount invested in life sciences and biotechnology companies shrank and that FDA approvals had the highest impact on the investors' decision making. One of the key factors that Fleming (2015) argued could affect funding was regulatory policies. Since compliance service packages

are designed to help clinical laboratories pass regulatory inspections and establish good laboratory practices, there is value in using instrument manufacturing organizations' validation products. These manufacturing organizations' representatives can take care of the compliance documentation while scientists focus on innovation.

In addition to facilitating innovations, instrument manufacturing organizations can help laboratories streamline the quality processes. Accurate and high-quality clinical support services are essential in the diagnostic process and treatment of patients (Hashjin et al., 2015). Quality assurance strategies in clinical inpatient and outpatient care involve checking reagent expiration dates, pharmacopoeia availability, equipment calibration, and identifying staff responsibilities (Hashjin et al., 2015). Lanman et al. (2015) suggested performing a thorough analytical validation on the entire NGS workflow to prevent false positive results. Lyon et al. (2015) stated NGS applications are unique which add complexity in validation quality control and data interpretation. The major challenge in validating an assay involves optimizing three components at once: the sequencing platform, the specific test of genes, and the bioinformatics pipeline (Lyon et al., 2015). Each time one of the three components changes, the entire workflow must be re-validated. Since these validations take days to weeks to complete, the costs associated with re-validation are not trivial (Lyon et al., 2015). Another commonly faced challenge is the ability to identify a gold standard set of samples and sequence data containing a broad heterogeneity of known sequence variants (Lyon et al., 2015). The instrument manufacturing organizations often manufacture the corresponding reagents, assays, and control samples. In addition to understanding the instrument specifications and functional

tests, representatives from the manufacturing organizations have access to workflow and instrument compatibility and test data. It is beneficial to clinical laboratories to collaborate with manufacturers on total workflow validations.

Having instrument manufacturing organizations perform instrument validation can help standardize laboratory quality because the validation process will be identical. Miller, Tate, Barth, and Jones (2014) argued that harmonization of clinical laboratory test results will lead to results comparable irrespective of the processing procedure used and where or when the results were obtained. The uniform test results can help physicians reach diagnoses more efficiently; however, poor coordination of the effort among different professional organizations can lead to terminology confusion, ambiguous calibration traceability to a reference system, poor reference material, and unclear specificity of the measurement of the biomolecule of interest (Mill et al., 2014). The solution to clinical harmonization is to have organized global support (Nkengasong & Birx, 2014). Instrument manufacturing organizations are often equipped with a support system to deliver cost effective and clinically optimized laboratory services to achieve clinical harmonization.

Having instrument manufacturing organizations perform diagnostic instrument validations does not always guarantee quality. Powell et al. (2013) concluded that third-party audits and inspections, although independent and within legal framework, cannot prevent all the mishaps. Understanding the limitations of inspections and the scope of third-party services is a more practical quality verification method (Powell et al., 2013). Sciacovelli et al. (2017) stated that active participation in inter-laboratory comparison

allows information on the performance level because laboratories can partake in numerous initiatives that promote the reduction of errors and enhancement of patient safety and at the same time, share experiences and resources with other clinical laboratories. Since many of the laboratories use the same brand of diagnostic instruments, the instrument manufacturing organizations can be the intermediaries that connect laboratories.

Acquisition of new equipment or implementation of any new diagnostic assay in clinical laboratories requires validation and verification (Revell & Chandramohan, 2014). It is critical that the laboratory collects subjective and objective specifications to map out the potential process change and define functional criteria. There are practical considerations involved in the selection and implementation of new equipment and assay so that the laboratories can maintain or improve the reliability, efficiency, and clinical utility of the testing systems. These considerations include: changing clinical needs of the community served by the laboratory, new guidelines or recommendations for diagnostic testing by regulatory agencies, emergence of new and promising technologies, a need for improved turnaround times for critical tests, and clinicians' interest in providing tests that have improved diagnostic confidence (Revell & Chandramohan, 2014). Verification and validation provide important objective evidence that the system is fit for purpose and meeting particular requirements for intended use (Sandhya et al., 2015). In addition, monitoring and disseminating information about trends in proficiency testing performance could assist individual laboratories in assessing their quality and performance compared to other similar laboratories (Revell & Chandramohan, 2014).

Instrument manufacturing organization provided validation services are helpful in achieving objective evidence and compare trends.

Official regulatory requirements for laboratories are getting more stringent. As a result, good laboratory practice, good automated laboratory practice, and good manufacturing practice carry increased values; however, with the required stringent validation of analytical equipment and methods the analysis costs increased significantly (McMillan, 2016). Clinical laboratories should use instrument hardware validated by manufacturers to gain efficiency in method development and to control costs.

Instrument manufacturing organizations' global presence and network can help bridge the gaps in laboratory accreditation programs between developing countries and developed countries. Smits, Supachutikul, and Mate (2014) argued that accreditation programs in the low- and middle-income countries follow the same basic structure and process as the developed countries; however, in low- and middle-income countries, the focus is primarily on improving overall care while supporting the under-performing facilities, different from developed countries where the accreditation efforts focus on identifying the best institutions that meet the stringent evaluations. Instrument manufacturing organizations' global product placement can help gather information on new accreditation requirements as well as standardize laboratory protocols through common customer training and documentation process.

Engineers in instrument manufacturing organizations set the instrument specifications' intended use. Scientists in these organizations design the control samples to verify test results that are generated by the instruments. As a result, the manufacturing

organizations own most technical knowledge for the equipment they design and manufacture (Hill, 2011). Instrument validation is a prerequisite for commissioning equipment, and it ensures that the intended process meets the desired outcomes (Agnihotri et al., 2013). Laboratories rely on information supplied by the manufacturers when introducing new measurements into the laboratory (Hill, 2011). Revell and Chandramohan (2014) found it is critical that the laboratory collects subjective and objective specifications to map out the potential process change and define functional criteria when introducing new equipment. Since verification of clinical instruments is mandatory for clinical diagnostic use (Vis & Huisman, 2016), using validation services provided by the instrument manufacturing organizations can be an efficient method to verify prevision, accuracy comparability, carryover, background, and linearity of diagnostic output according to the original designed range of acceptance criteria.

There is a trend leading towards personalized precision medicine. As a result, the broad and sustainable availability of accurate and precise diagnostic tests have become crucial factors for the success of the innovative targeted therapies (Enzmann, Meyer, & Broich, 2016). The current regulatory standards require in vitro diagnostics be certified based on their manufacturers' assessment (Enzmaan et al., 2016) and mandate laboratories to follow equipment manufacturing organizations' directions to operate the diagnostic instruments (Endrullat, Glokler, Franke, & Frohme, 2016) so that there is data traceability and reproducibility. Sandhya, Bonthagarala, Sai, and Sivaiah (2015) argued that installation qualification, operational qualification, and performance qualification are the most valid process validation methods to assure quality. Instrument manufacturing

organizations' validation packages include installation qualification, operational qualification, and performance qualification. By purchasing these validation packages, members in clinical laboratories can assure quality without the concerns for defining the process validation elements.

Aside from having the most technical knowledge of the instruments, manufacturing organizations often have more resources to follow regulatory requirements. Lyon et al. (2015) found that the ability to identify a gold standard set of samples and sequence data is critical for NGS data quality and validation success. Miller et al. (2014) argued that an extensive global reference system is the solution to data interpretation confusion, which can cause laboratories citations from local regulatory agencies. In developing countries, the regulatory requirements for clinical laboratories can vary vastly from developed countries (Nkengasong & Birx, 2014), and it can be a challenge for individual laboratories to follow constantly-updated regulatory information. Smits et al. (2014) concluded that when a clinical organization expands its business, they often need assistance in keeping up with the quality to pass accreditations. Zehnbauer et al. (2017) stressed the importance of standardization in achieving consistent and accurate testing results across test platforms. Keeping up with evolving regulatory requirements can be a challenge for clinical laboratories. Instrument manufacturers' dedicated regulatory and compliance teams have the resources to stay up-to-date with compliance rules and can alleviate such stress from their customers – the clinical laboratories.

Dynamic Capabilities

Dynamic capabilities are higher-level competences that allow organizations to integrate, build, and reconfigure internal and external resources to address and shape the rapidly changing business environments (Salvato & Vassolo, 2017). Barrales-Molina, Martinez-Lopez, and Gazquez-Abad (2014) argued that marketing resources and capabilities play an important role in determining the needs of customers and distribution channels. The organization's dynamic capabilities can directly impact its marketing resources (Barrales-Molina et al., 2014). Kaleka and Morgan (2017) argued that due to the expansion of trade and rapid competitive responses, business managers need to develop and maintain asset alignment capabilities and collaborate with each other to combine resources to deliver value to customers. The organization's ordinary capabilities allow it to perform efficiently; however, dynamic capabilities are what enable the enterprise to position itself to address market needs and the competitive opportunities of the future (Salvato & Vassolo, 2017). Due to the nature of dynamic capabilities, innovating organizations looking to pioneer a market or a new product category depend on them to succeed. The NGS market is relatively new in the clinical diagnostic industry (Cummings et al., 2016), and diagnostic instrument manufacturing organizations can utilize dynamic capabilities to drive sales in their instrument validation packages.

The purpose of an organization is to enable and facilitate coordination and collective effort by individuals; however, entrepreneurial and professional management ability often is not sufficient to manage the economic activity that exists in the organization (Kaleka & Morgan, 2017). Managers in the organization direct operations

and are often the agents of the principals. As a result, managers usually have considerable strategic discretion over the allocation of resources (Kaleka & Morgan, 2017). In a competitive market, entrepreneurs and managers need to orchestrate necessary responses to technological and market changes to maintain organizational continuation (Teece, 2014). The dynamic capabilities framework invites further research into entrepreneurship, organizational learning, and the role of managers in enterprise performance (Teece, 2014). In addition, dynamic capabilities focused on economic flexibility, adaptability, integration, and disintegration (Kaleka & Morgan, 2017). Current business environments with changing technology require the understanding of complex business organizations and contemporary management practices in high-performing enterprises, and dynamic capabilities framework could serve as practical guidelines.

There are relationships between laboratory staff and medical device representatives that can affect sales. The financial connections between the medical device industry and clinical staff can contribute to clinical reliance on industry product claims (O'Connor, Pollner, & Fugh-Berman, 2016). O'Connor et al. (2016) performed a study and showed medical device representatives who visited hospitals daily and were made available by phone for 7 days a week had better sales results. The relationship between the medical device representatives and the clinical staff impacted the costs and device selection dynamics (O'Connor et al., 2016). O'Connor et al. (2016) concluded that the two major factors influencing clinicians' equipment choices were the costs and the quality of the services offered by the medical device representatives who sold them. Beatty et al. (2016) argued that companies can struggle to deliver excellent service if they

do not understand and plan for customer requests. Failing to comply with customer requests can impact customer satisfaction. Since representatives from the diagnostic instrument manufacturing organizations already have interactions with their customers during the instrument sales, they have already established relationship with the clinicians and understood their customers' needs. Taking advantage of this existing relationship and providing the products and services to help increase customers' laboratory efficiency can be beneficial to the sales of instrument validation packages.

Dynamic capabilities have shaped the outcome of high-growth organizations. Barrales-Molina et al. (2014) posited that the organization's dynamic capabilities in marketing could impact its strategic position to absorb market knowledge. Szalavetz (2015) argued that managers should not create a single solution or routine for their operations, but continually re-configure or revise the capabilities they had developed. In addition, when necessary, leadership should reconfigure the organization's tangible and intangible assets to seize opportunities and maintain competitiveness (Szalavetz, 2015). Szalavetz's study in 2015 showed that successful entrepreneurs in technology-oriented sectors could seize opportunities if they were able to combine technology development with business development. The recurrent growth-related reconfigurations of organizational structures and introduction of various organizational innovations are the result of systematically developed dynamic capabilities and non-abating organizational learning (Szalavetz, 2015). NGS is a rapid growing technology, and organizations that manufacture and support NGS share similar backgrounds as the participants in Szalavetz's study (2015). Taking advantage of dynamic capabilities in marketing

development will help NGS manufacturing organizations gain opportunities and increase competiveness.

Although new products and innovation are often vital sources of revenue and competitive strength, the risk of these failing is often high, especially in organizations in a competitive environment (Zhang & Wu, 2017). Research focused on traditional success factors for new products: customer input, market orientation, technological synergy, and company resources. Nonetheless, there is an increasing impact from organization's external business networks. Some scholars argued that a strong internal resource base was key to the effective absorption of external knowledge while others argued that such an internal resource base could hinder external knowledge absorption due to internal resistance (Zhang & Wu, 2017). The resource-based view suggests that an organization's capability to use resources translates the benefits of individual resources into superior performance. Still, its lack of distinctive focus on resource interaction effects fails to explain the process through which resource-interplay might help an organization achieve new product success (Zhang & Wu, 2017). The dynamic capabilities perspective suggests that resources by themselves are not sufficient to create value for an organization, particularly in changing environments. Resource-interplay provides a necessary but insufficient condition for new product success and dynamic capabilities transform the benefits of resource-interplay into successful new product development (Zhang & Wu, 2017). When NGS instrument manufacturing organizations develop instrument validation packages, it is to their advantage to incorporate customer feedback and external resources so their offerings address practical customer needs.

Medical device and laboratory product sales performance can vary. Robinson (2008) argued that the performance of the medical device fell short of its potential because the way the products were assessed, purchased, and used was not optimized due to a misalignment of information and incentives. Services selected and prices paid sent important signals to diagnostic instrument manufacturing organization signals as to where to extend capabilities, to invest, and to innovate. In addition, understanding the consumers' purchasing choices allows manufacturing organizations to design products and services that could meet customers' expectations and needs (Robinson, 2008; Quail et al., 2012). Quail et al. (2012) compared NGS platforms across three different manufacturing organizations and found that customers made purchasing choices based on available resources, existing infrastructure, personal experience, finances, and the types of applications. When developing NGS validation packages, organizations can gain value in their products by taking account for the voice of the customers.

There are other ways for diagnostic instrument manufacturing organizations to gain value in their products and services aside from taking advantage of dynamic capabilities. Trajkovic and Milosevic (2016) stated that economic, technical, and policy standardization all play a role in helping business organizations achieve goals. As the world and businesses become interconnected, organizations should not ignore the power of collaboration and standardization (Trajkovic & Milosevic, 2016). The relationship between the customers, clinical laboratories, and the instrument manufacturing organizations can impact the value in products and services offered. Dang et al. (2014) showed customer perception is related to satisfaction in the clinical settings. O'Connor et

al. (2016) performed a study in medical centers and indicated that device representatives' relationship with the medical staff influenced the equipment choices. Beatty et al. (2016) showed when customers asked frontline employees to perform activities that went beyond their expectations, there was an increase in customer satisfaction which could lead to organizational benefits. Aside from customer relationships, Powell et al. (2013) argued that by developing a strong culture in quality, including risk-based verification steps throughout the safety system, manufacturing organizations can help find a more cost-effective way to provide an objective value. Robin (2008) argued that price transparency, performance data, and quality of the products contribute to the value of medical devices. To market products and services successfully, diagnostic instrument manufacturing organizations should use dynamic capabilities to rally internal and external resources to design and manufacture what customers need, build positive relationships, construct a culture of quality, and share performance data to provide product transparency.

Resource-Based Theory

Although dynamic capabilities allow organizations to integrate, build, and reconfigure internal and external resources in the rapidly changing business environment (Salvato & Vassolo, 2017), many scholars prefer using resource-based theory to explain how organizations can thrive under competition (Kozlenkova, Samaha, & Palmatier, 2014; Nalcaci & Yagci, 2014). Resource-based theory is a framework for explaining and predicting competitive advantages and performance outcomes (Kozlenkova et al., 2014). Resource-based theory addresses the value of resources as resources lead the

development of organizational skills and capabilities (Arend & Bromiley, 2009; Nalcaci & Yagci, 2014). The basis of organizational competitiveness consists of the accumulation of valuable, rare, inimitable, and non-substitutable resources (Lin & Wu, 2014). Kozlenkova et al. (2014) argued that the use of resource-based theory in marketing research has increased by more than 500% in the past decade, suggesting its importance.

Researchers argue that factors internal to the organization and the organization's resources and capabilities determine its profits and competitive advantage (Kozlenkova et al., 2014). Nalcaci and Yagci (2014) performed a study on manufacturing companies regarding their marketing capabilities and found that organizations' informational and financial resources, along with customer relation's capabilities, have a positive relationship with marketing success. Kozlenkiva et al. (2014) posited that a resource-based logic can often serve to investigate two goals of market expansion: expanding into new markets to gain advantages from existing resources and expanding into new markets to develop new resources that can generate advantages in both new and existing markets.

Although resource-based theory seems to compete with dynamic capabilities theory in marketing studies, Lin and Wu (2014) argued that there is a role of dynamic capabilities under the resource-based view framework. While resource-based view emphasizes the value of resources, the dynamic capabilities view addresses the need to incorporate changes in valuable resources (Arend & Bromiley, 2009). The changing industry environment can alter competitive foundations and dynamic capabilities of the organization, determining its ability to reconfigure resources to deal with volatile environment (Lin & Wu, 2014). The lack of distinctive focus on resource interaction

effects in resource-based view cannot address the complex resource-interplay (Zhang & Wu, 2017). The organization's internal resources can directly impact its integration, learning, and reconfiguration capabilities, which are types of dynamic capabilities (Lin & Wu, 2014). Combining resource-based view and dynamic capabilities view not only can help organizations accumulate resources but also mediate resources in the competitive environment (Lin & Wu, 2014).

The dynamic capabilities perspective suggests that resources by themselves are not sufficient to create value for organizations in changing and competitive environments (Zhang & Wu, 2017). Jeng and Pak (2016) argued that an organization's ability to deploy resources through its organizational capabilities is more important than the amount of resources itself. In small organizations, dynamic capabilities are crucial to withstand competition while in large enterprises, dynamic capabilities help build long-term strategic advantages (Jeng & Pak, 2016). Marketing dynamic capability refers to the organization's ability to increase the value of its products and services while differentiating them from those of its competitors (Jeng & Pak, 2016). Utilizing dynamic capabilities to build links between the organization and its customers can enable the organization to better compete by predicting changes in customer preferences (Jeng & Pak, 2016). Therefore, for new product and marketing development, the organization's dynamic capabilities can help combine both internal and external resources to increase competitive advantage (Jeng & Pak, 2016). Since NGS technology is relatively new (Kanagal-Shamanna et al., 2016) and the clinical regulatory environment is constantly

changing (Demortain, 2017), dynamic capabilities view can address marketing success in NGS instrument validation packages better than resource-based view.

Transition

Section 1 includes the problem statement, purpose statement, nature of the study, and the research question. These sections help define and guide the stages, reporting, and analysis of the study. The inconsistent quality of oncology diagnostic laboratories continues to produce false positive and false negative results, causing patient harm (Hicks, 2015). Diagnostic instrument manufacturing organizations' offering of validation packages can help laboratory streamline processes, increase efficiency, obtain accreditation, and improve test accuracy. Exploring how successful business development managers in a diagnostic instrument manufacturing organization design, develop, and market the validation packages will assist other managers in the same industry with marketing strategies that lead to increased sales, creating a laboratory culture with the standardized quality approach.

Dynamic capabilities determine an organizations' ability to build, integrate, and realign internal and external resources to address changing business environments (Teece, 2010). The purpose of this qualitative single case study was to explore what role dynamic capabilities play to help successful business managers market instrument validation packages that are appealing to their targeted customers, decision-makers in the oncology clinical laboratories. The review of professional and academic literature contained key and recent findings in the clinical, regulatory, business, and marketing field that were relevant to this study.

Section 1 includes (a) interview questions, (b) conceptual framework, (c) operational definitions, and (d) assumptions, limitations, and delimitations of the study. In addition, Section 1 includes the significance of the study and review of the professional and academic literature. Section 2 will cover the following subjects: (a) purpose statement, (b) role of the researcher, (c) study participants, (d) research methodology and design, (e) population and sampling, (f) ethical research, (g) data collection, (h) data organization, (i) data analysis, and (j) reliability and validity. Section 3 will include (a) presentation of the findings, (b) implications for social change, (c) recommendations for action and further research, and (d) research reflections and overall conclusions.

Section 2: The Project

The purpose of this qualitative exploratory single case study was to explore the marketing strategies business development managers use for integrating dynamic capabilities into clinical instrument validation packages. In Section 2, I will deliver information on the project, including the role of the researcher, participants, research method, and research design. I will also cover details regarding my population and sampling technique, data collection analysis procedures, ethical research, and the reliability and validity of the study.

Purpose Statement

The purpose of this qualitative single case study was to explore what marketing strategies successful managers in a diagnostic instrument manufacturing organization used to promote sales of validation packages for increasing the accuracy of oncology laboratory test results. The targeted population consisted of managers in an NGS instrument manufacturing organization located in the western United States who had successfully marketed validation packages. The population was appropriate for this study because research suggested compliance services lead to resource-efficient diagnoses (Gagan & Van Allen, 2015) and most in vitro diagnostics had been certified based on the manufacturers' assessment (Enzmann, Meyer, & Broich, 2016). The reduction of testing errors and decrease in inappropriate treatment would enhance the quality of healthcare for patients (Long-Mira, Washetine, & Hofman, 2016). The implication for positive social change includes positive improvement for patient care.

Role of the Researcher

Researchers have the role of an investigator in the data collection process and should abide by the guidelines of the Institutional Review Board (IRB) for the study (Bell & Waters, 2014). The relationship between researchers and study participants has been a recurrent concern in the methodological literature because the researcher's experiences, reasoning, and overall impact throughout the research process can affect study participants' behavior (Raheim et al., 2016). Many qualitative studies involve humans as the main research instrument; therefore, it is important for the researchers to keep an open mind throughout the study for unbiased analysis (Peredaryenko & Krauss, 2013). However, researchers' experience in the study topic can also improve the amount of details gathered in the interview (Dempsey, Dowling, Larkin, & Murphy, 2016). As a product manager in a clinical instrument manufacturing organization, I was familiar with various interview techniques as well as the various instrument validation packages that are available in the clinical diagnostic market. The concepts concerning the interview process recommended by Brinkmann (2016) helped me design and guide the interviews with unbiased respect and my professional experience in the clinical diagnostic field helped me construct contents related to my research question. My role was to interview four participants from an NGS instrument manufacturing organization, collect and analyze data, and manage the interview process while protecting the privacy of the participants.

The Belmont Report provides ethical principles and guidelines for the protection of human subjects of research, and is critical in protecting research participants and

maintaining the ethics in research (Friesen, Kearns, Redman, & Caplan, 2017). To avoid exposing participants to any potential harm and perform ethical research, it is the researcher's responsibility to conduct the study according to the Belmont Report protocol (Marshall & Rossman, 2016). The three major components of the Belmont Report—respect, beneficence, and justice (Miracle, 2016)—enhanced the research experience for both the researcher and the participants.

Biases often skew the interpretation of the results and affect the full dissemination of qualitative studies (Toews et al., 2017). Professional conversation during the research interview to enhance research experience for both the researcher and study participants (Brinkmann, 2014). Additionally, professionalism in research can increase participants' engagement, reduce interview stress, and minimize bias (Antes et al., 2016). To minimize personal prejudice in my study, I ensured that my relationship with the study participants remained neutral and professional. To warrant the integrity and credibility of research findings, I collected data with honesty and interpret the data fairly as suggested by Noble and Smith (2015).

One of the most common researcher biases during research is confirmation bias (Bashir, Sirlin, & Reeder, 2014). Confirmation bias occurs when the researcher poses subjectivity in the research process, resulting in subjective filtering of data (Paap, 2014). People with a cooperative mindset show more flexible thinking and less confirmation bias (Schwind & Buder, 2012). I performed a series of reassessments of my interpretation of participants and challenged my preexisting assumptions.

To reduce interview bias, Hilgert, Kroh, and Richter (2016) suggested using standardized interview process. Interview structure and standardization can reduce bias and variation (Levashina, Hartwell, Morgeson, & Campion, 2014). Standardized interviews reduce subjective outcomes and detection bias (Tully & Baumeister, 2015). I interviewed the participants based on their current job responsibility related to the study topic, and I used an interview protocol (Appendix A) to standardize the interview process.

Participants

To gain access to pertinent data to study business problems effectively, researchers need to recruit participants with relevant knowledge and experience (Palmatier, 2017). Chandler and Paolacci (2017) recommend researchers define eligibility criteria with details to ensure that the participants' characteristics align with the research topic. The participants in this single case study included senior managers currently employed by an NGS instrument manufacturer who had been successfully selling validation services to their clinical customers. The specific eligibility included a minimum of four employees and current achievement of revenue growth in compliance services offered to provide responses related to the overarching research question.

Participants' knowledge and experience affect the data for qualitative studies (Knapik, 2006). Chandler and Paolacci (2017) argued that blind recruitment of study participants may attract imposters who misrepresent theoretical relevancy. Dean et al. (2016) recommended recruiting study participants with relevant knowledge and experiences through internal resources. Recommendations from the regional service

manager of an NGS instrument manufacturer in the western United States —from two field applications scientists who were in customer-facing roles supporting clinical diagnostic sequencing laboratories and four field service engineers who were in customer-facing roles and were responsible for executing the validation packages for an NGS instrument manufacturer—helped establish an initial list of 10 participants. From the list of recommendations, I invited participants until a minimum of four qualified participants had given their informed consent. To ensure I have access to participants, I asked a director-level manager of the organization to sign a letter of cooperation based on previous researchers who used letters of cooperation (Bayu et al., 2016; Hadush et al., 2017; Tenaw, Yohannes, & Amano, 2017) .

Recruitment of participants into the research study is an essential part of the research process (Newington & Metcalfe, 2014). Failure in recruitment can not only fail the study but also lose the study's potential impact on the field of science (Joseph, Keller, & Ainsworth, 2017). Establishing a working relationship can help engage participants and improve data collection quality (Jack, DiCenso, & Lohfeld, 2016). Study participants receive better experience with a good working relationship (Kivlighan et al., 2016). To foster a working relationship with the participants, I wrote an e-mail to introduce myself and provided a summary of the goal of the study. All invited participants received descriptive information on the research design and the background of the study. I discussed the purpose of the study, details of intended questions, and an overview of the type of data I intended to collect during the qualifying conversation with the potential

research participants. Many of the potential participants were colleagues with whom I had collaborated in the past on various boards of project.

Participants' characteristics can affect data analysis and interpretation in qualitative studies (Bradley, Curry, & Devers, 2007). The characteristics of the participants might also influence the interactions between the researcher and the data quality (Holloway & Galvin, 2016). Recruiting participants with common experiences or characteristics related to the overarching research question is an efficient approach for the researchers as it helps the researcher reduce unnecessary variables (Lavallee et al., 2017). The research question for this study was "What marketing strategies did managers in oncology instrument manufacturing organizations use in validation packages to increase laboratory testing accuracy in the western United States?" I recruited managers currently employed by an NGS instrument manufacturing organization who had been selling validation packages to their clinical customers successfully. These managers' common characteristics in the achievement of revenue growth and employment in the same oncology instrument manufacturing organization aligned with the overarching research question for this study.

Research Method and Design

I performed a qualitative exploratory single case study with a purposeful sampling of participants. A qualitative case study offers insights into why people engage in particular actions (Leung, 2015; Rosenthal, 2016). A case study is most suitable for exploring an issue through analysis and in-depth description of a bounded system (Creswell & Poth, 2017). Therefore, performing a single case study allowed me to direct

the focus of this research on the success factors in a real-life context. I used a purposeful sample and methodological triangulation, including participant interviews, member checking, and observations at the Interservice/Industry Training, Simulation, and Education Conference (I/ITSEC) with virtual simulation and training.

Research Method

Scholars use one of three methods to conduct their research: qualitative, quantitative, or mixed methods. The qualitative research method is the most common method of data collection used in healthcare research as it offers insights into behavior (Leung, 2015). Additionally, Pierre (2017) stated that marketing research could greatly benefit from using the qualitative approach. Despite the value in using the qualitative method to conduct healthcare marketing research, many scholars have excluded qualitative research results because they considered quantitative studies more objective (Hammarber, Kirkman, & de Lacey, 2016). However, researchers cannot quantify the meanings that study participants assign to their feelings of a phenomenon in question (Mahoney & Vanderpoel, 2015). The scope of experiences of participants is broader than precise, statistical generalizations using hypothesis testing, set parameters, and mathematical analyses (Mahoney & Vanderpoel, 2015). I selected a qualitative method for this case study because I intended to explore actions of behaviors regarding marketing products to promote sales and no numerical data or statistical analysis was required. Since there were no statistical data involved, the mixed method approach was not appropriate.

The quantitative approach is focused on the systematic empirical investigation via statistical, mathematical, or computational methods (Creswell, 2009). Researchers use quantitative methods to collect and perform mathematical analyses (Bambale, 2014). Quantitative methods are suitable in identifying causality and correlate two or more variables (Hammarber et al., 2016). I did not intend on using the quantitative approach for this study because the goal of this study was to explore the strategies business development managers used for marketing NGS validation packages. I did not perform analyses using statistical data, and I did not present the analysis using mathematical interpretations.

Researchers use the mixed methods research design by combining the qualitative and quantitative approach (Creswell, 2009). McKim (2015) argued that there is value in performing a mixed methods study because the use of multiple research methods can make the research more comprehensive than a single method. The combination of qualitative and quantitative methods involves testing theories statistically while revealing the behaviors and perceptions of the study participants (Morse, 2016). However, because I did not intend on performing statistical, mathematical, or computational analyses, I did not use the mixed method.

Research Design

I considered four qualitative research designs before choosing a case study design: case study, narrative, ethnographic, and phenomenological. Case study research is used to study an event, program, or activity (Creswell & Poth, 2017). Researchers use the case study design to study complex phenomena within research contexts (Yin, 2014),

which is a valuable method for research in health science (Leung, 2015) and marketing (Pierre, 2017). A case study design is suitable for exploring an issue through analysis and in-depth description of a bounded system (Creswell & Poth, 2017). The case study design was the appropriate model because the focus of this research was to understand the strategies used by business development managers who had successfully marketed their instrument validation packages. The case study design allowed me to explore the marketing strategies and understand the success elements within a diagnostic instrument manufacturing organization.

The use of a narrative design is suitable to explore experiences of individuals that are expressed in lived stories (Tetnoski, 2015). The ethnographic design includes the description and interpretation of shared patterns of values, behaviors, beliefs, and language of a group (Creswell & Poth, 2017). Because the goal of this study to explore marketing strategies did not require analyses from lived stories or shared culture, I did not pursue the narrative or the ethnographic design. Phenomenological and case study designs are most popular for marketing research (Moller & Parvinen, 2015). The phenomenological design was not chosen because it is for exploring the human experience from the view of those who lived the phenomenon (Creswell & Poth, 2017), which was not the intent of this study.

The researcher should provide more in-depth questioning to gain richness in data to achieve validity due to a small sample size (Marshall et al., 2015; Yin, 2014). Purposeful sampling can assure the requisite knowledge of the phenomenon (Palinkas et al., 2015) and provides possible inclusion of new perspectives to the research topic and

makes the results more conceptually aligned with the research purpose (Benoot, Hannes, & Bilsen, 2016). Therefore, I employed purposeful sampling with a sample population that consisted of four business development managers with comprehension of marketing strategies, familiarity with the compliance products and their product lifecycles, the autonomy to make decisions, and the track record of contribution to increasing sales in instrument validation packages. Although the sample size was small, I performed member checking, interviewed business development managers responsible for various product lines, and collected data from the organization's website to obtain a representative glimpse into the research topic.

Researchers reach data saturation when adequate and quality data are collected to support the study (Walker, 2012) and no new information or themes appear (Saunders et al., 2017). The researcher determines when data saturation is reached (Tran et al., 2017). I asked probing questions to all study partakers until there were no new ideas from the responses, indicating that I had achieved data saturation.

Population and Sampling

I considered three types of sampling approaches for this qualitative interview-based exploratory study: snowball, quota, and purposeful sampling. Researchers use snowball sampling techniques to identify study participants by relying on initial participants to identify additional partakers (Heckathorn & Cameron, 2017). Snowball sampling is an effective sampling technique for identifying hidden populations (Waters, 2015). However, snowball sampling often leads to biases because participants often recruit their own associates (Marcus et al., 2016). The ideal participants for this study

were experienced business development managers. I did not employ snowball sampling technique for this study because no hidden populations were required.

Quota sampling is a nonprobability sampling strategy (Setia, 2016) that is suitable for studies involving more than one sample populations (Acharya, Prakash, Saxena, & Nigam, 2013). When conducting quota sampling, the researcher identifies variation categories and recruits a number of participants proportional to each category (Gorny & Napierala, 2016). I did not use quota sampling technique for this study because there was only one sampling population required for data collection.

Researchers use purposeful sampling technique to seek out participants who cover the full range of specific perspectives that will contribute to the research topic (Benoot et al., 2016; Bungay et al., 2016). Purposeful sampling is common in qualitative research because this sampling method provides rich information (Palinkas et al., 2015). I employed purposeful sampling technique for this study because the goal of this study was to understand what marketing strategies successful managers used to promote NGS validation packages. The participants were business development managers who possessed marketing experience and knowledge that contributed to my research topic.

The sampling size in a qualitative study is influenced by theoretical and practical considerations (Robinson, 2014). The ideal sampling size is large enough to test the theory reliantly while meeting the resource allocation for the study (Cleary, Horsfall, & Hayter, 2014). In interviews for a single case study, researchers should aim for a sample size that is sufficiently small for individual cases to have a locatable voice within the study and for an intensive analysis of each case, typically between 3-16 participants

(Robinson, 2014). The researcher must decide who and how many participants to include in a qualitative study and how to obtain knowledge from the participants for a productive study (Marshall et al., 2015; Morse, 2015). I decided to perform a single case study with a population of individuals who would satisfy the participant criteria in one organization. The industry and study population for this research was business development managers in an NGS instrument manufacturing organization located in the western United States who had marketed instrument validation packages aimed to help clinical customers with laboratory quality. For this study, I focused on a clinical diagnostic instrument manufacturing organization that had various types of customers in regard to the laboratory type, laboratory size, accreditation status, and the number of clinical tests performed. I established professional relationships with multiple business leaders and managers to enhance the research experience during the data collection phase (Raheim et al., 2016). The average sample population for a case study design consists of one to four study participants (Yin, 2014). The population of the study included four business development managers located in the western United States who had demonstrated success in the field of marketing in NGS instrument validation packages. I conducted the interviews in a reserved conference room in the study participants' organization.

There is a widespread acceptance for data saturation as a methodological principle in qualitative research (Saunders et al., 2017). Researchers reach data saturation when adequate and quality data are collected to support the study (Walker, 2012). Determining the point of data saturation can be difficult as researchers have information on only what they have collected (Tran, Porcher, Tran, & Ravaud, 2017). The decision to stop data

collection and when data saturation is reached is dictated by the judgement and experience of the researcher (Tran et al., 2017). I continued to ask probing questions to all study partakers until there were no new ideas from the responses, indicating that I had achieved data saturation.

Ethical Research

The written consent form not only provides information to study participants but also ensures confidentiality and protection of participants' rights during the data collection process (Gibson, Benson, & Brand, 2013). The informed consent provides assurance to the research participants by stating that the participation is not deceived or coerced (Koonrungsesomboon et al., 2016). The informed consent supports the participants' autonomy because it explains the scope of the research (Newington & Metcalfe, 2014). The consent process involves explaining to the participants the purpose of the study, how the research may contribute to the business, the procedures for conducting the research, and the voluntary nature of the study. The benefits and risks of partaking in the study will be listed in the consent form so that the participants can adequately evaluate the situation prior to signing the consent form. I provided the informed consent forms to the study participants via e-mail. Each participant replied to the email with the attached informed consent form and a statement of their consent.

Christians (2011) posited that research participants should not feel compelled to cooperate involuntarily. Drake (2013) recommended researchers inform participants that they can withdraw from the study for any reasons. Angelos et al. (2017) argued that to conduct ethical research, the researcher should allow participants to withdraw from the

study without questioning. The participants for this study could withdraw without penalty throughout the research process by notifying the researcher via phone or email.

Research compensation attracts participants to engage in the study (Collins et al., 2017). Harriss and Atkinson (2014) argued that to conduct ethical research, the researchers must inform the participants the details of any incentives or compensation. Many study participants who do not foresee harm from taking part in the research are willing to contribute without compensation (Killawi et al., 2014). I informed my research participants upon recruitment that I would not compensate them for contributing in this study.

To ethically protect the participants, I adhered to the Belmont protocol when conducting the research. There are three major components of the Belmont Report: Respect, beneficence, and justice (Miracle, 2016; Zucker, 2014). The respect component emphasizes the participants' right to participate of not participate in the study. The beneficence component focuses on the researcher's responsibility to minimize risk or harm to participants. The justice component concentrates on the likely benefit participants receive from participating in the study (Miracle, 2016). In addition, the Belmont Report serves as a guide to IRB deliberations to ensure that studies are conducted ethically (Honig, Lampel, Siegel, & Drnevich, 2014). Before commencing my proposal, I completed the National Institute of Health (NIH) Protecting Human Research Participants course to ensure that my understanding of ethical protection for my participants was up to date.

Prior to the commencement of data collection, I sought approval from Walden University's IRB. After I received authorization from IRB, I contacted the qualified participants and conducted the research after obtaining permission from the individuals and their organization. I documented the study electronically. I stored the digital data on a computer with a password. In addition, I saved another copy of the information on an external hard drive in a secured safe with a combination lock for a minimum of 5 years before I delete the files. I included the Walden University IRB approval number 05-14-18-0621252 on the final doctoral manuscript.

Morse and Coulehan (2015) suggest researchers use pseudonyms to represent study participants and business during research to extend privacy, anonymity, confidence, and trust. Leibenger, Moller, Petrlic, Petrlic, and Sorge (2016) argued that using pseudonyms for privacy protection is important in research both technically and legally. Allen and Wiles (2015) posit that the use of pseudonyms to confer anonymity is more than a technical procedure in qualitative research because it has psychological benefits to both the participants and the researcher. I used pseudonyms such as Pers1 through Pers4 to reference the four participants I interviewed for the study. I withheld the name of the participants from any documentation related to the study.

Data Collection Instruments

In qualitative research, the researcher often becomes the instrument for collecting data (Arriaza, Nedjat-Haiem, Lee, & Martin, 2015) because the researcher visualizes, records, and interprets the data (Denzin, 2014; Marshall & Rossman, 2015). I was the primary data collection instrument in this qualitative single case study using

semistructured interviews. Researchers use semistructured interviews to ascertain subjective responses from study participants regarding a specific situation or phenomenon they have experienced (McIntosh & Morse, 2015). This interview method includes following a detailed interview protocol or schedule and can provide reliable, comparable qualitative data (Jamshed, 2014). Researchers can stray from the interview protocol when it is appropriate in semistructured interviews, gaining opportunities for identifying new information to the relevant topic (Neergaard, Olesen, Andersen, & Sondergaard, 2009). A copy of the interview questions is available in the interview protocol in Appendix A. Attali, Laitusis, and Stone (2016) showed that participants would provide more detailed information when answering open-ended questions. There are eight open-ended questions contributing to the research question for the semistructured interviews. I followed the interview protocol in Appendix A when performing data collection.

Baillie (2015) posited that using a different source to collect data provides reassurance to the findings. Ajagbe, Isiavwe, Sholanke, and Oke (2015) suggested researchers review secondary documents to support findings. Marshall and Rossman (2016) recommended researchers use company or archival documents as an instrument to collect data related to the study. Flyers are a tool for marketing to reach customer awareness (Ziliani & Leva, 2015). Leva, D'Attoma, Ziliani, and Gazquez-Abad (2016) posited that flyers are key media featuring product and brand promotions. Luceri, Latusi, Vergura, and Lugli (2014) suggested that the characteristics of the flyers could impact the product-offering organization's performance as flyers are an avenue for organizations to

reach their customers. I used marketing flyers to investigate target markets, product offerings, and distribution channels to gain knowledge on what marketing strategies successful business development managers used to promote NGS instrument validation packages impacting their organization's profitability. A sampler flyer is in Appendix B.

Member checking is a technique for exploring the credibility of results as data or results are returned to participants to review for accuracy and quality of resonance with their experiences (Birt, Scott, Cavers, Campbell, & Walter, 2016). Baillie (2015) posited that member checking is the most crucial technique for qualitative research credibility. Researchers often use member checking to enhance reliability and validity (Cleary et al., 2014). I conducted follow-up interviews after the initial data collection session to perform member checking and identify recurrent themes as indicated in the interview protocol in Appendix A.

Data Collection Technique

Researchers gain more relevant insights in interviews compared to other research methods in qualitative research (DeMassis & Kotlar, 2014). There are many ways to conduct interviews: telephone, Internet, or face-to-face (Petty, Thomson, & Stew, 2012). Mathrick, Meagher, and Norbury (2017) posited that there is importance of nonverbal social communication during interviews, suggesting researchers may gain additional insights on the research topic when performing a face-to-face interview rather than an over-the-phone interview. I conducted face-to-face interviews for this study with open-ended questions.

I used qualitative, semistructured interviews to encourage participants in the study to describe their experiences with NGS instrument validation offerings, marketing strategies, and revenue growth. Researchers use data collection technique to systematically collect information regarding the research topic (Yin, 2014). There are advantages in conducting semistructured interviews. Participants in semistructured interviews answer preset open-ended questions, which is an avenue for detailed information (Jamshed, 2014). McIntosh and Morse (2015) and Neergaard et al. (2009) posited that semistructured interviews are an excellent approach for a researcher to focus on specific details for the research question because (a) they require the researchers to follow an interview protocol, which increases study reliability, and (b) they allow researchers to stray from the protocol when necessary, which provides opportunities to identify new information. I used semistructured interviews to explore strategies business development managers use to integrate dynamic capabilities to market NGS instrument validation packages. I conducted interviews to obtain detailed information regarding the participants' experience and opinions regarding the research topic. Before commencing data collection, I submitted an IRB application to request permission from Walden University to conduct the study and obtain a written authorization. After receiving IRB approval, I contacted my research participants via email, attaching an invitation letter and informed consent form. The invitation letter contained the purpose and the scope of the study while the informed consent form covered the participants' willingness to partake in the study. I asked the participants to reply *I consent* to my original email thread and attach the informed consent form.

I used the pre-designed open-ended semistructured interview questions to obtain detailed information relating to my research question, observe responses from participants, record the responses, and ensure the consistency with categories and themes. Morse and Coulehan (2014) argued that there are disadvantages with studies involving interviews because the participants' relationship with the researcher can impact their responses. Raheim et al. (2016) suggested that the researcher's experiences, reasoning, and overall impact throughout the research process can affect study participants' behavior. Building rapport and study participants' trust are critical in obtaining detailed data (Witty et al., 2014). I enhanced the research experience by maintaining professionalism throughout the interviews. Another disadvantage of interviews is that the participants can have verbose responses, resulting in challenges in data transcription and interpretation (Levit et al., 2017). McGonagle, Brown, and Schoeni (2015) suggest researchers record interviews to gain opportunities to transcribe the responses. Cridland, Jones, Caputi, and Magee (2014) also recommend researchers to record interviews for accurate data analysis. Anyan (2013) argued that recording the interviews allows researchers to focus on observing participants' nonverbal expressions, which can lead to better understanding of the research topic. I recorded the interviews to ensure that the transcription is complete and use pseudonyms such as Pers1 through Pers4 to reference the study participants.

Researchers use pilot studies to examine the feasibility of an approach (Kaae et al., 2016; Leon, Davis, & Kraemer, 2011). The application of pilot studies will help researchers identify problems related to participant recruitment and acceptability of the

interview protocol (Janghorban, Roudsari, & Taghipour, 2014). There are three specific functions of pilot studies in qualitative research: exercising epoch within the phenomenological study, increasing sensitivity in grounded theory, and allowing familiarity with fieldwork in ethnography (Janghorban et al., 2014). As a result, pilot studies were not applicable for this case study.

Member checking allows researchers to improve the credibility, validity, and accuracy of the study as data or results are returned to participants to review for accuracy and resonance with their experiences (Birt et al., 2016; Cleary et al., 2014). Drisko (2016) recommended using member checking as a method to validate research findings and confirm interpretations from the interviews. Baillie (2015) argued that because member checking provides both the participants and the researcher an opportunity to verify findings, it enhances the research validity and credibility. I conducted member checking within 48 hours after the interviews by providing participants with a brief one paragraph synthesis of my interpretation to the responses to the interview questions. I asked participants to verify whether or not my interpretation accurately reflected their responses.

Marketing flyers help raise customer awareness (Ziliani & Leva, 2015) and are key media for promoting products (Leva et al., 2016). Flyers often contain rich information regarding product offerings (Apostolova, Pourashraf, & Sack, 2015) and target markets (Gallo, Zamberleti, & Noce, 2015). I used marketing flyers available as my secondary data source. A sample marketing flyer is in Appendix B.

Data Organization Technique

To capture the participants' responses and document the intonations, I used Skype to conduct the interviews and record the audio. McGonagle, Brown, and Schoeni (2015) emphasized the benefits of recording interviews as it provides the researcher an opportunity to revisit the data. Anyan (2013) and Cridland et al. (2014) recommended researchers use interview recordings to ensure accurate interpretation of the responses. I examined the recordings and compared them with my notes after the interviews. Many researchers use NVivo 11 software to analyze research data (Woods, Paulus, Atkin, & Macklin, 2015). NVivo software allows researchers to compare the answers from the participants (Sotiriadou, Brouwers, & Le, 2014). I used NVivo 11 in conjunction with Microsoft Word 2010 to analyze the data. I filed my data digitally, and I used pseudonyms such as Pers1 through Pers4 to reference study participants and protect their identity. I created folders to represent different themes and placed documents associated with each participant in an individual folder. I stored the data files in a password-protected computer. I saved another copy of the information on an external hard drive, which will be kept in a secured safe for a minimum of 5 years before I delete the files.

Data Analysis

I performed data analysis via thematic analysis. The purpose of thematic analysis is to identify patterns or themes across a dataset that will lead to an answer to the research question (Clarke & Braun, 2014). Good thematic analysis will enhance the trustworthiness of the study (Elo et al., 2014). The key characteristic of thematic analysis is the systematic process of coding, examining of meaning of a description through the

creation of theme (Vaismoradi, Jones, Turunen, & Snelgrove, 2016). The thematic analysis process begins with the researcher reading and understanding the data (Vaismoradi et al., 2016). The second step of thematic analysis involves the researcher creating categories of the data as key themes emerge (Vaismoradi et al., 2016). After categorizing the key themes, the researcher should search for similarities between categories and organize them into subthemes (Vaismoradi et al., 2016). I followed the thematic analysis steps recommended by Vaismoradi et al. (2016) when performing data analysis. The steps included four stages: initialization stage, construction stage, rectification stage, and finalization stage (Vaismoradi et al., 2016). The initialization stage involves the researcher reading transcriptions, coding, looking for abstractions, and writing notes. The construction stage involves the researcher classifying, comparing, labeling, defining, and describing the topics and themes. The rectification stage involves the researcher relating themes to establish knowledge. Lastly, the finalization stage is when the researcher develops the storyline and concludes the findings.

Triangulation increases study credibility (Manganelli et al., 2014). Triangulation involves multiple methods in exploring the same phenomenon (Carter et al., 2014). Researchers performing qualitative studies often conduct methodological triangulation by collecting and analyzing data from multiple sources such as interviews and observations (Heale & Forbes, 2013). I included interviews, observation, audio recording, and the marketing flyers to achieve methodological triangulation in the thematic analysis. Cleary et al. (2014) suggested researchers use pseudonyms to conceal the identities of study participants during data collection, while Yin (2014) suggested the use of pseudonyms to

reinforce participants' protection during data analysis. Before performing data analysis, I used pseudonyms to represent the business entity and the participants' identity during the entire study and codes to identify major themes emerging from the interview process. I used pseudonyms such as Pers1 through Pers4 to reference the four study participants.

A part of the data analysis involved transcription of the notes and recording from the interview during the data collection phase. NVivo is a data analysis software that provides structure to texts, helping researchers to sort through rich interview transcripts (Robins & Eisen, 2017). Some researchers prefer using Microsoft Excel as a tool to transcribe data (Plamondon, Bottorff, & Cole, 2015) while others prefer NVivo to sort and organize data (Cooper, 2017; Woods et al., 2015). I first transcribed digital data using Microsoft Word 2010 and then continued the data organization with NVivo 11. I imported interview transcripts in Microsoft Word format to NVivo software. NVivo software allowed me to sort my interview transcripts efficiently because my semistructured interviews shared a uniform format.

During the data analysis phase, I examined the emerging themes from both digital and written data for consistency. I evaluated the data against the conceptual framework and findings from the similar studies during the process of iterating on the main themes. The conceptual framework for this study was dynamic capabilities by Teece et al. (1990). Dynamic capabilities theory drove the thematic analysis to deliver an understanding of the marketing strategies employed to increase NGS validation packages. Augier and Teece (2009) argued that due to the expansion of trade and rapid competitive responses, businesses need to develop and maintain asset alignment capabilities and collaborate with

each other to combine resources to deliver value to customers. I anticipated themes related to increasing product value and competitive edge to emerge. O'Connor et al. (2016) performed a study on medical device sales results used a similar approach. Beatty et al. (2016) also employed a similar approach attempting to understand customer expectations and the value in services. Understanding how prior studies applied dynamic capabilities enhanced my knowledge related to marketing strategies used by participants in the study.

Reliability and Validity

Reliability and validity are two major components of any research as they assure the results are as rigorous and trustworthy as possible. Qualitative researchers must avoid fatigue, errors of interpretation, and personal bias (Bengtsson, 2016; Noble & Smith, 2015). It is the researchers' responsibility to assure validity and reliability throughout the entire study (Cypress, 2017).

Reliability

In qualitative studies, reliability refers to consistency in the research outcome and the extent to which the research will yield the same or similar results if performed under the same conditions (Noble & Smith, 2015). It is the idea of replicability, repeatability, and stability of results or observation (Moon, Brewer, Januchowski-Hartley, Adams, & Blackman, 2016). In qualitative research, a thorough description of the entire research process that allows for inter-subjectivity indicates good quality (Cypress, 2017). Researchers can confirm reliability by applying consistency and care in the application of research practices throughout the study.

Dependability refers to maintaining consistency during the research process (Drisko, 2016). Funder et al. (2014) posit that avoiding questionable research practices by improving research decision transparency can increase study dependability. The audit trail technique refers to the researcher keeping records of all stages of their research and having the records available (Baillie, 2015), which helps with research transparency and dependability. Researchers should document research design and implementation, including the methods and details of data collection to increase dependability (Moon et al., 2016). I kept an audit trail by documenting the order of the data analysis, organization, and process. Drisko (2016) recommended researchers use triangulation and dependability audit to ensure dependability of data. I transcribed, documented, and analyzed the data as accurately as possible to achieve dependability. I transcribed the recorded interviews verbatim and paraphrased where necessary. Member checking is a technique for researchers to return the results to the participants to check for accuracy (Birt et al., 2016). Ballie (2015) argued that member checking is critical for qualitative research credibility while Cleary et al. (2014) posited that member checking would enhance study reliability and validity. To avoid inaccuracies, I used member checking to perform data validation and ensure that I accurately recorded the participants' response.

Validity

Validity ensures that the presentation of results truthfully reflect the phenomena studied (Bengtsson, 2016). A valid study should precisely demonstrate the themes as validity in research is concerned with the accuracy and truthfulness of the findings (Cypress, 2017). Researchers conduct credibility, transferability, and confirmability tests

to enhance validity in their studies (Noble & Smith, 2015). In addition, researchers often use member checking to improve validity (Cleary et al., 2014). I validated the results of the study by conducting applicability, consistency, and neutrality tests.

Creditability refers to tests performed to ensure research findings are accurate and truthful (Marshall & Rossman, 2015). I used protocols amid the research and interview process. Additionally, I identified and recorded recurrent themes by asking iterative questions, performing data triangulation, and using peer scrutiny to achieve creditability during the research process. Drisko (2016) suggested using member checking as a mean to validate research findings and interpretations from the interviews. Baillie (2015) recommends researchers to use member checking as a technique for credibility in qualitative research. Cleary et al. (2014) suggest that member checking enhances study reliability and validity because it provides the participants an opportunity to verify data accuracy. I performed member checking after conducting interviews with four business development managers by providing the participants my interpretation of the data collected in our initial interview for validation. The open-ended semistructured questions provided study participants flexibility and opportunity to share detailed information regarding strategies for marketing NGS instrument validation packages. Yin (2014) recommended using triangulation to increase research quality. Triangulation involves multiple methods in exploring the same phenomenon (Carter et al., 2014). Researchers performing qualitative studies often conduct methodological triangulation by collecting and analyzing data from multiple sources such as interviews and observations (Heale & Forbes, 2013). I performed triangulation by cross-checking the data obtained from the

interviews and analyzing the contents of marketing flyers to confirm that I had covered all aspects of the research question thoroughly.

Transferability refers to the extent to which a study is applicable in other contexts and environments (Drisko, 2016). Purposeful sampling not only involves selecting individuals that are especially knowledgeable about or experienced with a phenomenon of interest but also ensures the participants' availability and willingness to participate (Marshall & Rossman, 2016). Benoot et al. (2016) posit that purposeful sampling provides possible inclusion of new perspectives to the research topic and makes the results more conceptually aligned with the research purpose. Leung (2015) argued that purposeful sampling increases the ease of respondent verification because it is concept-oriented. I employed purposeful sampling to construct my research to gain a comprehensive understanding of all the studies that met the same pre-determined criteria to enhance transferability.

Confirmability refers to the degree to which the results can be confirmed or corroborated by others (Drisko, 2016; Noble & Smith, 2015). Confirmability of research findings through recorded evidence allows researcher reviewers to logically follow to the conclusions (El Hussein, Jakubec, & Osuji, 2016). The researcher can increase confirmability of the study by documenting the procedures for checking and rechecking the data (Thomas & Magilvy, 2011). I documented the procedures for examining the data throughout the study to achieve confirmability. In addition, I documented how I identified emerging themes from the data as recommended by Moon et al. (2016) to avoid potential bias and enhance study confirmability.

Reaching data saturation occurs when there is enough information to replicate the study, when the ability to obtain additional new information has been attained, and when further exploration is no longer feasible (Fusch & Ness, 2015). Researchers reach data saturation when adequate and quality data are collected to support the study (Hagaman & Wutich, 2016) and no new information or themes appear (Saunders et al., 2017). Failure to reach data saturation hampers content validity. I interviewed four business development managers who had successfully marketed NGS instrument validation packages in the western United States. I intended on recruiting additional study participants if new themes from data and ideas continued to emerge. I reached data saturation when themes from data became familiar and no new information was available.

Transition and Summary

Section 2 includes the purpose statement, role of the researcher, study participants, research methodology and design, population and sampling, ethical research, data collection, data organization, data analysis, and reliability and validity. These sections help describe and justify the study design. The goal of this study was to explore what strategies successful managers used in promoting NGS instrument validation packages. I performed a qualitative case study. I functioned as an investigator in the data collection process and abide by the IRB guidelines. I utilized my professional experience as a product manager in a clinical instrument manufacturing organization to recruit and maintain working relationships with the eligible participants. I protected the participants by adhering to the Belmont Report ethical guidelines. I provided the participants with an

informed consent form detailing the scope of the study. The participants were not compensated and were free to withdraw from the study. I used an interview protocol to avoid bias and standardize the interview process. I employed purposeful sampling to recruit participants with knowledge and experience related to marketing instrument validation packages. I planned on interviewing at least 4 business development managers from an oncology diagnostic instrument manufacturing organization for data collection. I intended on recruiting more participants until I reached data saturation where no new themes emerged. I performed a follow-up interview with the participants to perform member checking, enhancing validity. I used interviews, observation, audio recording, and marketing flyers to achieve methodological triangulation. I will preserve data in a secure location for five years. I will destroy the files after five years.

Section 3 will contain the research findings, application to professional practice, implications for social change, recommendations for action and future research, reflection, and a conclusion. This section will provide detailed information describing how and why successful marketing managers in an oncology diagnostic instrument manufacturing organization incorporated dynamic capabilities to achieve sustainable revenue growth. Interpretation of the findings will highlight potential transferability of the results for applications in professional practice. Additionally, I will present the findings and their impact on social change in this section.

Section 3: Application to Professional Practice and Implications for Change

The purpose of this qualitative exploratory single case study was to explore strategies business development managers used to integrate dynamic capabilities for marketing instrument validation packages aimed to increase clinical laboratory quality and test accuracy. From the interviews with business development managers of a NGS manufacturing organization in the western United States, I identified one overarching theme and four subthemes. The overarching theme was collaboration of cross-functional teams. The four subthemes included integration, effectiveness, partnership, and profitability. Results from this study show that collaboration of cross-functional teams was the most common element from the data collected. Section 3 includes presentation of my findings, discussion of applications for professional practice and implications for social change, recommendations for actions and future research, my reflections, and the conclusion to the study.

Presentation of the Findings

The overarching research question of this study was: What marketing strategies do managers in oncology diagnostic instrument manufacturing organizations use to promote instrument validation packages for increasing the accuracy of oncology laboratory test results. One overarching theme (collaboration of cross-functional teams) and four subthemes emerged from the analysis of interview responses and marketing flyers.

Overarching Theme: Collaboration of Cross-Functional Teams

Collaboration of cross-functional teams was the primary theme that emerged from the interviews with business development managers. In their responses to Interview Questions 3, 5, and 6, Pers1 through Pers4 indicated that the collaboration of cross-functional teams was key for the deployment of successful marketing strategies for instrument validation services. This theme is supported by previous researchers such as Salvato and Vassolo (2017), who argued that organizations that can integrate internal and external resources are more capable to compete in rapidly changing business environments. Szalavetz (2015) also posited that the relationship and reconfiguration of organizational internal structures could increase organizational competence. Additionally, Rosch and Schumacher (2018) showed that integration increased organizational flexibility, which can contribute to economic success (Kaleka & Morgan, 2017). The collaboration of cross-functional teams allowed the organization to obtain customer feedback and information regarding potential target markets quickly, aiding business development managers in creating strategies and objectives to gain positive results.

Successful marketing strategies from business development managers are dependent on the knowledge and experience of the managers and their interaction with their cross-functional teams. For example, Pers2 explained,

> many of our customers were not aware of the validation products that we offered, and they were not sure if the specific workflow that required validation could be included in the package. Our field service engineers who performed the installation of the customers' instruments often let the validation development

team know exactly what the customers were looking for, and then we distributed product information specifically for that particular customer needs.

Resources by themselves are not always sufficient to create value for organizations in competitive environment (Zhang & Wu, 2017). An organization's ability to deploy resources internally is more important than the amount of resources itself (Jeng & Pak, 2016). The marketing strategies using the collaboration of cross-functional teams helped sell NGS instrument validation packages according to all study participants. For example, Pers3 stated, "our customer-facing staff often build great relationships with our customers and because of the trust that our customers have for our field engineers, our validation packages practically sell themselves." This statement is consistent with the findings by Dang et al. (2014) that customer perception is key in clinical settings. O'Connor et al. (2016) also suggested that customer-facing representatives' relationship with the client can influence purchase choices.

As the business world becomes interconnected, organizations should not ignore the power of collaboration (Trajkovic & Milosevic, 2016), which can help in creating a strong culture in quality that helps create product value (Powell et al., 2013). Pers3 mentioned that in instrument validation industry, the goal is to provide documented proof that an instrument or device in a workflow is performing to the manufacturer's specifications. Therefore, the documentation provided by these services must be of quality. The business development managers work with the research and development teams to gain knowledge of a comprehensive instrument performance profile. With the understanding of instrument capabilities, the acceptable performance range is established.

In addition to working with the research and development teams, these business development managers frequently consult with the legal and quality teams to ensure that a formal documentation style is present to support their customers' quality systems. These actions support the argument that (a) producing instrument validation packages are a collaborated effort and (b) to successfully market a product, it must resonate with the customers' needs.

The literature in Section 1 relating to an organization's dynamic capabilities and how single-dimensional resources by themselves are not sufficient to create value in competitive environments (Zhang & Wu, 2017) coincides with the overarching theme that emerged from this study. The contribution from cross-functional teams cannot be overlooked in marketing NGS instrument validation services aimed to improve clinical diagnostic quality. The findings confirm the results in literature review: through collaboration and combination of resources, organizations gain dynamic capabilities that lead to competitive advantage.

Subtheme 1: Integration

Dynamic capabilities determine organizations' ability to build, integrate, and realign internal and external resources (Teece, 2010). Marketing dynamic capability refers to the organization's ability to increase the value of its products and services while differentiating them from those of its competitors (Jeng & Pak, 2010). When comparing different manufacturing organizations, customers make purchasing choices based on resources, infrastructure, experience, and applications available (Quail et al., 2012). In response to Interview Question 3 regarding the marketing strategies participants used for

NGS instrument validation packages, all participants said product integration played a key role. All the participants reported that although there was a dedicated marketing and sales team for validation products, targeting revenue generation, product integration was a major dealmaker for the NGS customers. Many clinical customers look for an end-to-end solution. Therefore, there is value in offering compliance packages starting from sample preparation to results verification. Pers2 shared an experience regarding a customer who purchased their competitor's instrument platform, but the competitor was not able to provide validations for the entire workflow. While exploring other options, this customer found out that Pers2's organization offered an end-to-end solution. In the end, the customer returned the competitor's products and bought the instruments from Pers2's organization instead, including the validation services.

Pers1, Pers2, and Pers3 stated unanimously that product integration provided customers a convenient solution that is cost effective. Pers3 explained in detail,

> an analytical validation service reduces the time to develop and launch a panel service, reduces the cost and resource investment to develop and launch a diagnostic panel, and facilitates global compliance with industry standards and template documentation.

Pers2 and Pers4 reported experiences with customers trying to tackle validations themselves but turned to purchasing the validation services offered by the organization instead because either the customers' "home-brewed" methods were not up to regulatory standards or the cost to complete the validation soared due to inexperience and operating mistakes. The findings suggest that integrating product offerings within an organization

helps market individual products. According to all the participants, integrating instrument hardware, reagent, consumables, and validation services helped convince the customers to purchase as many customers were looking for convenient end-to-end solutions. The conceptual framework for this study, dynamic capabilities (Teece, 2010), where resource integration increase an organization's competitive advantage, is consistent with the results of my study.

All participants gave examples of marketing strategies involving product integration. Pers1 and Pers2 stated that internally, they have classified customer accounts by their instrument base. Depending on what instruments the customers owned, different targeted marketing collateral would be emailed to the customers. This marketing strategy integrates information with hardware purchase records. In addition, according to Pers1, the managers in the organization "purchased lists of targeted clientele from clinical publications or clinical lists" so the marketing team could target potential customers by knowing specifically what type of clinical work is performed in the customer laboratory. This strategy integrates information with applications records. Pers1, Pers3, and Pers4 shared that there is an online, search engine marketing system in place along with digital banners, targeting customers purchasing specific chemistry kits as some chemistry kits suggested clinical diagnostic work was involved. This strategy integrates information with chemistry types. Pers4 stated that the teams in the organization used a cross-sell strategy for customers who purchased an assay or instrument that was compatible. Strategies to cross-sell included co-promoting products, pricing products in bundles, and placing products in the same marketing material and position them as complementary.

Additionally, according to Pers1 and the marketing flyers collected, there are marketing activities integrating service activities. For example, Per1 explained,

> the details for recent service visits can tell us if a customer is looking to switch from research and development phase to clinical setting, which is usually a sign that they will be performing some kind of validation soon.

These participant responses are also supported by previous research. For example, Xavier, Jacobi, and Turra (2018) posited that integration of different knowledge and information often led to mutual benefits. Integration of products and services can increase customer loyalty and satisfaction (Kasiri, Cheng, Sambasivan, & Sidin, 2017). Additionally, Gebauer, Saul, Haldimann, and Gustafsson (2017) showed that marketing strategies integrating hardware and services helped companies achieve competitive advantages. These findings are consistent with the results of my study that successful marketing strategies often involve integration.

Subtheme 2: Effectiveness

The second subtheme within this study was effectiveness. The need for assurance in quality, cost reduction, and regulation compliance has brought increased focus on validation in clinical diagnostic industry (Vijayasree et al., 2017). Diagnostic instrument manufacturing organizations are not just providers for the equipment but also facilitators in quality management (Fleming, 2015). Pers1 stated, “three things are always on the table when customers in diagnostic laboratories consider validations: time, cost, and compliance. And we often focus on these three things when we market our packages.” Time is indicated by whether the field staff from the instrument manufacturing

organization can get the customers running quickly as opposed to them attempting to do all the validation work on their own. Pers1 indicated, "our compliance packages are designed to demonstrate efficiency, especially when customers run into problems validating on their own." Cost is also important because when customers try to do validation themselves, often the process exceeds the costs of purchasing services from the instrument manufacturing organization. Compliance is indicated, as Pers1 articulated, by how "our customers have the comfortability knowing that we have performed validations multiple times. Our products have been audited in other laboratories without issues and our team members who execute validation services produce high quality documents that meet regulatory needs."

Pers3 shared comparable insights and explained, "one element that resonates with most customers is the fact our organization is the manufacturer of record for the instrument systems." The manufacturing organization is familiar with the designs and the qualification protocols reflect that knowledge with a comprehensive performance profile. This significantly reduces the burden of development on behalf of the customers and their quality system, allowing them to focus on more important tasks. In addition, the formal documentation style that the instrument manufacturing organization often includes in their packages supports good quality systems.

Confirmation from the literature review regarding NGS customers' purchasing choice supports the study participants' statements. For example, Quail et al. (2012) compared NGS platforms across major manufacturing organizations and found that customers made purchasing choices based on experience, finances, and applications.

Robin (2018) also posited that price, performance, and quality of products contribute to the value of medical devices. As regulatory requirements for clinical laboratories are getting more stringent, required clinical validation and methods can be costly (McMillan, 2016). Marketing instrument validation packages with an emphasis on saving time, reducing cost, and gaining efficiency can lead to success.

Compliance, as indicated by the literature review, is shown through three types of process validation according to the requirements stipulated by the FDA: prospective process validation, concurrent process validation, and retrospective process validation (Vijayasree et al., 2017). These process validations all entail documented evidence. Because quality has become a critical measure of performance and customer satisfaction, accreditation becomes an opportunity for laboratories to reassure their customers (Manickam & Ankanagarl, 2015). Powell et al. (2013) argued that by developing a strong culture in quality, including risk-based verification steps throughout the safety system, manufacturing organizations can help find a more cost-effective way to provide an objective value. As Pers1 explained, "when marketing, we focus on comfortability. Our customers know our products can survive strict audits and we are there to help them pass scrutiny."

Subtheme 3: Partnership

Dynamic capabilities allow organizations to integrate, build, and reconfigure internal and external resources (Salvato & Vassolo, 2017) because resources by themselves are not sufficient to create value for organizations in competitive environments (Zhang & Wu, 2017). Jeng and Pak (2016) suggested organizations

combine both internal and external resources to predict changes in customer preferences and gain competitive advantage. For Interview Question 3, marketing strategies used for compliance products, and Interview Question 6, distribution channels, Pers1, Pers2, and Pers4 indicated that their marketing scheme would not have been successful without the internal and external partnerships. Pers1 stated, "internally, our sales teams often help us identify potential customers." The sales teams include hardware sales teams, service warranty and contract sales teams, as well as consumables sales teams. These people are upfront sales teams that interact with the customers directly. The direct interaction with the customers allows the sales teams to understand their customers' needs. Based on the customers' requests, the sales teams can help the organization push for validation services that are tailored for the specific needs. Additionally, field service teams and field support teams also play an important role in marketing validation products because they interact with their customers at the very beginning, when the customer gets their instrument installed. Pers1 explained, "because of the early interaction, the customers tend to trust the service and support team members."

Pers2 concurred with the statement from Pers1 regarding internal partnerships and added, "our clinical applications consultants often bring leads back to the dedicated compliance sales and marketing team." The clinical applications consultants work with their customers on the diagnostic panels as well as help customers figure out the most suitable chemistry for the tests. Their job functions allow them to understand the specific workflow that the customer needs validation for and the timelines required for the validation. According to Pers2, the specific workflow and the validation timelines were

key information required to successfully promote compliance products as they provided the marketing teams an avenue to perform targeted marketing.

Externally, Pers1 stated that the team partnered with CAP and CLIA to design the compliance service package to attract target market. Both CAP and CLIA require clinical laboratories to verify performance characteristics, especially when introducing an unmodified approved test system, such as a medical diagnostic instrument. To comply with these requirements, periodic calibration and calibration verification should be performed (Killeen et al., 2014). Complying with clinical requirements helps make good medical decisions, and there is value in having periodic calibration and verification performed on diagnostic instruments (Ferreira-Gonzalez et al., 2014). Pers1 and Pers4 posited that the partnership with CAP and CLIA helped market the validation packages because the customers trust that contents in the packages would satisfy quality standards required by the regulatory agencies.

From the literature review, Trajkovic and Milosevic (2016) posited that economic, technical and policy standardization all play a role in helping business organization achieve goals. Partnership with internal teams and external organizations, such as CAP and CLIA, not only allows the employees in this NGS instrument manufacturing organization to standardize the technical and quality knowledge for their customers, but also facilitates business goals for both the manufacturing organization and the clinical laboratories. Pers1and Pers4 revealed that the enhanced partnership had improved their revenue in validation packages year after year. The findings support the conceptual

framework: combining internal and external resources increases an organization's dynamic capabilities and competitive advantage.

Subtheme 4: Profitability

Dynamic capabilities allow organizations to combine utilization of tangible and intangible assets and convert them into a stream of profits (Teece, 2017). According to O'Connor et al. (2016), there are relationships between clinical laboratory staff and representatives from instrument manufacturing organizations that impact profitability. The interaction between the two parties can directly affect sales as close relationships often lead to better sales results (O'Connor et al., 2016). Pers1 and Pers4 suggested that using field service and support teams to market instrument validation packages was effective because the field staff interacted directly with the customers for their daily tasks. They built "a trusting relationship with the customers and the customers relied on their recommendations," according to Pers1. Ind (2017) posited that customer facing employees should be part of marketing strategies because their interactions with the customers assist corporate branding and set the foundation for profitability. My findings aligned with Ind's study (2017).

Pers3 posited that the validation packages reduce the cost and resource investment to develop and launch a clinical panel from customers in laboratories, which led to indirect profitability for the customers. Pers4 concurred with Pers3 statement above, stating that it normally cost customers more to attempt instrument validations compared to purchasing a service package directly from the instrument manufacturing organization. In the literature review, Lyon et al. (2015) posit that validations take days to weeks to

complete, and the costs associated with validations are not trivial. The findings are consistent with the results from Lyon et al. (2015). Good laboratory practices improve laboratories' competitive edge and market share because these practices increase test efficiency (Manickam & Ankanagarl, 2015). Vijayasree et al. (2017) stated that testing quality and efficiency help clinical laboratories reduce costs. The findings support previous studies that there is financial value in purchasing validation packages from instrument manufacturing organizations. Finally, for the instrument manufacturing organization, there is profit margin for performing validation services. Successful marketing strategies that promote the sales of validation packages will have positive impact on the financial goals.

Applications to Professional Practice

The strategies highlighted in this study for marketing NGS instrument validation packages might help business managers improve profitability across any clinical business. The objective of the study was to explore the strategies successful business development managers used to integrate dynamic capabilities for marketing instrument validation packages aimed to increase clinical laboratory quality and test accuracy. Findings of the study are valuable to leaders in diagnostic instrument manufacturing organizations and other third-party clinical service providers seeking to understand and use strategies for integrating dynamic capabilities for marketing validation services. The results of the study may also help managers in clinical laboratories gain a better understanding of good laboratory practices, which may help them detect why the

validation packages were designed and offered and how these packages can impact clinical operations.

Cross-functional team collaboration in marketing has positive impacts on market orientation and business performance (Claro & Ramos, 2018). The marketing strategies involving internal cross-functional teams, including sales, field support, research and development, legal, and quality teams were successfully used by all four participants in the study. Bai, Feng, Yue, and Feng (2017) suggested, in the era of global competition, cross-functional collaboration is one of the most important keys of successful product implementation. Swanson, Jin, Fawcett, and Fawcett (2017) posited that modern organizations require dynamic capabilities to succeed and overcome powerful limiting conditions. Collaboration of cross-functional teams within the organization facilitates value creation by increasing the organization's dynamic capabilities. Having a great product is important. However, to market the correct products to the customers in need requires joint efforts from various teams.

An organization's ability to increase the value of its products and services while differentiating them from those of its competitors is critical in today's business environment (Jing & Pak, 2010). Integration of products and services often increase customer loyalty and satisfaction (Kasiri et al., 2017). According to the study participants, clinical customers sought end-to-end solutions. Therefore, integrating product offerings, from instrument hardware, reagent, consumables, to validation services, within their organization helped market individual products. Customer data integration can reveal the product that the customers might need (Deriyenko, Hartkopp,

& Mattfeld, 2017). There is strategic value in integration of relationship-oriented big data (Kitchens, Dobolyi, Li, & Abbasi, 2018). Business managers may incorporate customer data from various sources, for example, online purchase records, equipment history, and product interests, to market specific products and services.

Price, performance, and quality contribute to the value of medical devices (Robin, 2018). Clinical validation required by regulatory agencies can be costly (McMillan, 2016). Diagnostics instrument manufacturing organizations are the providers for the hardware and facilitators in quality management (Fleming, 2015). All four of the participants indicated that being able to execute validation services efficiently while producing high quality documentation that meets regulatory requirement was a major marketing emphasis. The effectiveness of the validation packages, a function of time, cost, and compliance, determines the value for the customers. When developing marketing strategies, business managers should consider factors what would contribute to the value of the products.

Resources by themselves are not sufficient to create value for organizations in competitive environments (Zhang & Wu, 2017). When managers in organizations combine both internal and external resources, they can predict changes in customer preferences and gain competitive advantage (Jeng & Pak, 2016). Aside from collaborating with internal cross-functional teams to develop and market validation services whenever possible, the participants in the study indicated that they partnered with external regulatory agencies to design the packages so the contents can be attractive

to target market. The findings suggest that partnership with external organizations may increase marketing effectiveness.

Customer satisfaction, service quality, and loyalty can impact customer behavior and customer profitability (Petersen, Kumar, Polo, & Sese, 2017). Participants in this study suggested that promoting validation packages via customer-facing staff was effective because the field staff interacted directly with the customers daily. In addition to using customer-facing staff as a marketing channel, participants had used profitability as a promoter. Validations take days to weeks to complete, and the costs associated with validations are not trivial (Lyon et al., 2015). Having a professional service team perform validations has the potential to reduce laboratory down time as the specialized service providers are often more efficient in validation execution. The reduction of down time increases the laboratory's profitability. When marketing clinical compliance services, business managers should consider highlighting the financial gain as an incentive to the customers.

Implications for Social Change

The results of the study contribute to social change by providing information on strategies for marketing and promoting oncology diagnostic instrument validation packages aimed to improve laboratory quality. Diagnostic laboratory results are involved for making medical decisions (Peter et al., 2010) and the laboratories' operating quality directly impacts the accuracy of tests and patient safety (Allen, 2013). Accreditation and validation have the potential to improve the quality of healthcare for patients through reduction of testing errors and inappropriate treatment (Peter et al., 2010). The marketing

strategies explored in this study may help managers in instrument manufacturing organizations promote validation packages to clinical laboratories and raise awareness of meeting regulatory requirements. In addition, the findings of the study provided insights on solutions to minimize the cost of implementing laboratory quality systems and develop a standard for better laboratory practice that would lead to safer healthcare.

Recommendations for Action

Findings and recommendations from this study may apply to any business manager considering strategies for marketing clinical instrument validation packages aimed to improve laboratory quality. Resources by themselves might not be sufficient to create advantage in rapidly changing and competitive environments (Zhang & Wu, 2017). This study highlights how collaboration of cross-functional teams, both internally and externally, can increase instrument manufacturing organizations' dynamic capabilities, generate marketing success, and profitability for the clinical customers.

Dynamic capabilities enable organizations to increase the value of products and services while differentiating them from those of its competitors (Jeng & Pak, 2010). In situations where clinical customers are looking for end-to-end validation solutions, business development managers should cross-sell, bundling and integrating instrument hardware, reagent, consumables, and validation services to offer a competitive and convenient solution. This strategy not only has the potential to secure market share, but also provides the customers with most confidence in validation as the same manufacturing organization is responsible for the entire workflow.

External partnership should not be overlooked in marketing instrument validation services. Both CAP and CLIA require clinical laboratories to verify performance characteristics, especially when introducing an unmodified approved test system, such as a medical diagnostic instrument (Killeen et al., 2014). Since CAP and CLIA publish checklists for clinical laboratories to comply with the requirements, partnering with CAP and CLIA can increase the value in validation packages as customers trust that the contents in the packages would satisfy quality standards stipulated by the regulatory agencies.

Utilizing the relationship between the customer-facing staff and customers can contribute to profitability. Marketing strategies should involve training customer-facing staff to promote validation packages as the staff interacts directly with the customers on a daily basis. The customer-facing staff understand the specific workflow that the customer performs and the timelines when the customer would require validations. When marketing instrument validation packages, business managers should recruit assistance from field employees.

Recommendations for Further Research

Marshall and Rossman (2016) stated that limitations are constraints beyond the researcher's control. The primary limitation of the study was what effects the relationship between the clinical laboratory and the compliance performance had on the success or failure of an accreditation or audit. If the laboratory managers opted to have the instrument manufacturers to perform compliance services, the results and documentation quality would rely heavily on the manufacturer representative who performed the tests. I

had not taken account for the manufacturer representatives' relationship with the clinical customers nor their ability to execute validation packages. Future research should be conducted to explore the marketing impact associated with the manufacturer-customer relationship and the representatives' technical aptitude. Additionally, the geographical area was limited to the western United States. Future researchers should perform a study on a larger geographical area and compare the data collected from this study.

This study did not differentiate customer types. According to Pers1, validation packages are designed for a variety of customer bases, for example, customers running clinical samples in a regulated space, pharmaceutical companies running under good manufacturing practice, and diagnostic laboratories focusing on cancer targets. Future studies could address the limitations of this study by exploring marketing impact on different customer segments. The findings accounting for various customer types would add to the knowledge base of strategies for target marketing.

Reflections

The goal of this study was to understand how successful business development managers market products and services aimed to improve patient care. I found the doctoral study process challenging but rewarding. As a previous field service engineer for diagnostic instrument organizations, I had been asked to promote the validation packages whenever possible. However, without marketing training and the understanding of the impact of clinical validations, I struggled to help my customers find solutions to their needs. My knowledge of clinical validations was limited to the contents in the validation documentation and I was interested to learn the elements critical to generating marketing

success. My findings from this study demonstrated the significance of collaboration, both internal and external, contributes to marketing success that leads to closing sales.

Prior to conducting the research, my objective was to find ways in which marketing managers could use dynamic capabilities to increase the sales of diagnostic validation packages. I had believed that convincing clinical customers to purchase validation packages not only contribute to instrument manufacturing organizations' profits but also increase customers' laboratory efficiency. After conducting the research, I concluded that successful marketing strategies are a collaboration of cross-functional teams. The literature review confirmed my belief that the implementation of accreditation and validation has the potential to improve laboratory quality, leading to better healthcare. This study has broadened my understanding of instrument validation packages, their impact in clinical settings, and the importance of internal and external collaboration.

Conclusion

The purpose of this single case study was to explore successful marketing strategies managers in a diagnostic instrument manufacturing organization use to promote sales of validation packages for increasing the accuracy of oncology laboratory test results. Instrument validation compliance assures that the workflow is developed, maintained, and operated as designed (Agnihotri et al., 2013), minimizing false diagnoses (Fitzgibbons et al., 2014). By promoting and marketing instrument validation packages, diagnostic instrument manufacturing organizations can help promote laboratory quality and efficiency.

Dynamic capabilities allow organizations to integrate and reconfigure resources to increase competitive edge (Teece, 2012). Dynamic capabilities also enable organizations to combine tangible and intangible assets and convert them to profits (Teece, 2017). Through continuous integration and collaboration internally and externally, business development managers were able to promote NGS instrument validation packages with success. Integration of products and services can increase customer loyalty and satisfaction (Kasiri et al., 2017) and marketing strategies integrating hardware and services may help companies achieve competitive advantages (Gebauer et al., 2017). To achieve profitability, diagnostic instrument manufacturing organizations should not overlook the importance of cross-functional team collaboration and external partnership.

References

Abdallah, A. (2014). Implementing quality initiatives in healthcare organizations: Drivers and challenges. *International Journal of Health Care Quality Assurance, 27*(3), 166-181. doi:10.1108/IJHCQA-05-2012-0047

Acharya, A. S., Prakash, A., Saxena, P., & Nigam, A. (2013). Sampling: Why and how of it? *Indian Journal of Medical Specialties, 4*, 330-333. doi:10.7713/ijms.2013.0032

Acuna, A., Collino, C. & Chiabrando, G. A. (2015). Laboratory Accreditation in Argentina. *The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine, 26*, 251-254. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4975361/pdf/ejifcc-26-251.pdf

Adcock, D. M., Favaloro, E. J., & Lippi, G. (2016). Critical pre-examination variables in the hemostasis laboratory and their quality indicators. *Clinical Biochemistry, 49*, 1315-1320. doi:10.1016/j.clinbiochem.2016.08.022

Agnihotri, A., Kaur, S., Kumar, J., & Chahal, R. (2013). Performance qualification: Critical to validation. *Asian Journal of Transfusion Science, 7*, 4-5. doi:10.4103/0973-6247.106711

Ajagbe, M. A., Isiavwe, D. T., Sholanke, A. B., & Oke, A. O. (2015). Qualitative inquiry for social sciences. *International Conference on African Development Issues, 2015*, 319-325. Retrieved from http://eprints.covenantuniversity.edu.ng/5293/1/Paper%20137.pdf

Al-Mutairi, A., Meyer, A. N. D., Thomas, E. J., Ethegaray, J. M., Roy, K. M., Davalos, M. C., . . . & Singh, H. (2016). Accuracy of the safer Dx instrument to identify

diagnostic errors in primary care. *Journal of General Internal Medicine, 31,* 602-608. doi:10.1007/s11606-016-3601-x

Allen, L. C. (2013). Role of a quality management system in improving patient safety – laboratory aspects. *Clinical Biochemistry, 46,* 1187-1193. doi:10.1016/j.clinbiochem.2013.04.028

Allen, R. E. S., & Wiles, J. L. (2016). A rose by any other name: Participants choosing research pseudonyms. *Journal of Qualitative Research in Psychology, 13*(2), 149-165. doi:10.1080/14780887.2015.1133746

Angelos, P., Hartl, D. M., Shah, J. P., Nixon, I. J., Owen, R. P., Rinaldo, A, . . . Ferlito, A. (2017). Ethical issues in non-intervention trials for thyroid cancer. *European Journal of Surgical Oncology, 2017,* 1-5. doi:10.1016/j.ejso.2017.03.002

Antes, A. L., Chibnall, J. T., Baldwin, K. A., Tait, R. C., Vander Wal, J. S., & DuBois, J. M. (2016). Making professional decisions in research: Measurement and key predictors. *Journal of Accountability in Research, 23*(5), 288-308. doi:10.1080/08989621.2016.1171149

Anyan, F. (2013). The influence of power shifts in data collection and analysis stages: A focus on qualitative research interview. *The Qualitative Report, 18*(18), 1-9. Retrieved from http://www.nova.edu/ssss/QR/QR18/anyan36.pdf

Apostolova, E., Pourashraf, P., & Sack, J. (2015). Digital leafleting: Extracting structured data from multimedia online flyers. *Human Language Technologies, 2015,* 283-292. Retrieved from https://aclweb.org/anthology/N/N15/N15-1032.pdf

Arend, R. J., & Bromiley, P. (2009). Assessing the dynamic capabilities view: Spare

change, everyone? *Strategic Organization, 7*(1), 75-90. doi:10.1177/1476127008100132

Arriaza, P., Nadjat-Haiem, F., Lee, H. Y., & Martin, S. S. (2015). Guidelines for conducting rigorous health care psychosocial cross-cultural/language qualitative research. *Social Work in Public Health, 30*(1), 75-87. doi:10.1080/19371918.2014.938394

Attali, Y., Laitusis, C., & Stone, E. (2016). Differences in reaction to immediate feedback and opportunity to revise answers for multiple-choice and open-ended questions. *Educational and Psychological Measurement, 76*, 787-802. doi:10.1177/0013164415612548

Aziz, N., Zhao, Q., Bry, L., Driscoll, D. K., Funke, B., Gibson, J. S., . . . Voelkerding, K. V. (2015). College of American Pathologists' laboratory standards for next-generation sequencing clinical tests. *Archives of Pathology and Laboratory Medicine, 139*, 481-493. doi:10.5858/arpa.2014-0250-CP

Bai, W., Feng, Y., Yue, Y., & Feng, L. (2017). Organizational structure, cross-functional integration, and performance of new product development team. *Procedia Engineering, 174*, 621-629. doi:10.1016/j.proeng.2017.01.198

Baillie, L. (2015). Promoting and evaluating scientific rigour in qualitative research. *Nursing Standard, 29*(46), 36-42. doi:10.7748/ns.29.46.36.e8830

Bari, A., Khan, R. A. & Rathore, A. W. (2016). Medical errors: Causes, consequences, emotional response and resulting behavioral change. *Pakistan Journal of Medical Sciences, 32*, 523-528. doi:10.12669/pjms.323.9701

Bambale, A. (2014). Research methodological techniques as a model for quantitative studies in social sciences. *British Journal of Economics, Management & Trade, 4*, 862-879. doi:10.9734/bjemt/2014/7665

Barrales-Molina, V., Martinez-Lopez, F. J., & Gazquez-Abad, J. C. (2014). Dynamic marketing capabilities: Toward an integrative framework. *International Journal of Management Reviews, 16*, 397-416. doi:10.1111/ijmr.12026

Bashir, M. R., Sirlin, C. B., & Reeder, S. B. (2014). On confirmation bias in imaging research. *Journal of Magnetic Resonance Imaging, 41*, 1163-1164. doi:10.1002/jmri.24720

Bayu, H., Berhe, Y., Mulat, A., & Alemu, A. (2016). Cervical cancer screening service uptake and associated factors among age eligible women in Mekelle zone, northern Ethiopia, 2015: A community based study using health belief model. *PLoS one, 11*(3), e0149908. doi:10.1371/journal.pone.0149908

Beatty, S. E., Ogilvie, J., Northington, W. M., Harrison, M. P., Holloway, B. B., & Wang, S. (2016). Frontline service employee compliance with customer special requests. *Journal of Service Research, 19*(2), 158-173. doi:10.1177/1094670515624978

Bengtsson, M. (2016). How to plan and perform a qualitative study using content analysis. *NursingPlus Open, 2*, 8-14. doi:10.1016/j.npls.2016.01.001

Benoot, C., Hannes, K., & Bilsen, J. (2016). The use of purposeful sampling in a qualitative evidence synthesis: A worked example on sexual adjustment to a cancer trajectory. *BMC Medical Research Methodology, 16*(21), 1-12.

doi:10.1186/s12874-016-0114-6

Bhat, S., Gijo, E., & Jnanesh, N. (2014). Application of lean six sigma methodology in the registration process of a hospital. *International Journal of Productivity and Performance Management, 63,* 613-643. doi:10.1108/IJPPM-11-2013-0191

Birt, L., Scott, S., Cavers, D., Campbell, C., & Walter, F. (2016). Member checking: A tool to enhance trustworthiness or merely a nod to validation? *Qualitative Health Research, 26,* 1802-1811. doi:10.1177/1049732316654870

Bouzon, M., Miguel, P. A. C., & Rodriguez, T. (2014). Managing end of life products: A review of the literature on reverse logistics in Brazil. *Management of Environmental Quality: An International Journal, 25,* 564-584. doi:10.1108/MEQ-04-2013-0027

Bradley, E. H., Curry, L. A., & Devers, K. J. (2007). Qualitative data analysis for health services research: Developing taxonomy, themes, and theory. *Health Services Research, 42,* 1758-1772. doi:10.1111/j.1475-6773.2006.00684.x

Brinkmann, S. (2014). *Encyclopedia of critical psychology*. doi:10.1007/978-1-4614-5583-7_161

Bungay, V., Oliffe, J., & Atchison, C. (2016). Addressing underrepresentation in sex work research: Reflections on designing a purposeful sampling strategy. *Qualitative Health Research, 26,* 966-978. doi:10.1177/1049732315613042

Caliendo, A. M., & Hanson, K. E. (2016). Point-counterpoint: The FDA has a role in regulation of laboratory-developed tests. *Journal of Clinical Microbiology, 54,* 829-833. doi:10.1128/JCM.00063-16

Carter, N., Bryant-Lukosius, D., DiCenso, A., Blythe, J., & Neville, A. J. (2014). The use of triangulation in qualitative research. *Oncology Nursing Forum, 41*(5), 545-547. doi:10.1188/14.ONF.545-547

Clarke, V., & Braun, V. (2014). Thematic analysis. In Teo T. (Ed.), *Encyclopedia of Critical Psychology* (pp. 1947-1952). doi:10.1007/978-1-4614-5583-7_311

Claro, D. P., & Ramos, C. (2018). Sales intrafirm networks and the performance impact of sales cross-functional collaboration with marketing and customer service. *Journal of Personal Selling and Sales Management, 38*(2), 172-190. doi:10.1080/08853134.2018.1437353

Cleary, M., Horsfall, J., & Hayter, M. (2014). Data collection and sampling in qualitative research: Does size matter? *Journal of Advanced Nursing, 70*, 473-473. doi:10.1111/jan.12163

Centers for Disease Control and Prevention. (2015). Health expenditures. *National Center for Health Statistics*. Retrieved from http://www.cdc.gov/nchs/fastats/health-expenditures.htm

Chandler, J. J., & Paolacci, G. (2017). Lie for a dime: When most prescreening responses are honest but most study participants are impostors. *Social Psychological and Personality Science, 8*, 500-508. doi:10.1177/1948550617698203

Chen, L., & Scheld, H. (2014). Compliance within medical information and the emergence of a medical information-dedicated compliance person: A benchmarking survey. *Therapeutic Innovation & Regulatory Science, 48*, 494-497. doi:10.1177/2168479014529570

Christians, C. G. (2011). Ethics and politics in qualitative research. *The Sage Handbook of Qualitative Research* (4th ed., pp. 61-80). Thousand Oaks, CA: Sage Publications.

Collins, A. B., Strike, C. S., Turje, S. B., McDougall, P. Parashar, S., & McNeil, R. (2017). "We're giving you something so we get something in return": Perspectives on research participation and compensation among people living with HIV who use drugs. *International Journal of Drug Policy, 39*, 92-98. doi:10.1016/j.drugpo.2016.09.004

Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches* (Laureate Education, Inc., custom ed.). Thousand Oaks, CA: Sage Publications.

Creswell, J.W., & Poth, C. N. (2017). *Qualitative inquiry and research design: Choosing among five approaches* (4th ed.). Thousand Oaks, CA: Sage Publications.

Cooper, A. C. G. (2017). Building physics into the social: Enhancing the policy impact of energy studies and energy social science research. *Energy Research and Social Science, 26*, 80-86. doi:10.1016/j.erss.2017.01.013

Cridland, E. K., Jones, S. C., Caputi, P., & Magee, C. A. (2014). Qualitative research with families living with autism spectrum disorder: Recommendations for conducting semistructured interviews. *Journal of Intellectual and Developmental Disability, 40*(1), 78-91. doi:10.3109/13668250.2014.964191

Cummings, C. A., Peters, E., Lacroix, L., Andre, F. & Lackner, M. R. (2016). The role of next-generation sequencing in enabling personalized oncology therapy. *Clinical*

and Translational Science, 9, 283-292. doi:10.1111/cts.12429

Cypress, B. (2017). Rigor or reliability and validity in qualitative research: Perspectives, strategies, reconceptualization, and recommendations. *Dimensions of Critical Care Nursing, 36*(4), 253-263. doi:10.1097/DCC.0000000000000253

Dang, M. V., François, P., Batailler, P., Seigneurin, A., Vittoz, J., Sellier, E., & Labarère, J. (2014). Medical record-keeping and patient perception of hospital care quality. *International Journal of Health Care Quality Assurance, 27*, 531-543. doi:10.1108/IJHCQA-06-2013-0072

Dean, D., Arroyo-Gamez, R. E., Punjaisri, K., & Pich, C. (2016). Internal brand co-creation: The experiential brand meaning cycle in higher education. *Journal of Business Research, 69*, 3041-3048. doi:10.1016/j.jbusres.2016.01.019

Dekaran, S., & O'Farrell, P. N. (2014). The impact of hospital accreditation on clinical documentation compliance: A life cycle explanation using interrupted time series analysis. *BMJ Open, 4*(8), 1-9. doi:10.1136/bmjopen-2014-005240

DeMassis, A., & Kotlar, J. (2014). The case study method in family business research: Guidelines for qualitative scholarship. *Journal of Family Business Strategy, 5*, 15-29. doi:10.1016.j.jfbs.2014.01.007

Demortain, D. (2017). Expertise, regulatory science and the evaluation of technology and risk: Introduction to the special issue. *Springer Science, 55*(2), 139-159. doi:10.1007/s11024-017-9325-1

Dempsey, L., Dowling, M., Larkin, P., & Murphy, K. (2016). Sensitive interviewing in qualitative research. *Research in Nursing and Health, 39*, 480-490.

doi:10.1002/nur.21743

Denzin, N. K. (2014). Triangulation 2.0. *Journal of Mixed Methods Research, 6*(2), 80-88. doi:10.1177/1558689812437186

Deriyenko, T., Hartkopp, O., & Mattfeld, D. C. (2017). Supporting product optimization by customer data analysis. *Operations Research Proceedings, 2015,* 491-496. doi:10.1007/978-3-319-42902-1_66

Drake, G. (2013). The ethical and methodological challenges of social work research with participants who fear retribution: to "do no harm." *Qualitative Social Work, 13*, 304-319. doi:10.1177/1473325012473499

Drisko, J. W. (2016). Introducing a special issue: Teaching qualitative research and inquiry. *Qualitative Social Work, 15,* 303-306. doi:10.1177/1473325016638197

Dubbink, H. J., Deans, Z. C., Tops, B. B. J., van Kemenade, F. J., Koljenovic, S., van Krieken, H. J. M.,…& Groenen, P. J. T. A. (2014). Next Generation diagnostic molecular pathology: Critical appraisal of quality assurance in Europe. *Molecular Oncology, 8*, 830-839. doi:10.1016/j.molonc.2014.03.004

Dwesar, R., & Rao, V. (2014). The skeptic consumer: Is information presented through advertisement and online reviews perceived differently. *Asia Pacific Marketing Review, 3*(1), 19-29. Retrieved from http://asiapacific.edu

El Hussein, M. T., Jakubec, S. L., & Osuji, J. (2016). The facts: A Mnemonic for the rapid assessment of rigor in qualitative research studies. *Journal of Nursing Education, 55*(1), 60-60. doi: 10.3928/01484834-20151214-15

Elbireer, A. M., Jackson, J. B., Sendagire, H., Opio, A., Bagenda, D., & Amukele, T. M.

(2013). The good, the bad, and the unknown: Quality of clinical laboratories in Kampala, Uganda. *PloS One, 8*(5), e64661. doi:10.1371/journal.pone.0064661

Elo, S., Kaariainen,M., Kanste, O., Polkki, T., Utriainen, K., & Kyngas, H. (2014). Qualitative content analysis: A focus on trustworthiness. *Sage Open, 4*(1), 1-10. doi:10.1177/2158244014522633

Endrullat, C., Glokler, J., Franke, P. & Frohme, M. (2016). Standardization and quality management in next-generation sequencing. *Applied and Translational Genomics, 10*(C), 2-9. doi:10.1016/j.atg.2016.06.001

Enzmann, H., Meyer, R., & Broich, K. (2016). The new EU regulation on in vitro diagnostics: Potential issues at the interface of medicines and companion diagnostics. *Biomarkers in Medicine, 10,* 1261-1268. doi:10.2217/bmm-2016-0233

Esserman, L. J., Thompson, I.M. & Reid, B. (2013). Overdiagnosis and Overtreatment in Cancer: An Opportunity for Improvement. *Journal of the American Medical Association. 310,* 797-798. doi:10.1001/jama.2013.108415

Evans, B. J., Burke, W., Jarvik, G. P. (2015). The FDA and genomic tests- getting regulation right. *New England Journal of Medicine, 372,* 2258-2264. doi:10.1056/NEJMsr1501194

Ferreira-Gonzalez, A., Emmadi, R., Day, S. P., Klees, R. F., Leib, J. R., Lyon, E., … Klein, R. D. (2014). Revisiting oversight and regulation of molecular-based laboratory-developed tests: A position statement of the association for molecular pathology. *The Journal of Molecular Diagnostics, 16*(1), 3-6.

doi:10.1016/j.jmoldx.2013.10.003

Fitzgibbons, P. L., Bradley, L. A., Fatheree, L. A., Alsabeh, R., Fulton, R. S., Goldsmith, J. D., ... Shen, S. S. (2014). Principles of analytic validation of immunohistochemical assays: Guideline from the college of American Pathologists Pathology and Laboratory Quality Center. *Archives of Pathology and Laboratory Medicine, 138*, 1432-1443. doi:10.5858/arpa.2013-0610-CP

Fleming, J. J. (2015). The decline of venture capital investment in early-stage life sciences poses a challenge to continued innovation. *Health Affairs, 34*(2), 271-276. doi:10.1377/hlthaff.2014.1051

Freedman, D. B. (2015). Towards better test utilization – strategies to improve physician ordering and their impact on patient outcomes. *The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine, 26*(1), 15-30. Retrieved from https://pdfs.semanticscholar.org/9904/10a65a9e240caccd88d61d5fa15a5667c986.pdf

Friesen, P., Kearns, L., Redman, B., & Caplan, A. L. (2017). Rethinking the Belmont report? *The American Journal of Bioethics, 17*(7), 15-21. doi:10.1080/15265161.2017.1329482

Funder, D. C., Levine, J. M., Mackie, D. M., Morf, C. C., Sansone, C., Vazire, S., & West, S. G. (2014). Improving the dependability of research in personality and social psychology: Recommendations for research and educational practice. *Personality and Social Psychology Review, 18*(1), 3-12.

doi:10.1177/1088868313507536

Gagan, F. & Van Allen, E. M. (2015). Next-generation sequencing to guide cancer therapy. *Genome Medicine, 7*(80), 1-10. doi:10.1186/s13073-015-0203-x

Gallo, I., Zamberletti, A., Noce, L. (2015). Content extraction from marketing flyers. *International Conference on Computer Analysis of Images and Patterns, 9256,* 325-336. doi:10.1007/978-3-319-23192-1_27

Gargis, A. S., Kalman, L., & Lubin, I. M. (2016). Assuring the quality of next-generation sequencing in clinical microbiology and public health laboratories. *Journal of Clinical Microbiology, 54,* 2857-2865. doi:10.1128/JCM.00949-16

Gebauer, H., Saul, C. J., Haldimann, M., & Gustafsson, A. (2017). Organizational capabilities for pay-per-use services in product-oriented companies. *International Journal of Production Economics, 192,* 157-168. doi:10.1016/j.ijpe.2016.12.007

Gershy-Damet, G. M., Rotz, P., Cross, D., Cham, F., Ndihokubwayo, J. B., Fine, G., ... Messele, T. (2010). The World Health Organization African Region Laboratory Accreditation Process. *American journal of clinical pathology, 134*(3), 393-400. doi:10.1309/AJCPTUUC2V1WJQBM

Gibson, S., Benson, O., & Brand, S. (2013). Talking about suicide: Confidentiality and anonymity in qualitative research. *Nursing Ethics, 20,* 18-29. doi:10.1177/0969733012452684

Giuseppe, L., Becan-McBride, K., Behulova, D., Bowen, R. A., Church, S., Delanghe, J.,…Simundic, A. (2013). Preanalytical quality improvement: In quality we trust. *Clinical Chemistry and Laboratory Medicine, 51*(1), 229-241. doi:10.1515/cclm-

2012-0597

Gorny, A., & Napierala, J. (2015). Comparing the effectiveness of respondent-driven sampling and quota sampling in migration research. *International Journal of Social Research Methodology, 19*, 654-661. doi:10.1080/13645579.2015.1077614

Grosu, D. S., Hague, L., Chelliserry, M., Kruglyak, K. M., Lenta, R., Klotzle, B., …Ong, F. S. (2014). Clinical investigational studies for validation of next-generation sequencing in vitro diagnostic device for cystic fibrosis testing. *Expert Review of Molecular Diagnostics, 14*, 605-622. doi:10.1586/14737159.2014.916618

Hadush, Z., Birhanu, Z., Chaka, M., & Gebreyesus, H. (2017). Foods tabooed for pregnant women in Abala district of Afar region, Ethiopia: An inductive qualitative study. *BMC Nutrition, 3*(40), 1-9. doi:10.1186/s40795-017-0159-x

Hafford-Letchfield, T. (2014). Doing a successful research project: Using qualitative and quantitative methods. *Social Work Education, 34*, 244-245. doi:10.1080/02615479.2014.941541

Hagaman, A. K., & Wutich, A. (2016). How many interviews are enough to identify metathemes in multisited and cross-cultural research? Another perspective on Guest, Bunce, and Johnson's (2006) landmark study. *Field Methods, 29*(1), 23-41. doi:10.1177/1525822X15540447

Hammarber, K., Kirkman, M., & de Lacey, S. (2016). Qualitative research methods: When to use them and how to judge them. *Human Reproduction, 31*, 498-501. doi:10.1093/humrep/dev334

Harriss, D. J., & Atkinson, G. (2014). Ethical standards in sport and exercise science

research: 2014 update. *International Journal of Sports Medicine, 34*, 1025-1028. doi:10.1055/s-0033-1358756

Harvey, L. (2014). Beyond member-checking: A dialogic approach to the research interview. *International Journal of Research & Method in Education, 38*(1), 23-38. doi:10.1080/1743727x.2014.914487

Hashjin, A. A., Kringos, D., Ravaghi, H., Manoochehri, J., Gorji, H. A., & Klazinga, N. S. (2015). Application of quality assurance strategies in diagnostics and clinical support services in Iranian hospitals. *International Journal of Health Policy and Management, 4*, 653-661. doi:10.15171/ijhpm.2015.96

Heale, R., & Forbes, D. (2013). Understanding triangulation in research. *Evidence Based Nursing, 16*, 98-104. doi:10.1136/eb-2013-101494

Heckathorn, D. D., & Cameron, C. J. (2017). Network Sampling: From Snowball and Multiplicity to Respondent-Driven Sampling. *Annual Review of Sociology, 43*, 101-119. doi:10.1146/annurev-soc-060116-053556

Hicks, L. K. (2015). Reframing overuse in health care: Time to focus on the harms. *Journal of Oncology Practice, 11*(3), 168-170. doi:10.1200/JOP.2015.004283

Hill, R. (2011). Verification and validation: Whose responsibility, manufacturer or end user. *Annals of Clinical Biochemistry, 48*, 93-94. doi:10.1258/acb.2011.011008

Holloway, I., & Galvin, K. (2016). *Qualitative research in nursing and healthcare.* Ames, IA: John Wiley and Sons, Ltd.

Honig, B., Lampel, J., Siegel, D., & Drnevich, P. (2014). Ethics in the production and dissemination of management research: Institutional failure or individual

fallibility? *Journal of Management Studies, 51*(1), 118-142. doi:10.1111/joms.12056

Ind, N. (2017). An integrated approach to corporate branding. *Journal of Brand Management, 1*, 109-118. doi:10.1057/978-1-352-00008-5_7

Imoh, L. C., Mutale, M., Parker, C. T., Erasmus, R., & Zemlin, A. (2016). Laboratory-based clinical audit as a tool for continual improvement: An example from CSF chemistry turnaround time audit in a South-African teaching hospital. *Biochemia Medica, 26*(2), 194-201. doi:10.101613/BM.2016.021

Jack, S., DiCenso, A., & Lohfeld, L. (2016). Opening doors: Factors influencing the establishment of a working relationship between paraprofessional home visitors and at-risk families. Canadian Journal of Nursing Research Archive, 34(4), 59-69. Retrieved from http://cjnr.archive.mcgill.ca/article/view/1792/1789

Jamshed, S. (2014). Qualitative research method-interviewing and observation. *Journal of Basic and Clinical Pharmacy, 5*(4), 87-88. doi:10.4103/0976-0105.141942

Janghorban, R., Roudsari, R. L., & Taghipour, A. (2014). Pilot stud in qualitative research: The roles and values. *Journal of Hayat, 19*(4), 1-5. Retrieved from http://hayat.tums.ac.ir/article-1-666-en.html

Jeng, D. J., & Pak, A. (2016). The variable effects of dynamic capabilities by firm size: The interaction of innovation and marketing capabilities in competitive industries. *International Enterprise Management Journal, 12*, 115-130. doi:10.1007/s11365-014-0330-7

Kaae, S., Sporrong, S. K., Traulsen, J. M., Wallach Kildemoes, H., Nørgaard, L. S.,

Jakupi, A., … Cantarero, L. A. (2016). Experiences from a pilot study on how to conduct a qualitative multi-country research project regarding use of antibiotics in Southeast Europe. *Journal of Pharmaceutical Policy and Practice, 9*(20), 1-10. http://doi.org/10.1186/s40545-016-0069-3

Kaleka, A., & Morgan, N. A. (2017). How marketing capabilities and current performance drive strategic intentions in international markets. *Industrial Marketing Management, NA*, 1-14. doi:10.1016/j.indmarman.2017.02.001

Kallio, H., Pietila, A., Johnson, M, & Docent, M. K. (2016). Systemic methodological review: Developing a framework for a qualitative semistructured interview guide. *Journal of Advanced Nursing, 72,* 2954-2965. doi:10.1111/jan.13031

Kanagal-Shamanna, R., Singh, R. R., Routbort, M. J., Patel, K. P., Medeiros, L. J., & Luthra, R. (2016). Principles of analytical validation of next-generation sequencing based mutational analysis for hematologic neoplasms in a CLIA-certified laboratory. *Journal of Expert Review of Molecular Diagnostics, 16*(4), 461-472. doi:10.1586/14737159.2016.1142374

Kasiri, L. A., Cheng, K. T. G., Sambasivan, M., & Sidin, S. M. (2017). Integration of standardization and customization: Impact on service quality, customer satisfaction, and loyalty. *Journal of Retailing and Customer Services, 35,* 91-97. doi:10.1016/j.jretconser2016.11.007

Killawi, a., Khidir, A., Elnashar, M., Abdelrahim, H., Hammoud, M., Elliott, H., … Fetters, M. (2014). Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: Findings from a qualitative

investigation. *BMC Medical Ethics, 15*(9), 1-13. doi:10.1186/1472-6939-15-9

Killeen, A. A., Long, T., Souers, R., Styer, P., Ventura, C. B. & Klee, G.G. (2014). Verifying performance characteristics of quantitative analytical systems: Calibration verification, linearity, and analytical measurement range. *Archives of Pathology and Laboratory Medicine, 138*, 1173-1181. doi:10.5858/arpa.2013-0051-CP

Kitchens, B., Dobolyi, D., Li., J., & Abbasi, A. (2018). Advanced customer analytics: Strategic value through integration of relationship-oriented big data. *Journal of Management Information Systems, 35*, 540-574. doi:10.1080/07421222.2018.1451957

Kivlighan, D. M., Hill, C. E., Gelso, C. J., & Baumann, E. (2016). Working alliance, real relationship, session quality, and client improvement in psychodynamic psychotherapy: A longitudinal actor partner interdependence model. *Journal of Counseling Psychology, 63*(2), 149-161. doi:10.1037/cou0000134

Knapik, M. (2006). The qualitative research interview: Participants' responsive participation in knowledge making. *International Journal of Qualitative Methods, 5*(3), 1-13. doi: 10.1177/160940690600500308

Koonrungsescomboon, N., Teekachunhatean, S., Hanprastertpong, N., Laothavorn, J., Na-Bangchang, K., & Karbwang, J. (2016). Improved participants' understanding in a healthy volunteer study using the SIDCER informed consent form: A randomized-controlled study. *European Journal of Clinical Pharmacology, 72*, 413-421. doi:10.1007/s00228-015-2000-2

Kornbluh, M. (2015). Combatting challenges to establishing trustworthiness in qualitative research. *Qualitative Research in Psychology, 12*, 397-414. doi:10.1080/14780887.2015.1021941

Kozlenkova, I. V., Samaha, S. A., Palmatier, R. W. (2014). Resource-based theory in marketing. *Journal of Academy Marketing Science, 42*, 1-21. doi:10.1007/s11747-013-0336-7

Lanman, R. B., Mortimer, S. A., Zill, O. A., Sebisanovic, D., Lopez, R., Blau, S.,…& Talasaz, A. (2015). Analytical and clinical validation of a digital sequencing panel for quantitative, highly accurate evaluation of cell-free circulating tumor DNA. *PloS one, 10*(10), e0140712. doi:10.1371/journal.pone.0140712

Lavallee, D. C., Comstock, B., Scott, M. R., Avins, A. L., Nerenz, D. R., Edwards, T. C., … Jarvik, J. G. (2017). Study of methods for assessing research topic elicitation and prioritization (SMARTER): Study protocol to compare research methods and advance patient engagement in research. *JMIR Research Protocols, 6*(9), e168. doi:10.2196/resprot.7565

Leedy, P D., & Ormrod, J. E. (2013). *Practical research: Planning and design* (10th ed.). Upper Saddle River, NJ: Pearson Education.

Leibenger, D., Mollers, F., Petrlic, A., Petrlic, R., & Sorge, C. (2016). Privacy challenges in the quantified self movement – An EU perspective. *Proceedings on Privacy Enhancing Technologies, 2016*(4), 315-334. doi:10.1515/popets-2016-0042

Leon, A. C., Davis, L. L., Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research, 45*, 626-629.

doi:10.1016/j.jpsychires.2010.10.008

Lester, S., Harr, K. E., Rishniw, M. & Pion, P. (2013). Current quality assurance concepts and considerations for quality control of in-clinic biochemistry testing. *Journal of the American Veterinary Medical Association, 242*(2), 182-192. doi:10.2460/javma.242.2.182

Leung, L. (2015). Validity, reliability, and generalizability in qualitative research. *Journal of Family Medicine and Primary Care, 4*(3), 324-327. doi:10.4103/2249-4863.161306

Leva, M., D'Attoma, I., Ziliani, C., & Gazquez-Abad, J. C. (2016). Do store flyers work? Implications for NBs and PLs from a subgroup analysis with experimental data. *Advantages in National Brand and Private Label Marketing, 2016*, 129-136. doi:10.1007/978-3-319-39946-1_16

Levashina, J., Hartwell, C. J., Morgeson, F. P., & Campion, M. A. (2014). The structured employment interview: Narrative and quantitative review of the research literature. *Personnel Psychology, 67*(1), 241-293. doi:10.1111/peps.12052

Levit, M., Huang, Y., Chang, S., & Gong, Y. (2017). Don't count on ASR to transcribe for you: Breaking bias with two crowds. *Interspeech, 2017*, 3941-3945. doi:10.21437/Interspeech.2017-164

Lewis, S. (2015). Qualitative inquiry and research design: Choosing among five approaches. *Health Promotion Practice, 16*, 473-475. doi:10.1177/1524839915580941

Li, H., Huang, X., Yang, Y., Huang, W., Chen, L., Song, P., & Zhang, W. (2016).

Reduction of pre-analytical errors in clinical laboratory through multiple aspects and whole course intervention measures. *International Medical Journal, 23*(4), 446-449. doi:10.1111/jebm.12115

Lin, Y., & Wu, L. (2014). Exploring the role of dynamic capabilities in firm performance under the resource-based view framework. *Journal of Business Research, 67*, 407-413. doi:10.1016/j.jbusres.2012.12.019

Lippi, G., Plebani, M., & Graber, M. L. (2016). Building a bridge to safe diagnosis in healthcare. The role of the clinical laboratory. *Clinical Chemistry and Laboratory Medicine, 54*(1), 1-3. doi:10.1515/cclm-2015-1135

Luceri, B., Latusi, S., Vergura, D. T., Lugli, G. (2014). The impact of store flyers on store performance: A format and customer related approach. *International Journal of Retail and Distribution Management, 42*(3), 219-234. doi:10.1108/IJRDM-11-2012-0101

Luga, A. O. & McGuire, M. J. (2014). Adherence and health care costs. *Risk Management and Healthcare Policy, 7*, 35-44. doi:10.2147/RMHP.S19801

Lyon, E., Cockerill, F. R., Bale, S. J., Beadling, C., Bry, L., Hagenkord, J., … Polomaki, G. E. (2015). Next generation sequencing in clinical diagnostics: Experiences of early adopters. *Clinical Chemistry, 61*(1), 41-49. doi:10.1373/clinchem.2014.222678

Mahoney, J., & Vanderpoel, R. S. (2015). Set diagrams and qualitative research. *Comparative Political Studies, 48*(1), 65-100. doi:10.1177/0010414013519410

Manganelli, J., Threatt, A., Brooks, J. O., Healy, S., Merino, J., Yanik, P., & Green, K.

(2014). Confirming, classifying, and prioritizing needed over-the-bed table improvements via methodological triangulation. *Health Environments Research and Design Journal, 8*(1), 94-114. doi:10.1177/193758671400800108

Manickam, T. S. & Ankanagarl, S. (2015). Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation. *Journal of Medical Laboratory and Diagnosis, 6*(5), 27-35. doi:10.5897/JMLD2015.0104

Marcus, B., Weigelt, O., Hergert, J., Gurt, J., & Gelleri, P. (2016). The use of snowball sampling for multisource organizational research: Some cause for concern. *Personal Psychology, 70*, 635-673. doi:10.1111/peps.12169

Marques, C. A. V., de Figueiredo, E. N. & de Gutierrez, M. G. R. (2015). Validation of an instrument to identify actions for screening and detection of breast cancer. *Acta Paulista de Enfermagem, 28*(2), 183-189. doi:10.1590/1982-0194201500031

Marshall, B., Cardon, P., Poddar, A., & Fontenot, R. (2015). Does sample size matter in qualitative research? A review of qualitative interviews in IS research. *Journal of computer information systems, 54*(1), 11-22. doi:10.1080/08874417.2013.11645667

Marshall, C., & Rossman, G. B. (2016). *Designing qualitative research* (6th ed.). Thousand Oaks, Ca: Sage Publications.

Mathrick, R., Meagher, T., & Norbury, C. F. (2017). Evaluation of an interview skills training package for adolescents with speech, language and communication needs. *International Journal of Language and Communication Disorders, 52*, 786-799.

doi:10.1111/1460-6984.12315

Mbah, H., Ojo, E., Ameh, J., Musuluma, H., Negedu-Momoh, O. R., Jegede, F.,…&Torpey, K. (2014). Piloting laboratory quality system management in six health facilities in Nigeria. *PloS one, 9*(12), e116185. doi:10.1371/journal.pone.0116185

McGonagle, K. A., Brown, C., & Schoeni, R. F. (2015). The effects of respondents' consent to be recorded on interview length and data quality in a national panel study. *Field Methods, 27*(4), 373-390. doi:10.1177/1525822X15569017

McIntosh, M. J., & Morse, J. M. (2015). Situating and constructing diversity in semistructured interviews. *Global Qualitative Nursing Research, 2*, 1-12. doi:10.1177/2333393615597674

McKim, C. A. (2015). The value of mixed methods research. *Journal of Mixed Methods Research, 11*(2), 202-222. doi:10.1177/1558689815607096

McMillan, J. (2016). Principles of Analytical Validation. *In Proteomic Profiling and Analytical Chemistry: The Crossroads: Second Edition* (pp. 239-251). Elsevier Inc. doi:10.1016/B978-0-444-63688-1.00013-6

Moon, K., Brewer, T. D., Januchowski-Hartley, S. R., Adams, V. M., & Blackman, D. A. (2016). A guideline to improve qualitative social science publishing in ecology and conservation journals. *Ecology and Society, 21*(3), 1-20. doi:10.5751/ES-08663-210317

Miller, W. G., Tate, J. R., Barth, J. H., & Jones, G. R. D. (2014). Harmonization: The sample, the measurement, and the report. *Annals of Laboratory Medicine, 34*(3),

187-197. doi:10.3343/alm.201434.3.187

Mira-Long, E., Washetine, K, & Hofman, P. (2016). Sense and nonsense in the process of accreditation of a pathology laboratory. *Virchows Archives, 468*(1), 43-49. doi:10.1007/s00428-015-1837-1

Moller, K., & Parvinen, P. (2015). An impact-oriented implementation approach in business marketing research: Introduction to the special issue on "implementing strategies and theories of B2B marketing and sales management". *Industrial Marketing Management, 45*, 3-11. doi:10.1016/j.indmarman.2015.02.025

Morse, J. M. (2015). Critical analysis of strategies for determining rigor in qualitative inquiry. *Qualitative Health Research, 25*, 1212-1222. doi:10.1177/1049732315588501

Morse, J. M. (2016). *Mixed method design: Principles and procedures*. New York, NY: Routledge.

Morse, J. M., & Coulehan, J. (2015). Maintaining confidentiality in qualitative publications. *Qualitative Health Research, 25*(2), 151-152. doi:10.1177/1049732314563489

Nalcaci, G., & Yagci, M. I. (2014). The effects of marketing capabilities on export performance using resource-based view: assessment on manufacturing companies. *Procedia – Social and Behavioral Sciences, 148*, 671-679. doi:10.1016/j.sbspro.2014.07.012

Neergaard, M. A., Olesen, F., Andersen, R. S., Sondergaard, J. (2009). Qualitative description – the poor cousin of health research? *BMC Medical Research*

Methodology, 9(52), 1-5. doi:10.1186/1471-2288-9-52

Newington, L., & Metcalfe, A. (2014). Factors influencing recruitment to research: Qualitative study of the experiences and perceptions of research terms. *BMC Medical Research Methodology, 14*(1), 1-20. doi:10.1186/1471-2288-14-10

Nkengasong, J. N., & Birx, D. (2014). Quality matters in strengthening global laboratory medicine. *African Journal of Laboratory Medicine, 3*(2), 1-4. doi:10.4102/ajlm.v3i2.239

Noble, H., & Smith, J. (2015). Issues of validity and reliability in qualitative research. *Evidence-Based Nursing, 18*(2), 34-35. doi:10.1136/eb-2015-102054

O'Connor, B., Pollner, F. & Fugh-Berman, A. (2016). Salespeople in the surgical suite: Relationships between surgeons and medical device representatives. *PLoS ONE, 11*(8), e0158510. doi:10.1371/journal.pone.0158510

Paap, K. R. (2014). The role of componential analysis, categorical hypothesizing, replicability, and confirmation bias in testing for bilingual advantages in executive functioning. *Journal of Cognitive Psychology, 26*(3), 242-255. doi:10.1080/20445911.2014.891597

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research, 42*, 533-544. doi:10.1007/s10488-013-0528-y

Palmatier, R. W. (2017). Marketing research centers: Community, productivity, and relevance. *Journal of the Academy of Marketing Science, 45*, 465-466.

doi:10.1007/s11747-017-05385

Panagiotou, N. (2013). Forces driving change in medical diagnostics. *Clinica Chimica Acta, 415,* 31-34. doi:10.1016/j.cca.2012.09.005

Pandey, R. V., Pabinger, S., Kriegner, A., & Weinhausel, A. (2016). ClinQC: A tool for quality control and cleaning of Sanger and NGS data in clinical research. *BMC Bioinformatics, 17*(56), 1-9. doi:10.1186/s12859-016-0915-y

Peredaryenko, M. S., & Krauss, S. E. (2013). Calibrating the human instrument: Understanding the interviewing experience of novice qualitative researchers. *The Qualitative Report, 18*(43), 1-17. Retrieved from http://nsuworks.nova.edu/tqr/vol18/iss43/1/

Peter, T. F., Rotz, P. D., Blair, D. H., Khine, A, Freeman, R. R. & Murtagh, M. M. (2010). Impact of laboratory accreditation on patient care and the health system. *American Journal of Clinical Pathology, 134,* 550-555. doi:10.1309/AJCPH1SKQ1HNWGHF

Petersen, J. A., Kumar, V., Polo, Y., & Sese, F. J. (2017). Unlocking the power of marketing: Understanding the links between customer mindset metrics, behavior, and profitability. *Journal of the Academy of Marketing Science, 2017,* 1-24. doi:10.1007/s11747-017-0554-5

Petty, N. J., Thomson, O. P., & Stew, G. (2012). Ready for a paradigm shift? Part 2: Introducing qualitative research methodologies and methods. *Manual Therapy, 17,* 378-384. doi:10.1016/j.math.2012.03.004

Phillips, V., Njau, J., Li, S., & Kachur, P. (2015). Simulations show diagnostic testing for

malaria in young African children can be cost-saving or cost-effective. *Health Affairs, 34*(7), 1196-13A. doi:10.1377/hlthaff.2015.0095

Pierre, J. M. (2017). Qualitative marketing research. *Qualitative Market Research: An International Journal, 20*, 390-392. doi:10.1108/QMR-03-2017-0068

Plamondon, K. M., Bottorff, J. L., & Cole, D. C. (2015). Analyzing data generated through deliberative dialogue: Bringing knowledge translation into qualitative analysis. *Qualitative Health Research, 25*, 1529-1539. doi:10.1177/1049732315581603

Plebani, M. (2017). Quality in laboratory medicine: 50 years on. *Clinical Biochemistry, 50*(3), 101-104. doi:10.1016/j.clinbiochem.2016.10.007

Plebani, M., Sciacovelli, L., Aita, A., Padoan, A., & Chiozza, M. L. (2014). Quality indicators to detect pre-analytical errors in laboratory testing. *Clinica Chimica Acta, 432*, 44-48. doi:10.1016/j.cca.2013.07.033

Powell, D. A., Erdozain, S., Dodd, C., Costa, R., Morley, K., & Chapman, B. J. (2013). Audits and inspections are never enough: A critique to enhance food safety. *Food Control, 30*(2), 686-691. doi:10.1016/j.foodcont.2012.07.044

Quail. M. A., Smith, M., Coupland, P., Otto, T. D., Harris, S. R., Connor, T. R., Bertoni, A.,…Gu, Y. (2012). A tale of three next generation sequencing platforms: Comparison of Ion Torrent, Pacific Biosciences and Illumina MiSeq sequencers. *BioMed Central Genomics, 13*(341), 1-13. doi:10.1186/1471-2164-13-34

Raheim, M., Magnussen, L. H., Sekse, R. J. T., Lunde, A., Jacobsen, T., & Blystad, A. (2016). Researcher-researched relationship in qualitative research: Shifts in

positions and researcher vulnerability. *International Journal of Qualitative Studies in Health and Well-being, 11*, 1-12. doi:10.3402/qhw.v11.30996

Revell, P., & Chandramohan, L. (2014). Selection and implementation of new equipment and procedures. *Clinical Laboratory Management, 2*, 506-514. doi:10.1128/9781555817282.ch27

Rife, S. C., Cate, K. L., Kosinski, M., & Stillwell, D. (2014). Participant recruitment and data collection through Facebook: The role of personality factors. *International Journal of Social Research Methodology, 19*(1), 69-83. doi:10.1080/13645579.2014.957069

Robins, C. S., & Eisen, K. (2017). Strategies for the effective use of NVivo in a large-scale study: Qualitative analysis and the repeal of don't ask, don't tell. *Qualitative Inquiry, 23*, 768-778. doi:10.1177/1077800417731089

Robinson, J. (2008). Value-based purchasing for medical devices. *Health Affairs, 26*, 1523-1531. doi:10.1377/hlthaff.27.6.1523

Robinson, O. C. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology, 11*(1), 25-41. doi:10.1080/14780887.2013.801543

Rosch, H., & Schumacher, S. (2018). Digital business outcomes: Digital innovation and its contribution to corporate development. *Digital Marketplaces Unleashed, 2018*, 607-617. doi: 10.1007/978-3-662-49275-8_54

Rosenthal, M. (2016). Qualitative research methods: Why, when, and how to conduct interviews and focus groups in pharmacy research. *Currents in Pharmacy*

Teaching and Learning, 8(4), 509-516. doi:10.1016/j.cptl.2016.03.021

Salvato, C., & Vassolo, R. (2017). The sources of dynamism in dynamic capabilities. *Strategic Management Journal, 38*, 1-29. doi:10.1002/smj.2703

Sandhya, C., Bonthagarala, B., Sai, P. D. L., & Sivaiah, K. V. (2015). Process validation: An essential process in pharmaceutical industry. *International Journal of Advances in Scientific Research, 1*(4), 179-182. doi:10.7439/ijasr

Sanjari, M., Bahramnezhad, F., Fomani, F. K., Shoghi, M., & Cheraghi, M. A. (2014). Ethical challenges of researchers in qualitative studies: The necessity to develop a specific guideline. *Journal of Medical Ethics and History of Medicine, 7*(14), 1-6. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4263394/pdf/jmehm-7-14.pdf

Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., … Jinks, C. (2017). Saturation in qualitative research: Exploring its conceptualization and operationalization. *Quality and Quantity, 2017*, 1-15. doi:10.1007/s11135-017-0574-8

Schroeder, L. F., Elbireer, A., Jackson, J. B., & Amukele, T. K. (2015). Laboratory diagnostics market in East Africa: A survey of test types, test availability, and test prices in Kampala, Uganda. *PLoS ONE, 10*(7), e0134578. doi:10.1371/journal.pone.0134578

Schwind, C., & Buder, J. (2012). Reducing confirmation bias and evaluation bias: When are preference-inconsistent recommendations effective – and when not? *Computers in Human Behavior, 28*, 2280-2290. doi:10.1016/j.chb.2012.06.035

Sciacovelli, L., Aita, A., & Plebani, M. (2017). Extra-analytical quality indicators and laboratory performances. *Clinical Biochemistry, S0009-9120*(17), 1-6. doi:10.1016/j.clinbiochem.2017.03.020

Setia, M. S. (2016). Methodology Series Module 5: Sampling Strategies. *Indian Journal of Dermatology, 61*, 505-509. doi:10.4103/0019-5154.190118

Sidawy, M. K. (2015). US food and drug administration regulatory oversight of laboratory-developed tests: Commentary on the draft guidance. *Cancer Cytopathology, 123*(10), 573-575. doi:10.1002/cncy.21566

Sikkens, E., van San, M., Sieckelinck, S., Boeije, H., & de Winter, M. (2016). Participant recruitment through social media: Lessons learned from a qualitative radicalization study using Facebook. *Sage Journals, 29*(2), 130-139. doi:10.1177/1525822X16663146

Singh, H., Meyer, A. N. D., & Thomas, E. J. (2014). The frequency of diagnostic errors in outpatient care: Estimations from three large observational studies involving US adult populations. *BMJ Quality and Safety, 23*, 727-731. doi:10.1136/bmjqs-2013-002627

Smith, A. (2016). Data collection dangers. *ITNOW, 57*(1), 10-12. doi:10.1093/itnow/bwv004

Smith, V. (2010). *A qualitative study: Clinical marketing strategies for medical devices innovations that increase adoption in the USA*. Saint Mary's University, Nova Scotia: Halifax.

Smits, H., Supachutikul, A., & Mate, K. S. (2014). Hospital accreditation: Lessons from

low- and middle- income countries. *Globalization and Health, 10*(65), 1-8. doi:10.1186/s12992-014-0065-9

Sotiriadou, P., Brouwers, J., & Le, T. (2014). Choosing a qualitative data analysis tool: a comparison of NVivo and Leximancer. *Annals of Leisure Research, 17*(2), 218-234. doi:10.1080/11745398.2014.902292

Swanson, D., Jin, Y. H., Fawcett, A. M., & Fawcett, S. E. (2017). Collaborative process design: A dynamic capabilities view of mitigating the barriers to working together. *International Journal of Logistics Management, 28*, 571-599. doi:10.1108/IJLM-02-2016-0044

Teece, D. J. (2010). Chapter 16 - Technological innovation and the theory of the firm: The role of enterprise-level knowledge, complementarities, and (dynamic) capabilities. *Handbook of the Economics of Innovation* (pp. 679–730). doi:10.1016/S0169-7218(10)01016-6

Teece, D. J. (2014). A dynamic capabilities-based entrepreneurial theory of the multinational enterprise. *Journal of International Business Studies, 45*, 8-37. doi:10.1057/jibs.2013.54

Teece, D. J. (2017). Business models and dynamic capabilities. *Long Range Planning, 2017*,1-10. doi:10.1016/j.irp.2017.06.007

Teece, D. J., Pisano, G. P., & Shuen, A. (1990). *Firm capabilities, resources, and the concept of strategy: four paradigms of strategic management* (pp. CCC-working). University of California at Berkeley, Center for Research in Management, Consortium on Competitiveness & Cooperation.

Teece, D. J., Pisano, G. P., & Shuen, A. (1997). Dynamic capabilities and strategic management. Strategic. *Strategic Management Journal, 18*, 509–533. Retrieved from http://www.jstor.org/stable/3088148

Tehrani, A. S. S., Lee, H., Mathews, S. C., Shore, A., Makary, M. A., Pronovost, P. J., & Newman-Toker, D. E. (2013). 25-Year summary of US malpractice claims for diagnostic errors 1986–2010: An analysis from the National Practitioner Data Bank. *BMJ Quality and Safety, 22*, 672-680. doi:10.1136/bmjqs-2012-001550

Tenaw, Z., Yohannes, Z., & Amano, A. (2017). Obstetric care providers' knowledge, practice, and associated factors towards active management of third stage of labor in Sidama zone, South Ethiopia. *BMC Pregnancy and Childbirth, 17*(292), 1-7. doi:10.1186/s12884-017-1480-8

Tetnowski, J. (2015). Qualitative case study research design. *Perspect Fluen Fluen Disord, 25*(1), 39-39. doi:10.1044/ffd25.1.39

Thomas, E., & Magilvy, J. K. (2011). Qualitative rigor or research validity in qualitative research. *Journal for Specialists in Pediatric Nursing, 16*(2), 151-155. doi:10.1111/j.1744-6155.2011.00283.x

Tosteson, A. N., Fryback, D. G., Hammond, C. S., Hanna, L. G., Grove, M. R., Brown, M.,…&Pisano, E. D. (2014). Consequences of false-positive screening mammograms. *JAMA Internal Medicine, 174*, 954-961. doi:10.1001/jamainternmed.2014.981

Trajkovic, A., & Milosevic, I. (2016). Model to determine the economic and other effects of standardization – a case study in Serbia. *Journal of Total Quality Management*

and Business Excellence, 27, 1-13. doi: 10.1080/14783363.2016.122549

Tran, V., Porcher, R., Tran, V., & Ravaud, P. (2017). Predicting data saturation in qualitative surveys with mathematical models from ecological research. *Journal of Clinical Epidemiology, 82*(e2), 71-78. doi:10.1016/j.jclinepi.2016.10.001

Tully, P. J., & Baumeister, H. (2015). Collaborative care for the treatment of comorbid depression and coronary heart disease: A systematic review and meta-analysis protocol. *BMJ Open, 5*(12), 1-6. doi:10.1136/bmjopen-2015-009128

Tzankov, A. & Tornillo, L. (2016). Hands-on experience: Accreditation of pathology laboratories according to ISO 15189. *Pathobiology, 84*, 1-9. doi:10.1159/000449254

U.S. Food and Drug Administration. (2014). *In Vitro Diagnostic Device Labeling Requirements*. Silver Spring, MD: U.S. Food and Drug Administration.

Vijayasree, P., Kalyani, T., Rao, K. M., Bonthagarala, B., Nagabhushanam, M. V., & Seetharamaiah, P. (2017). Process Validation: An essential process in pharmaceutical industry. *World Journal of Pharmacy and Pharmaceutical Sciences, 6*(3), 367-874. doi:10.20959/wjpps20173-8702

Vaismoradi, M., Jones, J., Turunen, H., & Snelgrove, S. (2016). Theme development in qualitative content analysis and thematic analysis. *Journal of Nursing Education and Practice, 6*(5), 100-110. doi:10.5430/jnep.v6n5p100

Vis, J. Y. & Huisman, A. (2016). Verification and quality control of routine hematology analyzers. *International Journal of Laboratory Hematology, 38*(S1), 100–109. doi:10.1111/ijlh.12503

Walker, J. L. (2012). The use of saturation in qualitative research. *Canadian Journal of Cardiovascular Nursing, 22*(2), 37-46. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/22803288

Washetine, K., Hofman, V., Lassalle, S., Long, E., Ilie, M., Butori, C., & Hofman, P. (2017). Accreditation of the pathology laboratories: Why it is unavoidable. *Revue Francophone des Laboratoires, 2017*(488), 31-37. doi:10.1016/S1773-035X(16)30417-8

Waters, J. (2015). Snowball sampling: A cautionary tale involving a study of older drug users. *International Journal of Social Research Methodology*, *18*, 367-380. doi:10.1080/13645579.2014.953316

Wilson, H., Dashiell-Aje, E., Anatchkova, M., Coyne, K., Hareendran, A., Leidy, N. K., … Wyrwich, K. (2017). Beyond study participants: A framework for engaging patients in the selection or development of clinical outcome assessments for evaluating the benefits of treatment in medical product development. *Quality of Life Research, 2017*, 1-12. doi:10.1007/s11136-017-1577-6

Wilson, I. G., Smye, M., & Wallace, I. J. C. (2016). Meta-audit of laboratory ISO accreditation inspections: Measuring the old emperor's clothes. *Microbiology Open, 5*(1), 95-105. doi:10.1002/mbo3.314

Witty, K., Branney, P., Bullen, K., White, A., Evans, J., & Eardley, I. (2014). Engaging men with penile cancer in qualitative research: reflections from an interview-based study. *Nurse Researcher, 21*(3), 13-19. doi:10.7748/nr2014.01.21.3.13.e1218

Woods, M., Paulus, T., Atkins, D. P., & Macklin, R. (2015). Advancing qualitative research using qualitative data analysis software (QDAS)? Reviewing potential versus practice in published studies using ATLAS.ti and NVivo, 1994-2013. *Social Science Computer Review, 34*, 597-617. doi:10.1177/0894439315596311

Xavier, L. Y., Jacobi, P. R., & Turra, A. (2018). On the advantages of working together: Social learning and knowledge integration in the management of marine areas. *Marine Policy, 88*, 139-150. doi:10.1016/j.marpol.2017.11.026

Yin, R. K. (2014). *Case study research: Design and methods* (5th ed.). Thousand Oaks, Ca: Sage Publications.

Zaini, R G., Dahlawi, H. A., & Siddiqi, A. (2016). Identification of the types and frequencies of pre-analytical errors in the clinical biochemistry laboratory: 1-year study at Hera'a General Hospital. *Archives of Medicine, 8*(4), 1-4. doi:10.21767/1989-5216.1000152

Zehnbauer, B., Lofton-Day, C., Pfeifer, J., Shaughnessy, E., & Goh, L. (2017). A model to demonstrate comparative laboratory test performance with an oncology companion diagnostic assay. *Journal of Molecular Diagnostics, 19*(1), 1-3. doi:10.1016/j.jmoldx.2016.10.001

Ziliani, C., & Leva, M. (2015). Retail shopper marketing: The future of promotional flyers. *International Journal of Retail and Distribution Management, 43*, 488-502. doi:10.1108/IJRDM-02-2014-0022

Zucker, D. (2014). The Belmont report. *Wiley StatsRef: Statistic reference online.* doi:10.1002/9781118445112.stat06924

Appendix A: Interview Protocol

What I will do	What I will say – the script
Start with Script – Introduce the interview and set the stage: e.g. in a single-person conference room to produce quality recording. • Collect signed consent forms • Use audio recording applications on my laptop and brief note taking	Thank you for agreeing to participate in this study. My name is Hsiao-Ching "Sandra" Teng and I am a graduate student at Walden University. You were invited to participate in this study because you are a senior level manager, marketing manager, or business development manager in your organization who makes decisions associated with marketing strategies for promoting clinical diagnostic instrument validation. The interview will last between 30 to 45 minutes. During this time, I will ask you a few questions. The purpose of this study is to explore what marketing strategies successful managers in a diagnostic instrument manufacturing organization use to promote sales in validation packages for increasing the accuracy of oncology laboratory test results. The focus of this study is not to evaluate your experiences or techniques. I would like to audio record this discourse today using my laptop to extend my note taking. Please let me know if this is okay with you. If so, please read and sign the consent form. This interview is confidential, and you are free to withdraw from the study at any time. I am the only person who will have access to this recording. All the data associated with this study that I will collect as well as the recording will be destroyed after 5 years. Please feel free to ask any questions at any time. If you do not have any questions at this moment, we can begin.

(table continues)

What I will do	What I will say – the script
• Identify non-verbal queues • Paraphrase as required • Ask follow-up questions to probe for more detailed or in-depth information	1. Describe the validation packages that you offer for your NGS platforms. 2. Describe the target customer base for the compliance products that you offer. 3. What are your marketing strategies for the compliance products? 4. What elements of the validation package provide a competitive advantage to your company? 5. How often does your organization revise the compliance service package to reflect customer needs and attract target market? 6. How does your organization evaluate the distribution channels for the validation packages? 7. How does your organization determine the effectiveness of your marketing strategies? 8. What additional information can you share regarding marketing strategies for promoting sales of instrument validation products?
End interview with script: Let participant know how I will proceed from here and what to expect after the interview.	Thank you again for allowing me to interview you today. Your perspective was very helpful in understanding how successful marketing strategies can promote clinical diagnostic instrument validation. I will synthesize your responses and schedule a follow-up interview in the next few days for you to verify the data and review my interpretations.
Schedule member checking interview that will take place in the next 5 days.	When will you be available to review your responses?

(table continues)

What I will do	What I will say – the script
Member Checking Follow-up Interview	
Introduce follow-up interview	Great to see you again and thank you for taking the time. As stated during our last interview, the purpose of this follow-up interview is to ensure that I interpreted your responses accurately. This interview will last no longer than 20 minutes. Please let me know if you have any questions. If not, let us begin.
Provide participant a copy of the synthesized individual questions. I will follow IRB guidelines. I will go through each question, provide my interpretation and ask the following: Have I covered all the information? Is there anything you would like to add?	These are the questions and synthesis of interpretations. Pease feel free to elaborate of change as necessary. • Question 1 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 2 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 3 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 4 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 5 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 6 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 7 and succinct synthesis of interpretation in 1 paragraph or more if required • Question 8 and succinct synthesis of interpretation in 1 paragraph or more if required
Provide participant with a copy of research results	Thank you again. I will provide you with a copy of the research results upon completion.

Appendix B: Sample Flyer Distributed by an NGS Manufacturing Organization

IQ/OQ/IPV service for [redacted] instruments

Helping you get into production faster

No one understands your [redacted]™ instruments better than the people who design, develop, and support them. When you use our qualification services, trained and certified engineers from Thermo Fisher Scientific will conduct Installation Qualification (IQ), Operational Qualification (OQ), and Instrument Performance Verification (IPV) as part of your overall system validation.

Help verify instrument accuracy and reduce your risk and workload

Our compliance services for [redacted] instruments help you bring your next-generation sequencing (NGS) lab into production faster. Depending on your requirements, these services may be necessary to comply with global standards (e.g., ISO 17025 and ISO 15189), country-specific regulations (e.g., US FDA 21 CFR Part 11), and other laboratory standards. All services come with audit-ready documentation.

Qualify your entire workflow

	Sequencing systems			
Library preparation	[redacted]			
[redacted]	✓	✓	✓	✓
[redacted]	✓	✓	✓	✓

Our qualification protocols cover the entire NGS workflow from template preparation through sequencing, helping you be audit-ready.

It is important to regularly have your instruments checked and formally tested to confirm they are working according to manufacturer's specifications and identify possible impact due to normal wear or inadequate user maintenance. The IQ/OQ/IPV service is recommended to verify:

- The operation of a newly installed Ion Torrent instrument
- The operation of a previously verified Ion Torrent instrument that has undergone repair or maintenance that is critical to the performance of the system
- The operation of an Ion Torrent instrument that has site requirements for a scheduled operation qualification
- Additions, exchanges, or upgrades that may affect data results of an Ion Torrent instrument

[redacted]