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Strategies for Automating Pharmacovigilance Adverse Event Case Processing

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Walden University
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Abstract

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Master of Science, Karnataka State Open University, 2004

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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Abstract

Business leaders who fail to implement innovative technology solutions in their companies face economic distress in these organizations. Guided by the task technology fit model as the conceptual framework, the purpose of this qualitative single case study was to explore strategies used by pharmacovigilance (PV) systems leaders to implement innovative technology solutions. The participants were 4 PV systems managers working in a pharmaceutical company in the Boston area of Massachusetts, United States, who used successful strategies to implement innovative technology solutions to automate adverse events case processing. Data were collected using semistructured interviews and company documents. The collected data were analyzed using Yin's 5-step data analysis, which included compiling, disassembling, reassembling, interpreting data, and concluding the findings. Three key themes emerged: automation solution selection and implementation strategies, business operation model changes, and communication and training strategies. The key recommendation is for PV leaders to implement automation solutions and redirect the savings from PV operations in terms of cost and workforce tasks toward investing in the actual PV tasks such as benefit-risk assessments of products. The implications for positive social change include the potential to identify strategies to improve patient outcomes and assist in making pharmaceutical medicines more efficacious and safer for human use in reducing unnecessary deaths.

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Dedication

To my family, for their endless support and encouragement.

Thank you, my sons Adi and Amar, for being so understanding. You are my inspiration, my best cheer team. Special thanks to my husband, Niranjan, for being my rock and for becoming a mom for our sons, taking over my home job many days. Gratitude to my loving parents and sister for standing by me. Thank you to my friends, for their constant support and encouragement.

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I express my sincere thanks to my Walden University committee members for guiding me through my DBA journey and assisting in creating a high-quality study that I am proud of. Heartfelt thanks to my chair, Dr. Ken Gossett. Dr. G., thank you for your support, expert guidance, and being my wall to lean on throughout my DBA journey. I would like to thank Dr. Hammoud, my second committee member for his keen eye for detail and Dr. Paluch, my university research reviewer for their contribution to successfully complete my DBA. Special thanks to my family, my sons and my husband for standing by me, and friends who provided the support, encouragement, and guidance throughout my DBA journey.

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Section 1: Foundation of the Study

The goal of pharmacovigilance (PV) is to protect patients from unnecessary harm. When a medicine is marketed, the identification and monitoring of adverse events (AEs) and reactions is a part of a post-marketing safety surveillance program as required by federal regulations (Kothari, Shah, & Patel, 2018; Tan et al., 2016). Health regulatory agencies have regulations to ensure that drug products are safe for human consumption. Companies that are licensed marketing authorization holders are required by regulation to perform active drug safety surveillance and monitor the safety profiles of the products during the entire marketing lifecycle (Basile, Yahi, & Tatonetti, 2019). Companies use safety databases and reporting software to process and report AEs to health authorities around the world (Lewis & McCullum, 2019). Companies can use innovative information technology solutions based on artificial intelligence and robotics to detect, process, and report AEs, thereby adopting automation (Beninger, 2018; Donzanti, 2018). Companies can adopt an automation-enabled digital PV path for drug safety surveillance and redirect the savings from PV operations toward investing in the actual PV tasks like benefit-risk assessments of products, thereby making the products more efficacious and safer for human use.

Background of the Problem

The safety of medicines is a global responsibility. A drug product or medicine will gain marketing authorization after a regulatory agency conducts comprehensive reviews of the drug product to evaluate the benefits and risks (Schurer, Bam, & de Kock, 2017). When the officials of the agency find a favorable benefit-risk balance, they

approve the drug product to be marketed within the jurisdiction of the relevant agency (Kothari et al., 2018). When the product is marketed and consumed by a large population, adverse reactions or side effects may occur (Pitts, Louet, Moride, & Conti, 2016). When a product is reported to have caused serious AEs, national authorities analyze the reports of the product and weigh the risks and benefits. They then decide on a course of action, which may include issuing an alert or, in extreme cases, taking the product off the market (McNaughton, Huet, & Shakir, 2014).

The goal of PV is to protect patients from unnecessary harm. Unsafe healthcare causes harm and leads to other forms of collateral damage such as loss of trust in the system and loss of reputation and credibility in health services (World Health Organization, 2017). The occurrence of AE is one of the top 10 causes of death and disability across the world (World Health Organization, 2019a). Officials of the World Health Organization reported that 134 million adverse events occur each year in hospitals, contributing to 2.6 million deaths annually due to unsafe care (World Health Organization, 2019c).

Biomedical informatics including artificial intelligence (AI) and robotics-based solutions can accelerate efficiencies and can be used to identify and process AEs faster and contribute to reduction of costs (Beninger, 2018; Donzanti, 2018). Despite multiple successful experiments, not many managers in pharmaceutical companies have developed and/or implemented innovative technology to realize the benefits.

Problem Statement

Business leaders who fail to implement innovative technology solutions in their companies face economic distress in these organizations (Bal & Erkan, 2019). Failure to implement innovative technology solutions result in high pharmacovigilance (PV) operational costs related to the 2.2 million adverse events (AEs) documented by the U.S. Food & Drug Administration (2019) that could cost pharmaceutical companies $900 million for drug recalls (Hall, Stewart, Chang, & Freeman, 2016). The general business problem is that PV systems managers may experience high operational costs for AE detection and reporting leading to poor financial performance. The specific business problem is that some PV systems managers in the pharmaceutical industry lack the strategies to implement innovative technology solutions to automate AE case processing.

Purpose Statement

The purpose of this qualitative single case study was to explore the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE case processing. The target population consisted of four PV systems managers working in a pharmaceutical company located in the Boston area of Massachusetts, United States, who had used successful strategies to implement innovative technology solutions to automate AE case processing. The implications for positive social change include the potential to improve patient safety by identifying successful strategies that PV systems managers can use or adapt to implement innovative technology solutions to automate AE case processing.

Nature of the Study

Qualitative studies are based on interpretive philosophy. Using an inductive approach, researchers use a smaller sample of participants' data to develop rich data and thick descriptions through a variety of methods for data collection to identify patterns associated with phenomena (Fusch, Fusch, & Ness, 2018; Saunders, Lewis, & Thornhill, 2015). In quantitative and mixed methods studies, researchers use quantitative measures and inferential statistics to examine relationships among variables (Saunders et al., 2015). Since not many company managers have implemented innovative technology like AI and robotics-based solutions for PV (Beninger & Ibara, 2016), I focused on a select group of managers who had successfully used strategies to implement innovative technology solutions to automate AE case processing. Therefore, because of the need to use qualitative data collection procedures like interviews and documentation reviews, a qualitative method was more appropriate than quantitative or mixed methods.

Qualitative case studies are flexible in nature, focusing on a phenomenon, and evolve over the course of the study (Yin, 2018). Using a case study strategy enables researchers to perform in-depth inquiry into a topic to generate insights in a real-life context experiences (Saunders et al., 2015; Yin, 2018). Using multiple case study design, researchers can collect and analyze data to gather perspectives and identify patterns and themes concerning a specific situation across multiple cases (Yin, 2018). Using ethnography and phenomenological study designs, researchers focus on people, culture, and phenomena (Saunders et al., 2015). Because I explored successful innovative technology implementation

strategies used by PV systems managers in a pharmaceutical company, a single case study design was more appropriate for this study than a phenomenological or ethnographic design.

Research Question

The primary research question for this study was: What strategies do PV systems managers use to implement innovative technology solutions to automate AE case processing?

Interview Questions

1. What strategies did you use to identify automation solutions for AE case processing?
2. What strategies did you use for implementing the identified automation solution?
3. What, if any, kinds of operational changes did the automation solution require to your PV business operations model?
4. What communication strategies were used to manage regulatory obligations and employee's expectations to enable employee's adoption of the automation solution?
5. What key difficulties did your organization face when implementing the automation technology solution?
6. How did your organization overcome the key difficulties to implementing automation technology solution?
7. How did your organization assess the implementation strategies' effectiveness?

8. What additional information can you add about the development and implementation of the strategies your organization used for automating AE case processing?

Conceptual Framework

The conceptual framework that I selected for my doctoral study was based on the information systems theory's task-technology fit (TTF) model. The TTF model focuses on the degree to which systems characteristics match user task needs. Goodhue (1995) proposed the TTF model to evaluate and measure success of information systems and posited that a high task-technology fit will positively impact the performance. Goodhue and Thompson (1995) further empirically tested the link between information technology and individual performance and asserted that the utilization of technology and the technology itself must be a good fit for the tasks it supports. TTF links the task requirements, individual abilities, and the functionality of technology. More recent researchers have improved the TTF model by incorporating additional characteristics and constructs or by integrating other theories such as the appropriation theories (Park, 2019). I compared the expected results from the TTF model with the actual results from my study to understand the study's findings.

Operational Definitions

Adverse events or reactions: Adverse events or reactions are unexpected harm caused by the normal use of medication at the normal dosage (Karimi, Wang, Metke-Jimenez, Gaire, & Paris, 2015).

Adverse event reporting: Adverse event reporting refers to the activities that marketing authorization holders perform to collect, and report AE cases reported by patients as required by a 2012 PV legislation (Kothari et al., 2018).

Digitalization: Digitalization involves using digitized data to make decisions and generate change (Gobble, 2018).

Healthcare information technology: Healthcare information technology is the application of computers for the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making (Alotaibi & Federico, 2017).

Pharmacovigilance: PV is studying the safety and effectiveness of drugs including the activities relating to detection, assessment, understanding, and prevention of the AE associated with the use of drugs (World Health Organization, 2019b).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions are unverified beliefs pertaining to a study (Locke, Spirduso, & Silverman, 2014). I made the following assumptions in this study: (a) the participants provided honest, truthful responses to the interview questions, (b) the participants had relevant information and experiences, (c) the responses provided by the participants assisted in understanding the strategies used to implement innovative technology solutions to automate AE case processing, and (d) the strategies provided by the participants improved efficiencies in processing AEs. Following the conclusion of my interviews with the participants, I found all these assumptions to be true.

Limitations

Limitations are potential weaknesses which are beyond the researcher's control (Singh, 2015). One of the limitations for this study was that the participants were employed in one pharmaceutical company. Restricting the study population to one company may limit the transferability of the methods used in my study for future research. Another limitation was that the member checking was conducted by emails since most of the follow-ups occurred during the actual interviews.

Delimitations

Delimitations are boundaries intentionally established to narrow the scope of a study for the researcher (Holloway & Galvin, 2016). The scope of my study was limited to participants from one pharmaceutical company. A purposeful sampling of four participants who were associated with the AE case processing automation project was a delimitation. Potential participants who did not work for the selected company, though eligible, were not a part of this study.

Significance of the Study

PV is a study of the safety and effectiveness of drugs including the activities relating to detection, assessment, understanding, and prevention of the AEs associated with the use of drugs (Beninger & Ibara, 2016; World Health Organization, 2019b). Processing of an AE is an expensive resource-intensive process, which includes high risk of errors and operational inefficiencies (Ghosh et al., 2020). In 2019, the U.S. Food & Drug Administration (2019) received 2.2 million AEs which is a 450% increase since 2009, which increased the derivative AE-related operational costs for pharmaceutical

companies. Biomedical informatics including AI and robotics-based solutions can accelerate efficiencies, identify and process AEs faster, and contribute to costs' reduction (Beninger, 2018; Donzanti, 2018). I explored the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE processing.

Contribution to Business Practice

Information technology (IT) offers a wide range of opportunities to organizations for automating, informing, and transforming their businesses. The IT-driven approach toward business process management enables business process innovation to align with industry best practices and emerging IT trends (Rahimi, Moller, & Hvam, 2015). Managers must build dynamic capabilities and learning in their organizational processes (Čiutienė & Thattakath, 2014), which in combination with business model innovation should result in higher value appropriation (Sorescu, 2017). PV technology systems can be effective in detecting what may be otherwise invisible to the human eye, increasing productivity, and more likely to identify important public health information within large data bases (Lu, 2009). Data mining, machine learning, AI, and robotics could result in new operating models for PV (Beninger & Ibara, 2016; Lai, 2017), improve efficiencies and reduce PV operations costs (Karimi et al., 2015; Lu, 2009; Schmider et al., 2018), better allocation of resources, and improve patient outcomes (Lewis & McCallum, 2019).

Implications for Social Change

The implications for positive social change include the potential to identify strategies to assist in making pharmaceutical medicines safer for human consumption. PV

leaders can redirect the savings from PV operations toward investing in the actual PV tasks like benefit-risk assessments of products, thereby improving patient outcomes and making the products more efficacious and safer for human use. The savings from PV operations could also be used to help or assist with community projects that could bring about social change like building a new playground, putting in a community garden, or creating a wheelchair fund that could be used to help purchase wheelchairs, walkers, or assisted living devices to help persons achieve greater mobility and freedom in their living environments. Companies can also use the savings to offer scholarships to students pursuing courses and majoring in PV.

A Review of the Professional and Academic Literature

The purpose of this qualitative single case study was to explore the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE case processing. As observed by Saunders et al. (2015), critical analysis and synthesis of the literature provided the context and theoretical framework for my research relating to application of innovative technology like AI or robotics-based solutions for PV. My goal was to identify knowledge gaps, provide a foundation to legitimize the research question, and justify the current study and research objectives (Azungah, 2018; Saunders et al., 2016). This section includes the findings of an integrative review that I conducted to understand the function of PV and its challenges, perspectives of technology on PV and AE reporting, and the conceptual framework based on technology adoption models and theories.

The literature review consisted of journal articles and book chapters (as shown in Table 1) relating to the PV function focusing on technology and the pharmaceutical industry, and the theoretical background of the technology adoption models specifically, TTF and technology acceptance model (TAM), and chaos theory (Faggini & Parziale, 2016; Lorenz, 1963). The literature review included an integrative review of articles from Walden University library, Google Scholar, PubMed, and ProQuest databases. Key search terms for conducting research for the literature review included: *technology adoption, innovative technology, pharmacovigilance, drug safety, adverse reaction reporting, adverse drug event reaction in combination with strategy, conceptual framework, technology acceptance, TAM, TTF, chaos theory*, and *qualitative research* or a combination of keywords. Throughout the study, the terms AEs, adverse reactions, and case reports are used interchangeably. The terms drug product, medicines, drug, and product are used interchangeably. The study included 176 references out of which 141 (80%) were published in or after 2016.

Table 1

Source of Data for Literature Review

	Total	Total Published in or After 2016	% Published in or After 2016
Peer-reviewed journals	88	80	91%
Books	2	2	100%
Non-peer-reviewed journals	15	14	93%
Total	105	96	91%

This academic literature review section is split into two subsections and is structured as follows: (a) technology adoption models: TTF model, including TAM as the

supporting model and chaos theory as the contrasting theory and (b) an introduction to PV including health information technology: the importance of the PV function and AE reporting for the health authorities, the pharmaceutical industry, automation, and innovative technology implementation, including the challenges and risks. I present the informatics and technology perspective including the challenges and opportunities.

Technology Adoption Models and Theories

Researchers have used the technology adoption models and diffusion theories to build a foundation for studies to understand innovation adoption and diffusion (Jha & Bose, 2016). In their study to understand the developments in the field of innovation research in information systems, Jha and Bose (2016) analyzed articles published in the past 15 years to conclude that technology acceptance models and diffusion theory are the most popular. During the exploration for a conceptual framework for my study, I analyzed technology acceptance models and decided on the task technology fit or the TTF model. Diffusion theory is a change model for adoption of technological innovations and helps in identifying the perception factors of innovation that influence adoption of innovative technology (Emani et al., 2018). Because I focused on implementation of innovative automation technology and not particularly perception of innovation and adoption, I believed the TTF model constructs provided better guidance to achieve the objective of this study. I have described The TTF model, and the applicability of the TTF model constructs to this study in this section. Overreliance on a theory can lead to confirmation bias with researchers looking for evidence to match the existing conceptions (Collins & Stockton, 2018). Therefore, as guided by Collins and Stockton (2018), I used

the constructs of the TTF model as a tentative theory or a map to understand the phenomenon.

TTF model. Goodhue (1995) proposed the TTF model to evaluate and measure success of information systems and posited that a high task-technology fit would positively impact the performance. Goodhue and Thompson (1995) proposed the TTF model by empirically testing the link between IT and individual performance to assert the utilization of technology and that the technology must be a good fit for the tasks it supports. TTF links the task requirements, individual abilities, and the functionality of technology (Goodhue & Thompson, 1995), as shown in Figure 1. Goodhue and Thompson (1995) concluded their research based on data collected from questionnaire responses from 600 individuals from two companies. Lai (2017) summarized the TTF model as suitable for investigating the utilization of new technology solutions.

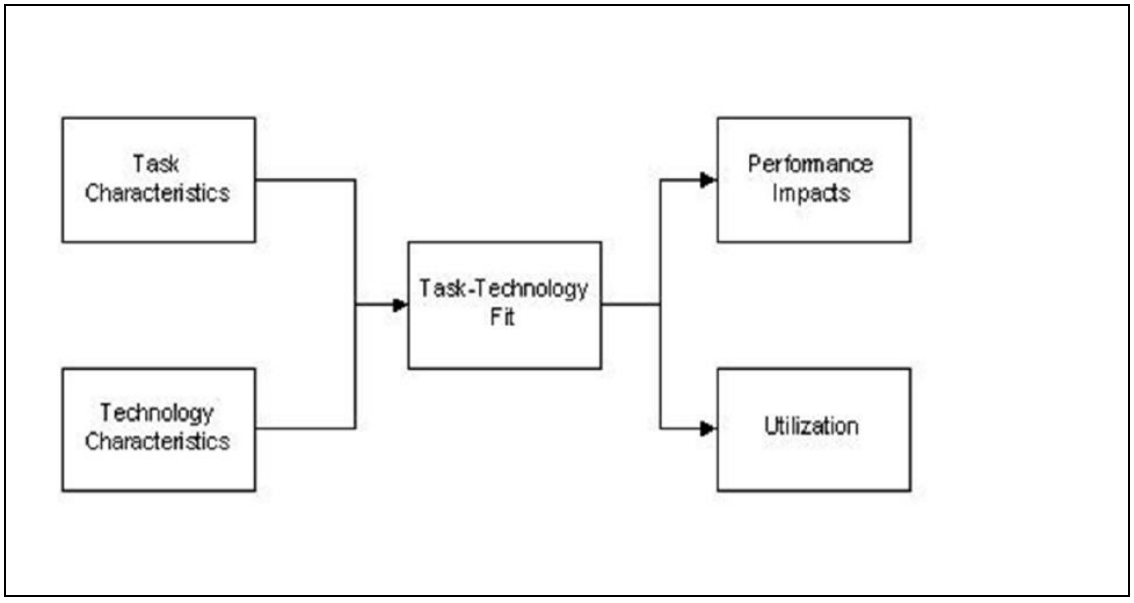

Figure 1. Task-technology fit model constructs. Adapted from "Task-technology fit and individual performance," by D. L. Goodhue and R. L. Thompson, 1995. *MIS Quarterly, 19*(2), p. 213.

TTF is a simple model that matches the tasks with the ability of a technology to address the events as they occur. TTF theory focuses on the application and the general reliance on technologies and does not recommend any task or technology pairings that could produce a strong effect (Howard & Rose, 2019). Common constructs are associated with the outcome of the task and technology fit, like performance, user reactions, utility, perceived utility, and utilization, and not the TTF model itself. Howard and Rose (2019) believed that the narrow scope of TTF theory may be the reason for alterations and inappropriate inferences, which may be rectified by extending TTF theory to better fit a wide range of settings.

Taherdoost (2018) performed a literature review of technology adoption models and noted that most information system researchers did not separate the affective emotional component of attitudes of like/dislike and the cognitive component of information a person holds about an object, issue, or person. Both cognitive processes and emotional and affective elements influence behaviors (Taherdoost, 2018). Therefore, integration of different models would help achieve the greater comprehensive view of the objectives of the research (Sombat et al., 2018; Dishaw & Strong, 1999).

Researchers have improvised the TTF model by incorporating other theories such as the technology-based models like TAM and the appropriation theories. TAM and TTF are two foremost models of information technology utilization and adoption (Dishaw &

Strong, 1999; Lai, 2017). The integrated TAM/TTF model combines an attribute/behavior model (TAM) with models of the task and technology fit with a conclusion that TTF constructs directly affect technology utilization and indirectly affect the technology utilization using TAM's variables alone (Dishaw & Strong, 1999). Dennis, Wixom, and Vandenberg (2001) introduced the fit-appropriation model by integrating TTF with the appropriation support the group receives in the form of training, facilitation, and software restrictiveness. Park (2019) proposed content characteristics such as knowledge, information, and data as a new determinant of fit to improve the explanatory power of TTF.

TAM. TAM was introduced by Fred Davis in 1989 (Davis, 1989) and is one of the most widely used models for technology acceptance (Lai, 2017; Taherdoost, 2018). TAM as a supportive model explains the causal relationship between a user's acceptance of technology and actual usage (Sombat, Chaiyasoonthorn, & Chaveesuk, 2018). TAM identifies ease of use and perceived usefulness to determine the user's attitude toward technology, intention to use, and actual use (Dishaw & Strong, 1999). Researchers can use TAM to explain the causal relationship between user's acceptance of technology and actual usage (Sombat, Chaiyasoonthorn, & Chaveesuk, 2018). TAM identifies ease of use and perceived usefulness to determine the user's attitude toward technology, intention to use, and actual use (Dishaw & Strong, 1999).

Integrated TAM/TTF model. To understand the how customers use the software and how the software functionality fits the perceived needs of the user, Dishaw and Strong (1999) provided an integrated TAM/TTF model. Integration of TAM and TTF

offers a stronger model because the variable constructs overlap in a certain way (Sombat et al., 2018). Dishaw and Strong (1999) devised the integrated model based on study data from questionnaire responses from three established firms from financial services, aerospace manufacturing, and insurance industries. The questionnaire contained items for each TAM variable: intention to use, attitude toward use, perceived ease of use, and perceived usefulness (Dishaw & Strong, 1999). The integrated TAM/TTF model combines an attribute/behavior model (TAM) with models of task-technology fit with a conclusion that TTF constructs directly affect technology utilization and indirectly affect the technology utilization using TAM's variables alone (Dishaw & Strong, 1999). Since I focused on selection and implementation of innovative technology in this study, the constructs of the TTF framework was deemed to be a better match in achieving the objectives of my study.

Chaos theory. Henri Poincare introduced the chaos theory with a principle that systems tend to self-organize to adapt to continuing challenges to overcome chaos (Faggini & Parziale, 2016). As a contrasting theory for this study, chaos theory can assist in understanding of the unpredictability of a system's behavior. To demonstrate the chaos theory, Lorenz (1963) used the butterfly effect, which is a phenomenon that generates small changes in the input but distributes dramatic consequences in the output. The chaos theory helps researchers understand how complex systems work and what causes ambiguity regarding the behavior of the dynamic systems.

In the perspective of technological innovation, Li and Wang (2019) found that chaos of the system is visible when the technological content is larger. Therefore, Li and

Wang (2019) summarized that companies use optimal technological contents to obtain maximum profits. Since the innovative technology solutions are a recent development for PV, the pharmaceutical companies implement and operate with optimal solutions to balance the profit margins with the stability of the market (Li & Wang, 2019) despite the need of using technological innovation to create competitive advantage.

Based on the literature review of original models and integrated models for technology implementation, as described in this paper, I chose the TTF model for my research study. Because a qualitative study is inductively grounded and based on philosophical and ethical grounds, my research could have followed a structured or unstructured approach, as guided by Cypress (2018). An inductive approach is used to explore a phenomenon and identify themes to create a conceptual framework (Saunders, Lewis, & Thornhill, 2015).

Researchers have applied the TTF model in a healthcare setting where business needs technology solutions. Ali, Romero, Morrison, Hafeez, and Ancker (2018) applied the TTF framework to evaluate how a patient portal helped improve the portal's fit to patient needs. The study concluded that patients lack a clear understanding of tasks that would help them accomplish personal health information management (Ali et al., 2018). Because my research topic included new strategies PV systems managers use to implement innovative technology, an unstructured inductive qualitative study based on the constructs of the TTF model assisted in achieving my study objectives.

PV and Healthcare Information Technology

In this section, I will describe the findings of the integrative review to understand the business of PV and IT in the pharmaceutical industry. This section includes PV-related topics such as the function of PV, mandated AE reporting, and related challenges like product recalls and AE detection and reporting. This section of the literature review also includes the perspectives of technology on PV and AE reporting, digital PV, automation, innovative technology implementation trends and risks, and implementing innovative technology for PV business processes.

PV. A search for approaches for pharmacovigilance or drug safety revealed a variety of research studies. PV is studying the safety and effectiveness of drugs including the activities relating to detection, assessment, understanding, and prevention of the AE associated with the use of drugs (Beninger & Ibara, 2016; Lu, 2009; World Health Organization, 2019b). A marketing authorization (MA) holder must prove a drug product's safety, efficacy, and quality to obtain a product license to market it (Lewis & McCallum, 2019). A drug product or medicine will gain a marketing authorization after a regulatory agency conducts comprehensive reviews of the drug product to evaluate the benefits and risks (Schurer, Bam, & de Kock, 2017), finds a favorable benefit-risk balance, and approves the drug product to be marketed within jurisdiction of the relevant agency.

When a drug product is marketed, and the drugs are used by large populations, unexpected adverse reactions or AEs may occur, which changes the risk-benefit ratio of the drugs, requiring a regulatory action in post marketing surveillance (Pitts et al., 2016).

AE is unexpected harm caused by the normal use of medication at the normal dosage (Karimi et al., 2015). No medicine is safe at the time of approval for sale or marketing authorization (Pitts et al., 2016). Only when the benefit of taking the drug outweighs the risks, consuming a drug can be justified (Kothari et al., 2018). Since clinical trials are conducted in a controlled environment with a small set of human patients, the adverse reactions and AEs collected are not representative of the large population that will consume the drug. AE from consuming drugs could remain undetected, exposing consumers to the unexpected risks and harm in the absence of a robust AE reporting system (Bailey et al., 2016). Therefore, the early detection, observation, and analysis of AE in the post-marketing period to identify the risks associated with the consumption of drugs (Munoz et al., 2020; Tan et al., 2016) and protect patients from unnecessary harm is a key goal of a PV system.

Drug safety is a priority for both the health agencies worldwide and the pharmaceutical industry. In the European Union, about 197,000 deaths are caused by AEs per year and the total cost to society of AEs is €79 billion (Mohiuddin, 2018). AEs are unexpected effects occurring from normal use of drugs taken in normal dosage (Basile et al., 2019). In 2013, medical errors including AEs were identified as the third leading cause of death in the United States (Makary & Daniel, 2016). Health authorities and agencies have implemented multiple mechanisms to monitor the safety of the drug products across the discovery, development, and marketed phases like the Center for Drug Evaluation and Research (CDER), the New Drug Application (NDA), and Post-

marketing Surveillance (PMS) program to assess and monitor drug safety risks by the U.S. FDA (Tan et al., 2016).

Unsafe healthcare causes harm and leads to other forms of collateral damage such as loss of trust in the system and loss of reputation and credibility in health services (World Health Organization, 2017). The occurrence of AE is one of the top 10 causes of death and disability across the world (World Health Organization, 2019a). Officials of the World Health Organization reported that 134 million adverse events occur each year in hospitals, contributing to 2.6 million deaths annually due to unsafe care (World Health Organization, 2019c).

Drug product recalls. Delayed detection of AEs can lead to legal risks and huge expense for a pharmaceutical company. Serious AEs can lead to drug recalls, market withdrawals, and safety alerts and can cost the company financially and loss of consumer trust and are an important safety issue for patients and healthcare providers (Hall et al., 2016; Liu, Zhao, & Zhang, 2016). A review of U.S. FDA recalls showed that AE was one of the top three reasons for drug recalls, which could cost a large pharmaceutical company $900 million (Hall et al., 2016). 644 products were withdrawn from the market because of AEs between 1953 and 2013 (Onakpoya, Henegan, & Aronson, 2016). The withdrawal of anti-inflammatory rofecoxib (Vioxx™) occurred only after millions of patients had been exposed, highlighting the need for earlier, more comprehensive data reporting (Bailey et al., 2016). Evidence from spontaneous reporting of AE and clinical research studies are used to support the decisions for revoking marketing authorization and withdrawal of products (McNaughton et al., 2014). Therefore, pharmaceutical

companies and MA holders must identify AEs at the earliest to avoid the expenses from recalls due to AEs and assist with patient safety.

Sources of AE. MA holders are required to collect, and report AE cases reported by patients by 2012 PV legislation (Kothari et al., 2018). Each national drug agency collects its own AEs in a database, so do the MA holders. Companies use relational databases to collect, store, and process AEs, which are linked to data warehouses that are used for reporting AEs to the health authorities (Lewis & McCullum, 2019). Sources of AE data include literature including mass media, clinical trials, observational studies, spontaneous reporting data analysis, case reports, clinical, non-clinical, and preclinical data (Onakpoya et al., 2016; Rasch et al., 2019; Schurer et al., 2017). Spontaneous reporting systems contain high quality data and have been the primary source of AEs traditionally (Kothari et al., 2018; Raschi et al., 2019). Recently due to increased awareness, multiple countries allow patients to directly report AEs. Patient reporting is an important source for AEs, which has increased recently despite challenges with reporting systems and confusions with reporting (Inacio, Gomes, Airaksinen, & Cavaco, 2018; Mohiuddin, 2018). Patients, manufacturers, and healthcare professionals report AEs (Schurer et al, 2017) in variety of ways by phone calls, e-mails, and report directly to the manufacturers and the health authorities or discuss on social media such as blogs and social networking sites. Typical process of collecting, processing, and reporting AEs within a MA holder company is shown in Figure 2.

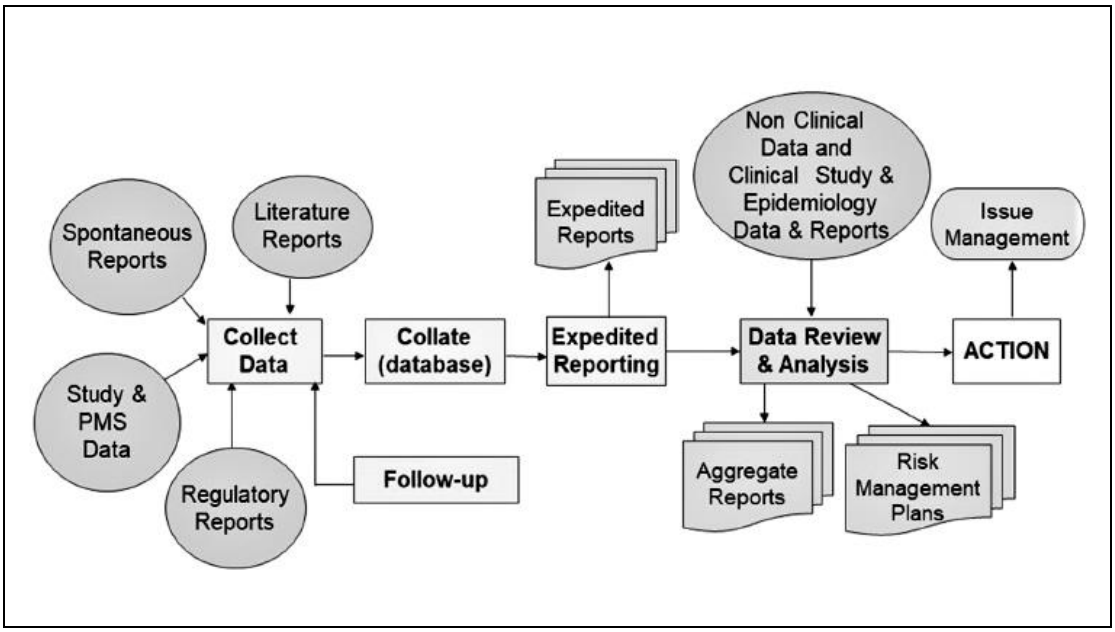

Figure 2. Typical process for AEs case processing and reporting within a marketing authorization holder. Adapted from "Utilizing advanced technologies to augment pharmacovigilance systems: Challenges and opportunities," by D. J. Lewis and J. F. McCallum, 2019. *Therapeutic Innovation & Regulatory Science*, p. 2.

High volume of cases reported creates a challenge for governance to perform PV (Mitchell, Schuster, Smith, Pronovost, & Wu, 2016). Though there is an exponential increase in the number of AEs reported, under-reported, inaccurate, and delayed post marketing spontaneous cases is a challenge for PV (Elkin, Johnson, Callahan, & Classen, 2016; Pitts et al., 2016; Schurer et al., 2017). Traditional AE data sources such as spontaneous reporting data, electronic health records, pharmaceutical databases, and biomedical literature are limited by under-reporting ratio, privacy issues, high cost, or long publication cycle (Yang & Yang, 2018). Despite being obligated to participate in the PV process and spontaneous AEs reporting, pharmacists do not fully comply (Kopciuch et al., 2019). Only 16% of pharmacists were found to be trained in PV in Poland

(Kopciuch et al., 2019). Nurses generally report AEs since doctors are not engaged and do not report AEs, which causes bias and missed critical diagnosis (Mitchell et al., 2016). Under-reporting is a result of non-standard reporting process, inadequate knowledge of reporting, negligence, time constraints, and gaps in safety information systems (Mohiuddin, 2018). The median under-reporting rate was 94% (Lexchin, 2015). Only 5-10% of AEs are reported and about 95% of health care professionals do not report AEs (Mohiuddin, 2018). Under-reporting of AEs could cause delays in making decisions regarding withdrawing the drugs from the markets (Onakpoya et al., 2016). Standardizing reporting and encouraging patient reporting by creating a safe and secure environment can improve voluntary spontaneous reporting and reduce incomplete and insufficient data (Schurer et al., 2017). Padgett, Gossett, Mayer, Chien, and Turner (2017) recommended organizations transition into high-reliability organizations in order to increase AE reporting, which could contribute to industry-wide improvement in patient safety and reduce operational costs.

The information about the type and variety of AE data elements collected within AE reporting systems varies internationally. Timely communication of AEs is a challenge though the AEs are recognized sooner (Lexchin, 2015). Bailey et al. (2016) identified 108 reporting systems, containing 1,782 unique data fields mapped to 33 reporting concepts. A minimum required dataset for a valid AE case report included an identifiable patient, an AE, a suspect medicinal product, and an identifiable reporter. However, the absence of standardized AE data collection and reporting data elements and variations across

systems rendered aggregate reporting a challenge, which directly affected safety surveillance (Bailey et al., 2016; Schurer et al., 2017).

With the increase in awareness about AE reporting, regulatory agencies have improved their safety surveillance guidance for the MA holders (Stergiopoulos, Fehrle, Caubel, Tan, & Jebson, 2019). Since the spontaneous reporting of AEs is biased with challenges, PV function leaders from the industry and the regulatory agencies are exploring other sources and advanced computational methods to supplement existing methods (Basile et al., 2019; Toki & Ono, 2018). Many researchers have concluded that social media is a good source of AE information and that technology can be used in social media mining to find cases (Pitts et al., 2016). However, based on a systematic review, Convertino, Ferraro, Blandizzi, and Tuccori (2018) concluded that despite the possibility of mining AE data quicker from social media than traditional spontaneous reporting, the poor quality of information makes it a challenge for social media to be considered a viable source of AE for PV. The user posts on social media contain colloquial language and misspellings, which disrupts the balance between sensitivity and specificity in identifying AEs (Raschi et al., 2019).

The current process of collecting and processing AE in the pharmaceutical industry is manual, complex, and poses high risk of errors. The challenges on the pharmaceutical industry's perspective include the management of the high volume of AEs, globally diverse and changing regulations, complex and evolving systems, and sparse PV expertise and talent (Price, 2018). In 2019, the U.S. Food & Drug Administration received 2.2 million AEs ("FDA adverse event", 2019), which is a 450%

increase since 2009 and increased AE-related operational costs for pharmaceutical companies. Pharmaceutical companies must invest in PV to avoid risks and frequently manage PV as a cost-center. Processing of an AE is an expensive resource-intensive process, which includes high risk of errors and operational inefficiencies (Ghosh et al., 2020). The increasing costs of PV have led to outsourcing of PV activities to service providers operating in low-cost locations (Price, 2018). A continuous, digitized, automated data management within a computerized system that leverages AI, machine learning, and blockchain can address the talent shortfall (Price, 2018) and refocus the PV effort from data management toward ensuring effective use medicines.

Healthcare information technology. Healthcare information technology is the application of computers for the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making (Alotaibi & Federico, 2017). Marante (2018) posited that clinical experience could not be contemplated in the algorithms, and that contributes enormously to the establishment of the causal relationship between a product and AE. However, Marante (2018) concluded that the clinical judgment method poses difficulties in standardization of evaluation; and therefore, a need for a universally accepted high-quality assessment tool.

Recently, innovative technologies are impacting the way companies process and evaluate AEs. Beninger and Ibara (2016) and Donzanti (2018) summarized that the rapidly developing innovations in informatics pose challenges for PV, however, offer opportunities for close collaboration. Innovative technologies like robotics and AI have permeated the pharmaceutical industry and assist in enhancing the drug discovery process

and reducing the research and development effort (Agrawal, 2018; Donzanti, 2018). Implementing AI technologies can be a breakthrough for the future market sustainability of biopharmaceutical organizations (Agrawal, 2018).

Automation. The pharmaceutical industry is actively engaged in an automation race. Automation is an intelligent organizational process that delivers responsiveness and agility, which is created as an outcome of effective usage of technology like robotics (Buyukozkan & Gocer, 2018). Automation accelerates innovation by increasing productivity and relieving human resources, which can lead firms to gain significant cost and competitive advantages (Bal & Erkan, 2019; Nylund, Ferras-Hernandez, & Brem, 2018). Technology and innovation are two of the five top factors leading to economic success (Bal & Erkan, 2019). Expert systems use an inference or cognitive engine, which provide information by replicating the decision-making processes performed by a human expert (Tomita, 2019). Investing in and implementing emerging technologies will create a sustained competitive advantage for companies through enhancing access to information, reducing costs, improving products quality, as well as responsiveness, and collaboration abilities (Agrawal & Narain, 2018). By investing in automation, companies generate value by lowering expenses on human resource and increasing revenue and productivity though process innovation (Nylund et al., 2018). Companies who have embraced digital strategies are seeing real value, boosting revenue more than 9%, market valuation more than 12%, and profitability by over 26% (Rakowski, 2015).

Pharmaceutical industry as a business sector is a slow adopter of new and emerging technology for automation like artificial intelligence (Lewis & McCallum,

2019; Streefland, 2018). Most healthcare organizations face challenges to innovate in terms of management, systems, and culture, despite recent innovation practices like open innovation and innovative management practices (Kim, Gaukler, & Lee, 2016). Companies attempt to incorporate automation into all functions, including research and development (R&D) and PV. For example, cognitive technology-based systems like IBM Watson can leverage Big Data to improve insight and accelerate life sciences discoveries (Chen, Elenee Argentinis, & Weber, 2016). Investing in automation in PV can provide better quality of safety data quickly with lesser manual effort (Lewis & McCallum, 2019). PV systems managers focus on the development, acquisition, and incorporation of related technologies to profit from automation. Most companies partner with suppliers who possess the expertise with automation technologies and invest in co-innovation based on a knowledge sharing and open innovation strategy (Nylund et al., 2018; Trantopoulos, von Krogh, Wallin, & Woerter, 2017). Another critical aspect is organization culture.

An organization must have a common culture that is aligned with the organizational goals. Organizations are exposed to technology, globalization, and cutting-edge production, which result in creation of new organization structures, business processes, and ways of working (Fusch, Fusch, Booker, & Fusch, 2016). Leaders must invest in building a resilient organization with an innovative culture that can withstand the exposure and maintain their competitive edge.

While planning for a digital future, company managers must critically evaluate the technologies and business models they can adopt to reach their objectives. Selecting

the most suitable technological solutions and reaping the maximum benefits of the digital means requires companies to internalize digitalization as an integral part of their overall operations methodology and their organizational structure (Buyukozkan & Gocer, 2018). Dalenogare, Benitez, Ayala, and Frank (2018) recommended companies targeting differentiation focus on product development technologies and those targeting low cost, productivity or operational flexibility can prioritize manufacturing technologies.

Innovative technology implementation trends. Organizations can incorporate innovation externally from a supplier or partner by joint development, which is more suitable for customer-supplier collaborations. With an emphasis on external collaboration to encourage and implement open innovation, Rodriguez-Ferradas and Alfaro-Tanco (2016) presented strategies for small and medium enterprises to collaborate with different kind of partners. For example, innovation contests can be used for company-university collaborations.

Organization leaders have realized that proactive external collaboration is beneficial for creation of new products and solutions (Di Fiore, Vetter, & Capur, 2017). Di Fiore et al. (2017) identified four specific areas of benefits:

- deeper knowledge: collaboration between experts and end users offers in-depth knowledge of the business context of use.
- lower marketing costs: collaboration based on joint development and testing partnership can lower marketing costs.
- decreased risks: innovation driven by direct collaboration with the end users produce solutions with lower risk and fit the business purpose better.

- increased trust: close collaboration improves relationship and increase trust between the partners.

Different open innovation practices can be utilized for new product development in companies collaborating with different kinds of partners (Rodriguez-Ferradas & Alfaro-Tanco, 2016). Organizations must internalize digitalization and incorporate in the operations methodology and structure in order to select the most suitable technological solutions and reap the maximum benefits (Buyukozkan & Gocer, 2018). Rose, Jones, and Furneaux (2016) and Trantopoulos et al. (2017) identified knowledge, innovation management, and the team process as the significant innovation drivers in small and medium sized enterprises.

Organizations engage in outsourcing of transactional systems to enable service innovations or new product development in the form of contract agreements (Susarla & Mukhopadhyay, 2019). Automation and cognitive systems have permeated service management to a next generation of integrated network, systems, and service management (Keller, 2017). Service management is built based on service level agreements with the outsourcing partner, which can be hosted on cloud or traditional or hybrid setups blending cloud with traditional or virtualized on-premise infrastructure (Keller, 2017).

To enable business model innovation, organizations with inhouse digitization and IT development capabilities can adopt agile development methodology. Agile development refers to practices for software development based on iterative and incremental delivery of working software, collaboration with customers and response to

change (Ghezzi & Cavallo, 2018). Managers have multiple options to implement technologies and value propositions and adopt a leader or follower strategy in the digitization arena (Ritter & Pedersen, 2019). Since innovative technology does not provide any guarantees, companies leverage iterative ideation and experimentation.

Innovative technology risks. There are multiple risks associated with using technology for competitive advantage. Thorough analysis of all innovation stages is required when innovation is considered, owing to the complex multistage nature of the innovation process and lifecycle (Jha & Bose, 2016). Carr (2003) called IT a commodity and strongly recommended focusing on the risks rather than the strategic advantages it provides. A disruption to IT supply can paralyze a company. Overspending on IT can place a company at a cost disadvantage. Sourcing of technology development, support, and management of IT functions from vendors introduces risks. Companies must carefully invest in technology and IT solutions because great spending on IT does not equate to superior financial results (Carr, 2003).

Managers might not understand the implications of disruptive technologies because their views of the world are shaped by their prior experiences of technologies and markets (Vecchiato, 2017). Innovative technology can lead to cultural changes in the organizations progressing toward building a smart, creative and dynamic innovation culture (Keles, & Battal, 2017). Change is difficult, the managers must use the right strategies to communicate and motivate the team members to build an innovative culture (Eggers & Kaul, 2016).

Despite the various advantages and benefits of external collaboration for innovation initiatives, many innovations fail to deliver the expected successful outcomes and lead to significant value creation (Di Fiore et al., 2017). Di Fiore et al. (2017) identified the following four traps that collaboration can lead to and potential solutions to avoid them:

- treating collaboration as an event. Instead, manage collaboration like a seamless process. Innovation requires careful planning, agreeing on ways-of-working, intellectual property management, resource management, and defined oversight and governance.
- defining the problem statement alone. Instead, co-design the problem statement. All the parties and stakeholders involved must be in complete agreement on the problem that is being solved to ensure the solution matched the business need and problem.
- diverging time horizons. Instead, generate value across multiple time horizons. Shared understanding of the timeline expectations will drive the resource allocation and management, which will directly impact the financials. Time span and financial goals must be defined upfront with transparency.
- failure to generate empathy. Instead, empathize throughout the process. During the collaborative innovation process, the stakeholders must include the human or end-user perspective in the ideation stage of the process.

Digital PV. Digitalization involves using digitized data to make decisions and generate change (Gobble, 2018). Gobble (2018) further explained that the digitalization process leads to digital transformation, which is the re-structuring and re-defining of the business organizations considering opportunities from emerging technology. Digitization and innovations like Big Data and analytics have led to new operating models in multiple functions within healthcare industry, but, not PV (Beninger & Ibara, 2016). Karimi et al. (2015) summarized that drug safety had not been comprehensively surveyed from the viewpoint of computer science to understand the influence of technology on drug safety detection.

Schmider et al. (2018) summarized that despite the significant opportunity provided by PV, there are no comprehensive technology solutions for expensive process-AE processing and reporting. Beninger and Ibara (2016) concluded that both the fields PV and informatics have separately grown exponentially, with a substantially low rate of overlap between the two despite the increase in awareness of innovative technology in PV. Beninger and Ibara (2016) presented a detailed analysis of the PV adverse event case processing process and the corresponding technology used starting from relational databases and faxes to the recent technology like Blockchain and artificial neural networks. Beninger and Ibara (2016) identified advanced technology like AI for PV is emerging and growing and concluded with an emphasis for implementing informatics and developing structures to facilitate an approach to adopt informatics. Prior to deploying automation, organizations must embark on a business process re-engineering journey (Mishra, Devi, & Narayanan, 2019).

In 2014, the FDA received 528,192 new AE reports indicating a serious or fatal outcome, 4.7% directly from health professionals and consumers, and 95.3% from drug manufacturers (Moore, Furberg, Mattison, & Cohen, 2016). Majority of the AEs received by the FDA are from the manufacturers and MA holders since most AEs are reported directly to the manufacturers (Stergiopoulos, Brown, Felix, Grampp, & Getz, 2016). A study on AE quality and completeness by Moore et al. (2016) concluded that the report completeness from drug manufacturers was poor compared with direct submissions. More than one third of the AEs submitted by the manufacturers did not include basic information to establish a causal relationship between an AE and a drug product, which can be an issue for the detection of safety signals (Plessis, Gomez, García, Cereza, & Figueras, 2017). Innovative technology including new algorithms and data mining tools can assist in improving the quality and timely extraction and reporting of AEs (Lewis & McCallum, 2019; Plessis et al., 2017). The future of adverse event reporting had to take full advantage of the rapidly developing electronic health records and technologies to automate voluntary reporting of incidents (Mitchell et al., 2016).

A study by Ribeiro, Motta, Marcondes-Fonseca, Kalil-Filho, and Giavina-Bianchi (2018) revealed that in a hospital setting, there were a total of 94 adverse drug reactions in 75 patients and most reactions were predictable and of moderate severity. For each medication introduced during hospitalization, there was a 10% increase in the rate of AEs with the probability of observing an AE was 1 in 104 patients per day. 134 million AEs occur each year in hospitals, contributing to 2.6 million deaths annually due to unsafe care (World Health Organization, 2019c).

Proactive prevention of risks can be achieved using AI for analysis of data from post marketing studies, electronic medical records, and the Internet among other trends (Fermont, 2019). Organizations must understand and identify the opportunities and implications of implementing innovative technology to add value at a conceptual level (Lewis & McCallum, 2019) as shown in Figure 3. Despite multiple successful experiments with using innovative technologies to improve performance and efficiency, the primary challenges are transparency and traceability (Spasic, Uzuner, & Zhou, 2020).

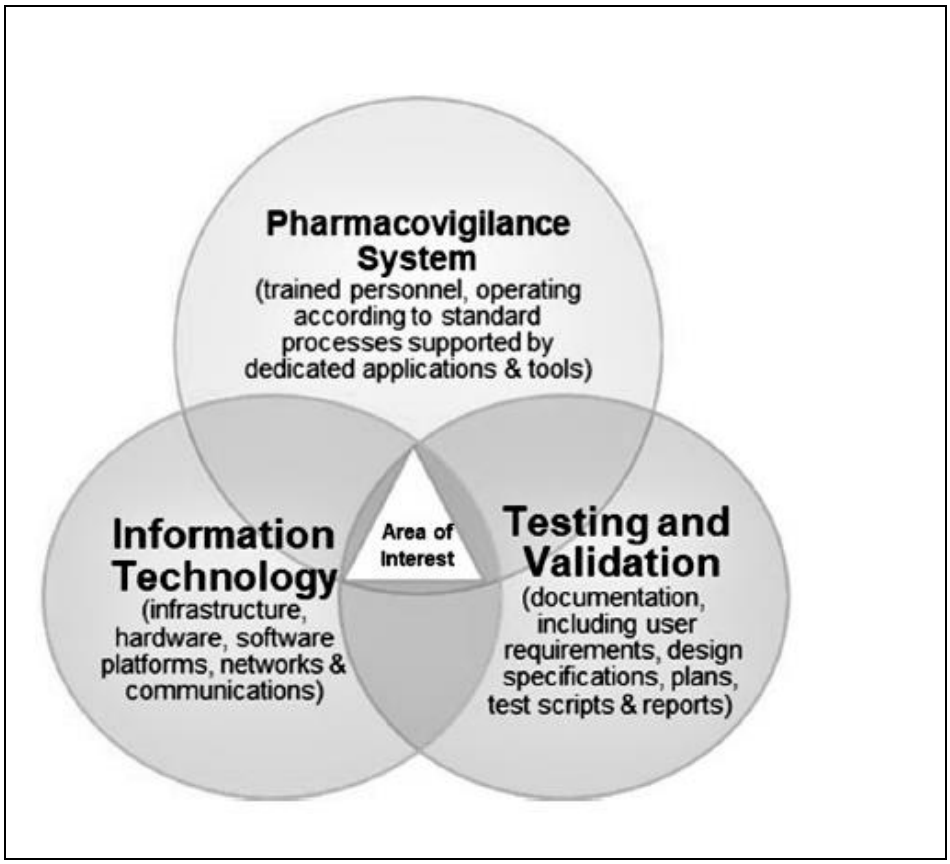

Figure 3. PV systems automation: Conceptual diagram showing the different entities relating to PV systems automation. Adapted from "Utilizing advanced technologies to augment pharmacovigilance systems: Challenges and opportunities," by D. J. Lewis and J. F. McCallum, 2019. *Therapeutic Innovation & Regulatory Science*, p. 2.

Leaders must adopt a systems thinking approach and focus on systems, processes, and measures to build a learning organization which is both reliable and resilient (Gossett, Padgett, Pierce, & Scott, 2019). Emerging technology and intelligent automation in the PV business systems function is complex, and are not readily understandable by the PV business professionals who are trying to implement them (Lewis & McCallum, 2019). Eseryel (2019) summarized three strategies for non-IT managers to achieve digital business transformation: create and procure endorsement for an IT-enabled business transformation vision, develop a change management function for the transformation, and build a strong non-IT business leadership team.

Lewis and McCallum (2019) envisioned all stakeholders within the PV industry working on a single database that is based on blockchain technology. Arlett, Straus, and Rasi (2019) made three predictions for PV, by 2030 PV function will be smarter in collecting and reporting of AE, measurement of on-market performance of medicines, and improved engagement of patients and healthcare professionals. Streefland (2018) highly recommended the PV system to focus on the patient rather than on regulations and recognized a need to work toward optimal analysis of real-time medicine use insights, instead of AE creation, reporting, and adherence to procedures.

Innovative technology trends in PV. Mesko (2017) recognized that medicine requires a variety of disruptive technologies to be implemented into developing treatments, practicing medicine, and delivering care. Recent developments in the innovative technologies include text analytics, robotic process automations, cognitive technologies including machine learning and deep learning. Since rule-based

technologies are traceable, the applications are abundant. Despite multiple successful experiments with using these innovative technologies to improve performance and efficiency, the primary challenges are transparency and traceability (Spasic et al., 2020).

Ghosh et al (2020) considered the innovative automation technologies like natural language processing (NLP), AI, machine learning, optical character recognition, and robotic process automation (RPA) as "intelligent" since they are more advanced. Ghosh et al. (2020) also predicted that the risk of failure or malfunction of these technologies will reduce over time as the technologies evolve. The automation requirements for small and mid-size companies might be different from large companies since they may have specific process approaches that may not be conducive for automation (Ghosh et al., 2020).

RPA is an automation technology that can be used enterprise-wide to automate repetitive manual processes which are rule-based, thereby enabling manual resource cost savings, reducing errors, and improving efficiency (Dey & Das, 2019). Carden, Maldonado, Brace, and Myers (2019) listed accuracy, audit trail, consistency, flexibility, location agnostic, low-risk and non-invasive technology, productivity, reliability, availability, and productivity as the value proposition for RPA. RPA software robots (bots) only work on the user interface, which are simple to develop and do not require complex programming (Phillips & Collins, 2019). Phillips and Collins (2019) compared bots, which follow a set of rules with AI-based solutions, which are neural networks designed to replicate human brain process. Since bots are straight forward and rule-based, they can be built to replace any repetitive and mundane tasks and applied in any industry.

RPA can be applied successfully for PV; however, the PV systems managers and the business users must work closely to identify highest potential processes and identify the most beneficial automation approach (Carden et al., 2019; Phillips & Collins, 2019). Innovative technology must be used intelligently. For example, processes that involve decision making, the RPA solutions must be blended with AI-based cognitive solutions (Mishra et al., 2019)

Multiple researchers have identified a variety of applications for text analytics in the healthcare and pharmaceutical clinical functions such as triaging patients, decision support, clinical research, and PV (Spasic et al., 2020). In the recent years, clinical NLP systems have matured to accurately extract medical information buried in texts that contribute to PV (Tan et al., 2016). Schmider et al. (2018) conducted a pilot test to verify the feasibility of using AI and robotics to automate the processing of AE reports. The results confirmed the viable use of AI-based solutions for AE case processing regarding extraction of case information by training the machine learning algorithms (Schmider et al., 2018). NLP can structure and customize automatically extracted AE information and store in a way that healthcare professionals can specifically share AEs that are of the individual patients' interest (Kusch, Zien, Hachenberg, Haefeli, & Seidling, 2020). NLP can be used to detect healthcare associated infections in hospital facilities and NLP chain processing can facilitate a standardized AE detection process across multiple hospitals (Tvardik et al., 2018).

Social media is a potential rich source of AEs. Considering the median under-reporting rate of AE to be 94% in spontaneous reporting systems, social media and

crowd-sourced data can be potential sources to detect AE related to health products including pharmaceuticals, medical devices, biologics and natural health products (Tricco, Zarin, Lillie, Pham, & Straus, 2017). Despite the possibility of mining AE data quicker from social media, poor quality of information makes it a challenge for social media to be considered a viable source of AE (Convertino et al., 2018). Data from social media is not rich because of the use of slangs and colloquial posts, which cause a negative impact on the AE extraction program (Arnoux-Guenegou et al., 2019). In their study, Gattepaille, Hedfors Vidlin, Bergvall, Pierce, and Ellenius (2020) concluded that there was a large discrepancy between the expected and actual results of automatically identifying AEs from Twitter. The authors justified the lack of an all-purpose automated social media AE extraction solution in the industry was potentially due to the challenges with practical AE detection from independent data.

Complex medical concepts can be extracted from informal, user generated content. Nikfarjam, Sarker, O'Connor, Ginn, and Gonzalez (2015) devised a machine learning-based approach that was scalable and suitable for social media mining, as it relied on large volumes of unlabeled data, which removed the need for large, annotated training data sets. Yang and Yang (2018) developed a framework to facilitate drug safety signal detection by harnessing online health community data, a timely, informative, and publicly available data source like MedHelp, which collected patient-contributed content. Advanced NLP techniques like feature-based and kernel-based methods that can effectively identify and separate AEs and non-AEs from the informal text in the social media (Liu et al., 2016).

Cognitive technologies have proven to successfully detect AEs in experimental setting. Based on multiple pilot projects, Chen et al. (2016) summarized that IBM Watson can assist the drug safety process through faster recognition and coding of AE from text. Watson can be used to improve the efficiency of existing drug safety personnel and support timely reporting of AEs to regulatory agencies.

Machine learning models pose risks when PV managers must justify the decisions made by the system in the event of a health agency inspection or an audit. PV managers must ensure they understand the implicit rules that the machine learning models use to make the decisions (Tomita, 2019). A combination of a machine learning approach and human review can be a potential effective and scalable solution for AE detection from social media (Comfort et al., 2018). Automated identification using machine learning models is a more efficient way to provide initial review of AEs and the human resources can be redirected to review and remedial actions more quickly to respond to emerging safety issues (Wang, Coiera, Runciman, & Magrabi, 2017).

Negi, Pavuri, Patel, and Jain (2019) proposed a novel method of combining machine learning and NLP technology to assist with automating AE and suspect drugs extraction from medical reports. The first method tried to establish a causal relationship between the drug and the medical condition. The second method classified a drug into a suspect drug or a non-suspect drug using NLP features and machine learning for classification. Deep learning-based models and multi-task learning-based models can assist NLP in significantly improving the probability of identifying and extracting AEs from electronic health records (Li, Liu, & Yu, 2018). Most methods use annotated

datasets to predict AEs, neural nets, attention mechanisms, and multitask learning are popular choice for NLP applications for PV (Basile et al., 2019). Basile et al. (2019) noted that the use of machine learning and deep learning are common in academic research for PV but are not used in practice in the industry yet.

Blockchain technology stores data in a list of securely linked blocks. Blockchain technology is currently widely used in the financial industry (Lewis & McCallum, 2019). Blockchain can be adopted for PV where the PV system is contained within a single protected environment. Lewis and McCallum (2019) envisioned a blockchain-based centralized PV system used by the various stakeholders in the future.

Physicians can use innovative technology systems to predict an occurrence of AE before prescribing new medicines. Lee and Chen's (2019) developed a machine learning-based conceptual framework to predict the occurrence of AE which can benefit drug manufacturers, healthcare providers, and patients. Dynamic systems can be integrated into PV, thereby enabling predictive analytics and reasoning. However, due to the lack of regulatory guidance and problems with system validation, implementing and adopting dynamic intelligent systems is a challenge (Lewis & McCallum, 2019).

Strategies for implementing innovative technology in PV. Regulatory agencies worldwide have improved and changed their safety monitoring processes, which has led to increased reporting requirements (Stergiopoulos et al., 2019). Due to the changing regulations for safety surveillance, MA holders in the pharmaceutical industry create new internal processes or include new data sources to detect AEs (Stergiopoulos et al., 2019). Multiple factors determine the successful implementation of innovative technology

including the approach and strategy, types of data, and change management. Alotaibi and Federico (2017) presented that the same technology used in different companies produce varied outcomes. Different kinds of data can be handled with different technology solutions like machine learning for unstructured data (Karimi et al., 2015).

In their study focused on PV operational costs and drivers, Stergiopoulos et al. (2019) reported that several companies out of the 12 that participated in the survey had plans for including automation technology like machine learning. But none had implemented them as of 2018. Outsourcing was considered as one of the strategies for organizations to focus on the core competencies, reduce costs (Mishra et al., 2019), and eliminate internal resources. However, most companies are bringing PV operations back in-house due to operational inefficiencies and increased risks (Stergiopoulos et al., 2019).

The impact of innovative technology solutions on the organizational structure and job profiles will be evident since the AI solution will replace certain manual processes. Beninger (2018) emphasized on the new skillsets, which will define the roles of the next generation of professionals who perform PV activities. Mesko et al. (2018) identified human resource crisis like accessibility and shortages in healthcare. Although Mesko et al. (2018) did not directly associate the resource problems to PV in the article, the authors concluded that the gaps in the human resource could be filled using advanced technologies like AI. Mesko (2017) strongly recommended that data analysis solutions must be implemented to support the skills of physicians and must not replace the traditional physician–patient relationship. Organizations must expect to supplement the

human workforce with expert systems and AI that can provide aggregated information for making decisions (Tomita, 2019). However, AI also raises ethical questions.

Digital transformation includes alignment of technology with the company's culture, people, structure, and tasks (Kiron, Kane, Palmer, Phillips, & Buckley, 2016). The human and technology relationship should also include user training, interaction, and collaboration sub-goals in order to be effective (Oyekan et al.,2017). While concluding that automation technology like deep learning can support with managing the AE volume, complexity, and time constraints of AE report processing, Routray et al. (2020) emphasized that human intervention will be required, and the technology must only augment human review of AE seriousness. Internal drivers of a company, specifically, organizational culture and environmental issues must be considered to leverage advantages of data analytics (Hawley, 2016). A smart, creative, and dynamic innovation culture will help organizations to see the value of invention (Keles & Battal, 2017). Ali and Khan (2019) identified two categories of assessing organizational readiness for implementing business intelligence: readiness of managerial proficiency and readiness of information systems environment. Mishra eta l. (2019) strongly recommended that organizations must setup a governance structure like center of excellence for the automation and digitization initiatives.

AEs have increased exponentially over the years, and the processing and reporting impose substantial costs (Karimi et al., 2015; Schmider et al., 2018). Cost of implementing innovative technologies is high, which can be offset by savings post-implementation (Mesko, Hetenyi, & Gyorffy, 2018). Automated identification can help to

find misidentified incidents and enhance data quality (Lewis & McCallum, 2019; Wang et al., 2017). Stergiopoulos et al. (2019) noted that all PV leaders believed implementing AI-based solutions will decrease costs for PV operations including simplifying AE detection and processing. Data mining, machine learning, AI, and robotics can be used to reduce costs and improve efficiency (Karimi et al., 2015; Lu, 2009; Schmider et al., 2018). Therefore, pharmaceutical companies use technology increasingly to automate various tasks within PV.

To enable adoption, PV managers must create a vision and project new technology as a product designed to create, attract, and satisfy demand (Gherasim, 2011). Creating mission statements is the first step in strategic management establishing objectives, formulating strategies, and communicating with the customers (David, David, & David, 2014). All stakeholders must provide endorsement and work toward making a digital future a reality. PV managers must ensure the technology solutions are aligned with the business needs and led by business operations (Mishra et al., 2019). Aligning business needs with IT governance and executive management IT competence had a strong and positive effect on innovation (Heroux & Fortin, 2018). Managers must implement technology solutions that improve employees' job satisfaction by matching the task requirements and long-term professional needs (Wang, Wang, Zhang, & Ma, 2020).

Mishra et al. (2019) summarized that business process simplification, standardization, and re-engineering are the critical factors for a successful automation strategy. IT solutions alter business processes and existing work patterns leading to re-

training and re-learning, which could increase employees' work-related stress (Wang et al., 2020). Training and re-learning initiatives assist in preparing and guiding the in-house staff for digital transformation (Mishra et al., 2019) and to incorporate and blend RPA and AI bots in their daily job. This will assist in adoption of innovative technology by the employees.

Social influence can be a moderating factor for both adoption and resistance of innovation. Social influence can reduce innovation resistance for inexperienced users potentially through usage (Matsuo, Minami, & Matsuyama, 2018). To enable adoption of innovative technology, which could change the role or even replace a human user, leaders much perform effective change management, which transforms the way people perceive innovative technology solutions.

Transition

The purpose of this qualitative single study was to explore the strategies used by PV systems managers to implement innovative technology solutions to automate AE case processing. I used the conceptual framework to understand the strategies provided by the participants to address the research problem identified in Section 1. In Section 1, I covered the key elements of the study including the problem statement, its purpose, research question, conceptual framework, and a review of literature. In Section 2, I provide justification for the selected research method and approach that was used for this study, including my role as the research instrument, the population, participants and sampling, data collection, analysis, and reliability and validity of the study. Upon approval from the IRB, I contacted my participants, collected the data, performed data

analysis, and then expanded this study to include the data analysis and findings. In Section 3, I describe the findings of the study, recommendations for future research, reflections, and conclusion.

Section 2: The Project

In this section, I discuss the design of this single case qualitative study by restating the purpose of this study and including the role of the researcher, participants, research method and design, population and sampling, ethical research, data collection, data analysis technique, and reliability and validity.

Purpose Statement

The purpose of this qualitative single case study was to explore the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE case processing. The target population consisted of four PV systems managers working in a pharmaceutical company located in the Boston area of Massachusetts, United States, who had used successful strategies to implement innovative technology solutions to automate AE case processing. The implications for positive social change include the potential to improve patient safety by identifying successful strategies that PV systems managers can use or adapt to implement innovative technology solutions to automate AE case processing.

Role of the Researcher

The researcher plays a critical role in conducting a research. The inquirer is the primary data collection instrument performing the data collection and analysis activities in qualitative research (Cypress, 2018). As the researcher, I conducted this qualitative single case study using interviews as the primary method to gather information. I served as the data collection instrument by enrolling participants and interviewing them using

open-ended questions and collecting and analyzing the data from the semistructured interviews.

My employment in the pharmaceutical industry and the professional relationships I have established may have influenced the participants' willingness and interest to participate in this study. I have interacted with other PV industry leaders and managers as a part of my professional engagement at my place of work. Though social relationships and personal contacts of the researcher can be leveraged, the researchers must build a respectful and trusting relationship with the participants and the relationship could lead to bias (Joseph, Keller, & Ainsworth, 2016). As the researcher, I ensured that data collection and analysis were objective by assessing the implications, as stated by Cypress (2018) and decreasing my personal views about the phenomenon in an attempt to minimize and mitigate bias and help achieve research integrity as recommended by Overgaard (2015). Because I was familiar with my research topic, I used bracketing during the research process by listing all my assumptions prior to data collection and including them as a part of the study data analysis to identify any potential bias. I used one of the many methods of bracketing to minimize bias. Reflective journaling as a method of bracketing can be used to identify researcher's preconceptions toward the research topic before or during the research process (Tufford & Newman, 2010). I used reflective journaling as a method to identify my assumptions regarding the research since I worked in the PV systems function in a pharmaceutical company. Triangulation strategy is used to reduce risks and remove systemic bias (Cypress, 2018). I used multiple data collection methods like

semistructured interviews, documents and presentations, and the reflective journal to facilitate triangulation.

I used semistructured interviews to understand the strategies that the PV managers use to implement innovative technologies. Interviews provide a more complete picture of the phenomenon by reconstructing and interpreting the past (Cypress, 2018). Good and actionable questions are used to gather rich and deeper understanding of the issues and events (Jonsen, Fendt, & Point, 2017). In order to regulate the interview procedure and maintain control (Leonidaki, 2015) and enable consistency and inform participant about their rights (Castillo-Montoya, 2016), I established an interview protocol (Appendix A) to conduct the interviews. I captured notes and audio recorded the interview upon receiving consent from the participants. I requested additional documents from the participants and reviewed any publicly available information. I transcribed the information gathered and subjected it to triangulation and member checking.

I used the Belmont Report to guide my ethical behavior during this study. The Belmont Report focused on three ethical principles and their applications to conduct research. Informed consent, risk/benefit assessment, and selection of subjects of research requirements cover the principles-respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects and Biomedical and Behavioral Research, 1979). I adhered to the three principles by using confidentiality procedures to protect the participants and maintain privacy. By explaining the study objective, the interview process, the use of data collected, and obtaining informed consent, I mitigated

ethical issues as recommended by Cypress (2018). I will store the data collected in a password-protected flash drive and duly discard after 5 years.

Participants

I purposively selected a pharmaceutical company in the Boston area of Massachusetts, United States as the single case for this study. Qualitative studies that aim to explain a phenomenon in a specific context tend to use a purposive sampling design (Sovacool, Axsen, & Sorrell, 2018; Tobi & Kampen, 2017). The primary criteria for selecting the participants for this single case study included systems managers in the PV or Safety department related to the PV Systems function employed in the selected company. The participants were involved in successfully developing and implementing innovative technology strategies to automate AE case processing and were willing to participate in this study.

Researchers must gain access to the qualified individuals who must be willing to participate in the study (Peticca-Harris, deGama, & Elias, 2016). I obtained authorization from Walden University's Institutional Review Board (IRB). Walden University's approval number for this study is 04-24-20-0972741 and it expires on April 23, 2021. The number of participants depend on the characteristics of population from which they are chosen (Saunders & Townsend, 2016). I identified eligible and qualified employees for this study prior to inviting them to participate.

The relationship between the researcher and the participant is crucial. The participants must be at ease to respond honestly to the questions, therefore, building trust and establishing a respectable relationship are imperative (Malterud, Siersma, &

Guassora, 2016; Yin, 2018). To build the relationship, I followed the best practices suggested by Yin (2018) for credible qualitative research. I explained the objective and the process of the study to the participants and obtained their willingness to participate. I established a professional working relationship with the participants by talking to them over the phone and maintaining confidentiality.

Research Method and Design

The research method and design define the intention of the study and represent the characteristics of the proposed research. In addition, the method and design connect the study with the procedures for data collection and data analysis processes (Ward, Comer, & Stone, 2018). Research methodology impacts theory development, the analysis, research duration, and the outcomes of the research (Saunders et al., 2015). In this section, I justify the reasons for deciding to conduct a qualitative case study to explore the strategies used by PV systems managers to implement innovative technology solutions for AE case processing automation.

Research Method

A research method guides the investigators to obtain answers to the research question while ensuring rigor in the research and reliability of results (Dresch, Pacheco Lacerda, & Cauchick Miguel, 2015). There are three types of research: qualitative, quantitative, and mix-methods research (Yin, 2018). During the research for a methodology, I considered all the three types of research. Upon detailed research, I decided to conduct a qualitative study to explore the strategies managers use to implement innovation technologies.

The primary purpose of my study was exploration, with a pursuit of identifying strategies to address my research question. Exploratory studies allow researchers to understand an issue, a problem, or a phenomenon (Saunders et al., 2015). Qualitative studies focus on phenomena based on ideas related to human knowledge, including an objective to share knowledge and extend research data (Ward et al., 2018). Using a qualitative method, the researcher can understand a phenomenon through a participant's perspective based on rich data and thick descriptions (Azungah, 2018; Barnham, 2015). Using the qualitative approach, researchers can gain an understanding of reasons behind a phenomenon using an open-ended, exploratory stance, instead of proving or disproving hypotheses (Taguchi, 2018). A qualitative approach can be valuable in case of novel questions in business where there is less data or where little or no theory exists to deduce research hypothesis (Reinecke, Arnold, & Palazzo, 2016). Therefore, a qualitative approach was an appropriate methodology for this study.

Developing generalizable rules and verification or falsification of hypotheses are the focus of quantitative research methods (House, 2018). Researchers collect numerical data in order to test theories or hypotheses using measurement of specific variables (Saunders et al., 2015). The research problem and question of my study did not require testing correlations, hypotheses, or existing theories using statistical analysis or mathematical models. Therefore, a quantitative approach was not suitable for this study.

Researchers use mixed method research when their research question can be best answered by an integrated qualitative and quantitative research than either of them alone (House, 2018; Saunders et al., 2015). Challenges of mix method include the large amount

of time the study requires, size of samples, and quality of data and related interpretation during analysis (House, 2018). Mixed method is complicated and is discouraged for students (Fusch et al., 2018). Though a mixed method approach may have fit my research problem, required sample size, large amount of time, and potential for discrepancies during analysis were major deterrents.

Research Design

A research design is a plan to collect and analyze data in order to obtain answers to the research question to maximize validity and efficiency (Palinkas et al., 2015). Case study, ethnography, and phenomenology are the common qualitative research designs. Research questions pertaining to the understanding of organizational processes can be best addressed using a case study approach (McIntosh & Morse, 2015). The two main purposes of case study are exploration and theory-building (Runfola, Perna, Baraldi, & Gregori, 2017). A case study is used to identify what decisions that were made, why, and how they were implemented which yielded certain results (Yin, 2018). Using a case study strategy enables researchers to perform in-depth inquiry into a topic to generate insights in a real-life context experiences (Saunders et al., 2015; Yin, 2018). A case study focuses on how things are and how they behave (Dresch et al., 2015). Case study facilitates collecting richer information pertaining to a phenomenon (Dasgupta, 2015). Semistructured interviews can assist in ascertaining participants' perspectives of their experiences related to the study topic (McIntosh & Morse, 2015).

A researcher selects a case study design to explore a smaller sample using multiple approaches to gather data (Dresch, Pacheco Lacerda, & Cauchick Miguel, 2015)

and conducts investigation and builds theories where the phenomenon is newer or poorly understood (Runfola et al., 2017). A case study design can be conducted on a single case or multiple cases. A single case study design is appropriate when researching a unique case (Dasgupta, 2015). Multiple case design allows researchers to build theories by proving a strong base for cross case analysis (Yin, 2018). A single case study design was deemed more appropriate to explore strategies used by some PV managers to implement innovative solutions for automation.

Case studies are more common (Sovacool et al., 2018) and popular than the other qualitative research designs like phenomenology and ethnography. Phenomenology is concerned about a less known lived experience (Lewis, 2015), whereas a case study focuses on a phenomenon to be studied in the environment it takes place (Tobi & Kampen, 2017). Researchers conduct phenomenological studies to analyze lived experiences. Because my study focused on strategies used for implementation of automation solutions, and not on lived experience of an employee, phenomenology was not an appropriate design. The purpose of ethnography is exploration of a phenomenon in a cultural context (Lewis, 2015). Because cultural context was not critical for my study, ethnography was not a suitable design.

Data saturation is an important aspect of qualitative case studies. Data saturation is reached when no new information or themes are observed and the information can be used to replicate the study, making it capable of generalization (Fusch & Ness, 2015; Saunders et al., 2017). The depth and richness of data will determine the data saturation and not solely the sample size of the population (Boddy, 2016; Fusch & Ness, 2015). I

ensured I collected in-depth information and rich and thick descriptions and continued the interview process until no new information was discovered. I used member checking as recommended by Fusch and Ness (2015) to achieve data saturation.

Population and Sampling

The study population is the total number of people within the organization eligible for sampling consideration in the interview study (Yin, 2018). To fit the purpose of the study and collect relevant knowledge, researchers following qualitative approach use specific criteria to purposively sample participants (Lewis, 2015; Sovacool et al., 2018). The target population for this single case study consisted of PV systems managers who were involved in successfully implementing innovative technology strategies to automate AE case processing and employed in the selected pharmaceutical company in the Boston area of Massachusetts, United States. The participants were willing to participate in this study.

Because this study is set in a specific function within a pharmaceutical industry, a purposive sampling design was used to select participants for this study. A purposive sampling design is used when a particular phenomenon is studied in a specific context (Tobi & Kampen, 2017; Yin, 2018). The participant sample must be representative of the population (Boddy, 2016). The sampling technique did not yield a large and diverse selection of participants from the PV function of a small pharmaceutical company. Therefore, I invited four PV systems managers to participate in the study.

To decide the number of participants to be interviewed for this study, I followed the principles of data saturation. Data saturation is reached when no new information or

themes are observed and the information can be used to replicate the study, making it capable of generalization (Fusch & Ness, 2015; Saunders et al., 2017). The number of participants for a study is contingent on the population chosen (Saunders & Townsend, 2016). The depth and richness of data will determine the data saturation and not solely the sample size of the population (Boddy, 2016; Fusch & Ness, 2015).

I interviewed four PV systems managers, selected using the purposive sampling method. In their qualitative study, Palaya, Pearson, and Nash (2018) conducted eight interviews since the authors could not find additional participants matching the participation criteria. Morley (2020) recruited and interviewed four participants for her study. Kawano (2017) interviewed two sets of three participants each for her qualitative study. Since no standards for sample size exist for qualitative studies (Malterud, 2016), sample size for qualitative studies are varied, driven by data saturation. Also, since my study participation criteria did not yield many participants, I interviewed four PV systems managers working in a single pharmaceutical company.

I obtained authorization from Walden University's IRB using which, I obtained consent from potential candidates to participate. Walden University's approval number for this study is 04-24-20-0972741 and it expires on April 23, 2021. I contacted the study participants by phone or email requesting their participation in the study and their response indicating their willingness to participate was documented. Quantitative interviews provide rich descriptions of complex organizational realities and offer ecological validity (Saunders & Townsend, 2016). The interview protocol and the interview questions as shown in the appendix A were administered to the participants via

telephonic interviews. I digitally audio recorded and transcribed the interviews to facilitate reliability of the data. Reliability is also ensured through member checking, which is the process of involving the participants in the interpretation of data to enhance the credibility of the results (Birt, Scott, Cavers, Campbell, & Walter, 2016). The participants were asked additional questions if needed to confirm accuracy and obtain any additional information or potential correction of data (Birt et al., 2016; Morse, 2015). Member checking follow-up interviews were originally planned to be conducted if required, to assist with interpretation of the transcripts. However, analysis and interpretation of the transcripts did not require follow-up interviews.

Ethical Research

All research, regardless of methodology and context, face various ethical issues when focusing on human experience needs, actions, and beliefs (Islam, 2019). Methods of access, informed consent, conflict of interest, research design, relationship with the participants, and understanding of contextual risks contribute to ethical concerns (Wallace & Sheldon, 2015). I used confidentiality procedures to protect the participants and maintain their privacy by following the protocols defined in the Belmont report (National Commission for the Protection of Human Subjects and Biomedical and Behavioral Research, 1979). To ensure adherence to the ethical standards, I obtained approval from Walden University's IRB. Walden University's approval number for this study is 04-24-20-0972741 and it expires on April 23, 2021.

Consent is a combination of the form or document and communication with the participants as a part of the conversation (Wall & Pentz, 2016). I used the consent form

and held an informed consent conversation prior to the interview to ensure the participants understood the key elements and their rights pertaining to informed consent as a recommended best practice by Koyfman, Reddy, Hizlan, Leek, and Kodish (2016). The consent process must include the privacy and confidentiality protection (Ennever, Nabi, Bass, Huang, & Fogler, 2019). I provided a student participant invitation and informed consent form to all participants and obtained their consent to participate prior to data collection. The participants had the right to withdraw from the study at any point before and during the interview process and were asked to communicate their withdrawal via email or by refusing to answer the interview questions and exit at any time. Participation in this study was voluntary and no incentives were offered.

I conducted telephonic interviews by following the interview protocol and questions (Appendix A). I followed the same protocol to interview all participants. I digitally recorded the interviews after obtaining consent from the participants. To protect the rights of the participants, I will store the data collected as password-protected files on a flash drive for 5 years. After 5 years, I will duly destroy the data collected including the recording files and any documents. To ensure confidentiality, I did not use the participants' names, organization name, or any identifiable information as a best practice recommended by Ennever et al. (2019) and instead, assigned codes such as P1 and P2 to the participants to ensure participant privacy. This study was voluntary. There was no payment for participation.

Data Collection Instruments

The researcher is the primary data collection instrument performing the data collection and analysis activities in qualitative research (Cypress, 2018; Houghton, Murphy, Brooker, & Casey, 2016). Qualitative researchers must begin to be reflexive and must consider the ethicality of their methodology (Thurairajah, 2019). As the researcher, I conducted this qualitative single case study using interviews to gather information. I served as the data collection instrument by enrolling participants and interviewing them using open-ended questions and collecting and analyzing the data from the semistructured interviews.

The interview protocol (Appendix A) was used to conduct interviews and collect data. Using a protocol ensured that the important aspects of the research questions from the literature review were included in the interview (Azungah, 2018). Interview questions for data collection covered important concepts of interest, which as suggested by Yin (2018), provided a direction for data analysis. The quality of the interview protocol impacts the study (Zhu & Mostafavi, 2017). The interview protocol (Appendix A) contained multiple sections including an introduction and the list of questions developed from the important aspects of the research question. I started with explaining the background and the objective of the study, included the confidentiality statements, and reminded the participants about withdrawal as defined in the protocol.

Interviews are a primary source of data for qualitative case studies (Runfola et al., 2017; Yin, 2018). I used semistructured interviews guided by the interview protocol to collect data to explore strategies used by PV systems managers to implement innovative

technology solutions for automation. I included multiple sources of data to determine convergent or divergent findings (Reinecke et al., 2016). Multiple sources of data like interviews, reflective journals, or documents promote study validity via triangulation (Morse, 2015; Yin, 2018). I searched for publicly available information like announcements or presentations and additionally requested the participants for documents they will be willing to share after the interview. I called the participants on their preferred phone number at an agreed time. I obtained participant consent to audio record the interview. To ensure data accuracy and reliability, I initiated the member checking process and triangulation. Member checking or participant validation is the process where the participant is involved in the interpretation of the data and is asked additional questions during and after the interview to confirm accuracy and obtain any additional information or potential correction of data (Birt et al., 2016; Morse, 2015). I shared my interpretations with the participants and requested approval or corrections as a part of member checking process. All participants confirmed accuracy and one participant responded with minor corrections. The final versions of the transcript and interpretation was used for data analysis.

Data Collection Technique

To explore strategies that PV systems managers used to implement innovative technology solutions for automation, I collected data directly from the PV systems managers in the form of interviews and additional documents. Yin (2018) identified four principles of data collection to ensure high-quality case studies: use multiple sources of evidence, a case study database, maintain a chain of evidence, and exercise care using

electronic sources of evidence. The primary data collection technique I used is telephonic semistructured interviews guided by the interview protocol (Appendix A). In addition, I reviewed any publicly available information or presentation and documentation shared by the participants related to this study. Interviewing, field observations, and document analysis are the primary methods of data collection in qualitative studies (Chenail, 2011). I obtained approval from Walden University IRB prior to interviewing the participants. Walden University's approval number for this study is 04-24-20-0972741 and it expires on April 23, 2021. To focus on a particular phenomenon, I used the purposive sampling design recommended by Tobi and Kampen (2017) to identify participants. I called the participants at a predetermined time to conduct interviews. I shared the informed consent form, reviewed the content of the form, and requested an email response confirming willingness to participate in the study. Upon receiving permission from the participants, I audio recorded the interviews using the voice recorder application installed on my Samsung mobile phone. To enable consistency, maintain order, and ensure the participants understand their rights, I used the interview protocol as a guide (Castillo-Montoya, 2016). The same interview protocol was used with all the identified participants to ensure consistency. Since reflective journaling can be used to improve critical thinking and problem solving (Taliaferro & Diesel, 2016), I captured notes and used reflective journaling approach and made notes to gain insight into events described by the participants.

The use of semistructured interview approach allows the researcher to ask open-ended questions (Yin, 2018) and facilitate open interaction with the participants so they

can provide rich data and thick descriptions. Interviews can be targeted to focus on a specific topic and well-informed interviewees can offer credible insights. However, as noted by Yin (2018), interviews are subject to problems of bias, inaccurate articulation, and poor recall. To mitigate the problems, I shared the interview questions ahead of the interview so the participants could collate the information and formulate their responses.

I transcribed the recorded interviews, and the transcripts and the interpretations were shared with the participants to confirm accuracy and enhance validity by achieving data saturation. Data saturation is achieved when no new information or themes are observed and the information can be used to replicate the study (Fusch & Ness, 2015; Saunders et al., 2017). Data saturation is critical to establish study validity (Morse, 2015). Member checking and follow-up member checking interviews can also assist in reaching data saturation (Yin, 2018). I included my assumptions and bias identified in my reflective journal during the transcription of the interviews, with the objective of surfacing any additional questions or clarifications to pursue as a part of follow-up interviews. During the transcribing and interpretation, I did not have any additional follow-up questions. All participants confirmed accuracy and one participant responded with minor corrections. I had originally planned on conducting member checking follow-up interviews or email correspondences and edit the transcripts and interpretations accordingly until data saturation was achieved. However, I did not need to conduct any follow-up interviews and I was able to achieve data saturation.

In addition to providing answers to interview questions, I requested participants for any documentation to corroborate the data. Documents such as standard operating

procedures, policies, and best practices can help discover underlying themes (Yin, 2018). Documents are stable and can corroborate evidence from other sources (Yin, 2018). Yin (2018) also added that document review could result in contradictory evidence and the findings might not corroborate with collected data, which can result in further investigation. I triangulated the analysis of the documents received from the participants and those publicly available and the interview data. Triangulation is a process of authenticating information using multiple sources of data or methods concerning the same event to decrease bias and increase validity of the study (Fusch et al., 2018; Joslin & Müller, 2016). By performing triangulation and member checking, I created an advantage for myself as the researcher to attempt to reduce bias and enhance the validity and reliability of this study.

Data Organization Technique

To achieve the objectives of this study and ensure I conduct a high-quality study, the following information was collected for this study: audio recording of every semistructured interview captured via mobile phone, notes and journal entries, transcriptions of the interviews, informed consent, reflective journal, project documents and presentations regarding the innovative technology implementation as shared by the participants. I had requested the participants for any project documents, public presentations, procedures, policies, and best practice documents, and internal communications. I collected the aforementioned documents and files electronically and will store in a password protected flash drive for 5 years. I had planned to convert any hard copies into electronic format to be able to store them digitally, after which the hard

copies will be returned to the participants or destroyed by shredding. However, I did not receive any hard or paper copies. I used ATLAS.ti software to organize the collected data and maintain a list of codes and keywords, including bias from my reflective journal to compile, disassemble, reassemble, interpret, and conclude the findings. In addition, I established a case study database as recommended by Yin (2018) to track all the data collected and maintain a chain of evidence. To ensure confidentiality and protect the participants from harm, I refrained from using the participants' names as recommended by Ennever et al. (2019) and Wall and Pentz (2016) and instead, assign codes such as P1 and P2 to ensure participant privacy. A few participants identified names of the organization during the interview. To maintain participant privacy, I removed all occurrences of their names or the organization names while transcribing. I labeled the data collected from the participants per the assigned codes. All the collected data will be stored for 5 years after the completion of the study and duly destroyed after.

Data Analysis

Organizing the collected data and identifying realistic meaning and drawing conclusions is the purpose of performing data analysis (Bengtsson, 2016). To enhance the validity and reliability of my study and ensure data saturation, I performed triangulation and member checking. Triangulation is a process of authenticating information using multiple sources of data or methods concerning the same events to decrease bias and increase validity of the study (Fusch et al., 2018; Joslin & Müller, 2016). Methodical triangulation involves multiple methods of data collection to view a phenomenon (Fusch et al., 2018; Sovacool et al., 2018; Yin, 2018). I used methodical triangulation approach

and triangulate the data I collected from the interviews, internal and publicly available company and project documentation as evidence of strategies the PV systems managers used to implement innovative technology solutions for automation. The constructs of the TTF model and the research question assisted in focusing the data analysis on the themes identified from the literature review.

Based on Yin's (2018) recommended five-step data analysis, I used the ATLAS.ti software to compile, disassemble, reassemble, interpret, and conclude the findings. I transcribed the data. After confirmation of accuracy from the participants, I used the final version of the transcripts and interpretation for data analysis. I performed content analysis by identifying themes and patterns in ATLAS.ti. The objective of content analysis is to systematically identify themes and patterns by coding of interview transcripts and documentation (Sovacool et al., 2018). I had identified a list of codes from my literature review as my initial set of codes for analysis. I also included my assumptions and biases recorded in my reflective journal for coding in ATLAS.ti software for data analysis. This process assisted in successfully performing bracketing and the researcher bias was included while performing content analysis. ATLAS.ti software assisted in organizing the collected data, maintaining a list of codes and keywords to maintain consistency (Bengtsson, 2016; Yin, 2018), and identifying themes. I established a case study database as recommended by Yin (2018) to track all the data collected and maintain a chain of evidence.

Reliability and Validity

Reliability

Researchers must be methodical in order to establish rigor and ensure reliability of their findings. Reliability refers to replication or repeatability to achieve consistent findings (Bengtsson, 2016; Yin, 2018). To ensure dependability, repeatability, and consistency during data collection, I used an interview protocol with a set of interview questions (Appendix A) and administered the same protocol to all the participants. Reliability can be achieved by designing a well thought out, consistent research process by promoting stability while coding and analyzing the data, and being transparent with reporting (Saunders et al., 2015). Despite being an efficient way of collecting data, interviews can be biased, which can affect the reliability of the study (Runfola et al., 2017). An unreliable research will be invalid since errors or bias will affect the findings, the analysis, and the interpretation (Saunders et al., 2015). Strategies to ensure reliability included using a coding system, member checks, thick description, and triangulation (Morse, 2015).

Validity

Validity refers to appropriateness of measures, accuracy of analysis, and generalizability (Saunders et al., 2015) that truthfully and accurately describes the phenomena (Bengtsson, 2016). Validity refers to the credibility, transferability, and confirmability of the findings. A study is credible when the results presented with the context are recognizable to people who share the experience, which refers to truthfulness or the internal validity of the study (Hammarberg, Kirkman, & de Lacey, 2016).

Transferability is the extent to which the study findings are useful to other people, which is achieved by researchers being transparent (Connelly, 2016). Confirmability refers to the degree to which a study is consistent and can be repeated (Connelly, 2016). Validity is one of the prime concerns of researchers using qualitative methodology (Fusch et al., 2018). The subjective nature of unstructured data collection poses a threat to validity (Morse, 2015). To determine validity, Morse (2015) identified prolonged engagement, peer review, negative case analysis, using a coding system, member checking, triangulation, etc. Data saturation is important to establish validity and is reached when there is enough information to replicate the study and there is no additional new information (Fusch & Ness, 2015; Saunders et al., 2017).

I used two techniques to establish reliability and validity in this study: (a) triangulation which is a process of authenticating information using multiple sources of data or methods concerning the same phenomenon to decrease bias and increase validity of the study (Fusch et al., 2018; Joslin & Müller, 2016). (b) member checking or participant validation: the process where the participant in involved in the interpretation of the collected data and is questioned during the interview process to confirm accuracy and obtain any additional information or potential correction of data (Birt et al., 2016; Morse, 2015). I used both triangulation and member checking as methods to reach data saturation. Data saturation is reached when no new information or themes are observed and the information can be used to replicate the study, making it capable of generalization (Fusch & Ness, 2015; Saunders et al., 2017). Data saturation refers to the depth of the data (Fusch & Ness, 2015). I ensured I collected in-depth information and

rich and thick descriptions and continued the interview process until no new information was discovered. I used member checking as recommended by Fusch and Ness (2015) to achieve data saturation.

I gathered rich data and thick descriptions and documentation during the interviews (Sovacool et al., 2018) to allow for transfer of the study findings to another context, thereby increasing credibility. I shared the interview transcripts and my interpretation with the participants to review and confirm the accuracy of the transcripts and my interpretation of the events. To increase confirmability, I included my assumptions and bias identified in my reflective journal during the transcription of the interviews, with the intention of surfacing any additional questions or clarifications to pursue as a part of follow-up interviews. I also included my assumptions and bias during data analysis to perform bracketing and assist with mitigating bias. To ensure confirmability and data saturation, member checking was conducted until no new information emerged. However, I did not conduct follow up interviews. I triangulated the information gathered from the interviews with the documentation to further confirm data saturation. To increase the reliability of the study, I established a case study database as recommended by Yin (2018) to track all the data collected and maintain a chain of evidence. I addition, I maintained an audit trail and recorded the approach for the data collection, interpretation, and analysis to enable retracing of the steps and duplication, thereby increasing transferability.

Transition and Summary

The purpose of this qualitative single study was to explore the strategies used by PV systems managers to implement innovative technology solutions to automate AE case processing. In section 2, I provided justification for selecting qualitative single case design for this study and focused on the strategies and approaches used for key components of this study. I explained the research method and design, population and sampling of participants, my role as the research instrument, and my approach for ethical research, data collection instruments and techniques, data organization techniques, data analysis, reliability, and validity that were used for this study. Upon approval from the IRB, I collected the data, performed data analysis, and then expanded this study to include the data analysis and findings of this doctoral study. In the next section, I describe the findings of the study, recommendations for future research, reflections, and conclusion.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative single case study was to explore the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE case processing. I used a purposive sampling technique to select four PV systems managers working in a pharmaceutical company located in the Boston area of Massachusetts, United States, who have used successful strategies to implement innovative automation technology solutions for AE case processing. I collected data from semistructured interviews, conducted using an interview protocol (Appendix A) until data saturation was reached, and triangulated the data with documents collected from the participants.

Three themes with nine strategies emerged during data analysis. The themes were (a) automation solution selection and implementation strategies, (b) business operational model changes, and (c) communication and training strategies. Internal drivers like vision, objectives, timelines, cost, and compliance; ensuring solution is fit for purpose; open communication, collaboration, and engagement; strong project management; and simplified, standardized, and efficient business processes emerged as the key strategies from these themes. The organization had contracted an external vendor to build a strategic long-term partnership for their PV database, which was their foremost selection and implementation strategy. The findings supported the existing findings on strategies from the academic literature review. In the next sections, I will present the study findings,

application to professional practice, implications for social change, recommendations for action, recommendations for further research, reflections, and conclusion.

Presentation of the Findings

In this study, I focused on the strategies that PV systems managers use to implement innovative technology solutions to automate AE case processing. I conducted semistructured interviews to collect data from four PV systems managers from a pharmaceutical company in the Boston area of Massachusetts, United States. I used the TTF model as the conceptual framework to guide my research on identifying the strategies PV systems managers use for automating PV case processing.

Lai (2017) noted that the TTF model is suitable for investigating the utilization of new technology solutions. Therefore, the constructs of the TTF model were used as the conceptual lens to identify the strategies from the collected data. I used ATLAS.ti software to organize and analyze the data collected from the interviews. I manually analyzed the documents collected from the participants for document review. For initial analysis, I used word cloud for a visual representation of word frequency to get the first look and summarize the interview transcripts. The word cloud showed *system, project, vendor, automation, implementation, communication, change, issues,* and *users* as the key and most frequently used words by participants in the interviews as shown in Figure 4. The words mapped to the themes and strategies that were identified during detailed analysis.

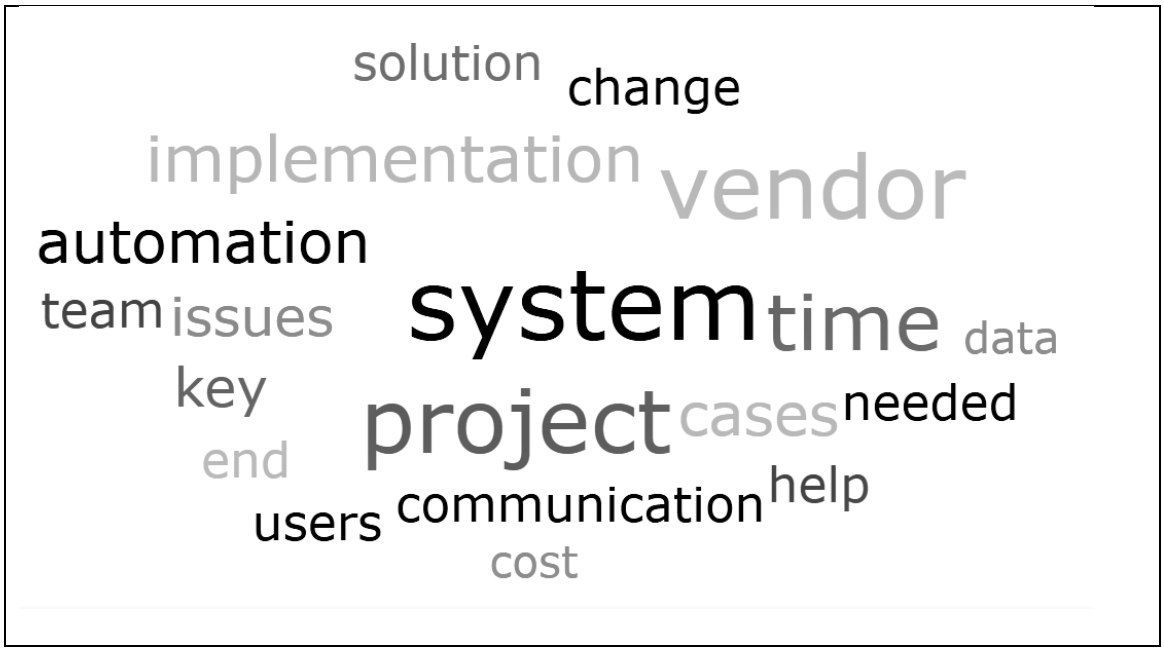

Figure 4. Word cloud showing the most frequently used words in the interview data. Created from ATLAS.ti.

The organization had contracted an external vendor to build a strategic long-term partnership for their PV database, which was their foremost selection and implementation strategy. The following key themes emerged with detailed analysis of the interview data: (a) selection and implementation strategies, (b) business operational model changes, and (c) communication and training strategies.

The automation solution selection and implementation strategies theme included five key strategies: internal drivers like vision, objectives, timelines, cost, and compliance; ensuring solution is fit for purpose; strong project management; strategic partnership with an external vendor; and defined metrics to measure effectiveness of the solution and project. Business operational model changes theme included two strategies: Simplified, standardized, and efficient business processes by supplementing and reducing

operational workforce and changes to organizational structure and job profiles. Communication and training strategies included open communication, collaboration, and engagement and training. The three main themes and the nine key strategies are shown in Table 2 below. The references coded refers to the number of times the data references were coded to the strategies.

Table 2

Themes and Strategies

Themes	Strategies	References coded
Selection and implementation strategies	Internal drivers like vision, objectives, timelines, cost, and compliance	18
	Ensure solution is fit for purpose	18
	Strong project management with a defined plan, dedicated resources, and stakeholders	16
	Strategic partnership with an external vendor	14
	Defined metrics to measure effectiveness of the solution and project	7
Business operational model changes	Simplified, standardized, and efficient business processes by supplementing and reducing operational workforce	15
	Changes to organizational structure and job profiles	8
Communication and training strategies	Open communication, collaboration, and engagement with stakeholders incl. end users and vendor	17
	Training	5

Theme 1: Selection and Implementation Strategies

Automation solution selection and implementation strategies was one of the key themes that emerged from the interview data. I analyzed the data in two steps, initial and detailed analysis. Initial analysis of the word cloud created by ATLAS.ti included *vendor, system, project, time, implementation, automation,* and *communication* as the key words as shown in Figure 5.

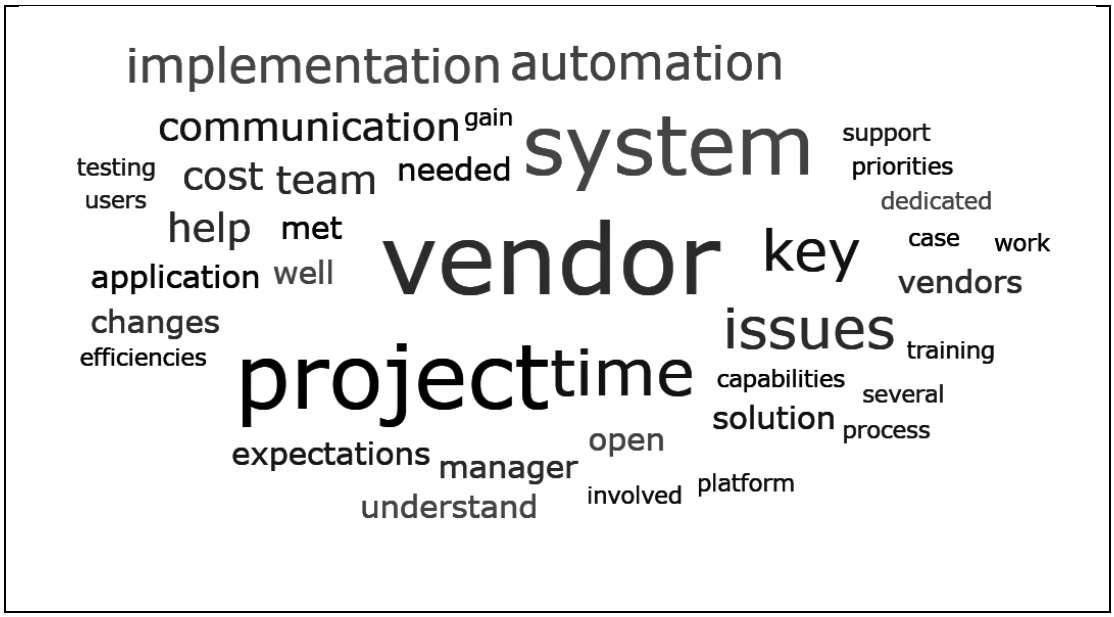

Figure 5. Word cloud for selection and implementation strategies in the interview data. Created from ATLAS.ti.

The word cloud for automation solution selection and implementation strategies reflected the strategies identified in the analysis of data. The leaders of the PV organization decided to strategically engage with an external vendor to supply the automation solution and implement the same. Managers have multiple options to implement technologies and value propositions and adopt a leader or follower strategy in the digitization arena (Ritter & Pedersen, 2019). This organization adopted the leader

strategy for automation. P4 indicated that the company was the first to implement this intake automation solution from the vendor. The following five key strategies emerged for selection and implementation strategies from the interview data:

Internal drivers like vision, objectives, timelines, cost, and compliance. All participants identified internal drivers as one of the important strategies to guide the selection and implementation of automation solutions for AE case processing. The participants identified multiple internal drivers or factors like organization vision and objectives for automation, tight timelines, cost, and competing priorities while ensuring regulatory compliance. P1 and P2 stated that the PV organization created a long-term vision to leverage automation as much as possible to build efficiencies within PV business operations. In addition, P2 stressed on selecting a vendor who had a long-term vision and were invested in building and supporting the product. All participants identified tight timeline and P1 and P3 listed cost and capabilities as key internal drivers in addition. All participants stressed on staying compliant with regulations to process AEs and building a validated, compliant system.

Ensure the solution is fit for purpose. All participants unanimously identified the fit of the automation solution to effectively perform as expected and match the tasks and constraints as a key strategy. P2 and P4 identified technical constraints like the solution platform must be on the Cloud and be compatible with the newly implemented PV database. Certain tasks which were performed manually were now replaced by a tactical automated solution. Therefore, the solution must be a fit for the tasks that needed to be performed, only more efficiently. Though the team had challenges with the solution

functioning as expected initially, they overcame the issues by leveraging the partnership with the vendor using collaboration and adjusting the business process and the solution to find an acceptable compromise.

Strong project management with a defined plan, dedicated resources, and stakeholders. The project team consisted of internal employees and the external vendor team members. To successfully execute the project, a strong project management function was led by an internal temporarily contracted project manager to track the project and manage stakeholder engagement. To ensure the milestones and deliverables were met as defined in the project plan, a structured project plan was built, and dedicated resources and stakeholders were identified. All participants indicated strong project management and leadership as a key strategy.

Strategic partnership with an external vendor. Because the automation solution was sourced and implemented by an external vendor, the PV systems managers decided to strike a strategic partnership with the vendor selected after a rigorous vetting process. Participants shared the realization that being a small pharmaceutical company, they did not have the relevant expertise inhouse. Therefore, PV management decided to build a strategic partnership with an external vendor who can source the automation solution and implement it. In addition, P2 stressed on partnering with a vendor with a vision who was invested in the technology and the solution for a long term. P4 recommended having vendor support onsite during “go-live” though the vendor was offshore and implementation project was executed remotely. Participants summarized that a good partnership ensured the vendor was engaged and acted on any issue

escalations.

Defined metrics to measure effectiveness of the solution and the project. The PV leaders built multiple metrics to measure the effectiveness of both the automation solution and the execution of the project. To ensure the solution was fit for purpose, before and after metrics measuring the time and resources were built. All participants indicated that the metrics measured the amount of time taken to create and process AEs before and after the automation solution was implemented. To ensure the project matched the internal drivers, the project was closely monitored to ensure all the milestones were achieved.

Documents provided by the participants showed automation, business process improvements, elimination of nonvalue-added activities, and metrics were the key internal strategies of focus. The documents also indicated strong leadership, open communication, and collaboration as key strategies for successfully implementing automation solution for AE case processing. Technical limitations like multitenant cloud implementation and adopting ISP configuration were included as internal drivers. The document review revealed timeline as an internal driver, as mentioned by all the participants in their interviews.

The findings matched the academic literature review. PV managers must create a vision and project new technology as a product designed to create, attract, and satisfy demand (Gherasim, 2011). Though many companies automate many steps in the PV process, plenty of opportunities exist to make PV agile and efficient (Ghosh et al., 2020). Organization leaders have realized that proactive external collaboration is beneficial for

creation of new products and solutions (Di Fiore et al., 2017). Therefore, the PV leadership decided to partner with an external vendor. PV managers must ensure the technology solutions are aligned with the business needs and led by business operations (Mishra et al., 2019). Managers must improve employees' job satisfaction and solution adoption by implementing IT solutions that fit the tasks and employees' long-term professional needs (Wang et al., 2020). Internal drivers of a company, specifically, organizational culture and environmental issues must be considered to leverage advantages of data analytics (Hawley, 2016). Automation can support human workforce in managing the increasing AE volume, complexity, reporting timelines, and increasing efficiency, consistency, and compliance (Routray et al., 2020). Companies typically measure the benefits of automation in terms of quality, compliance, and efficiency (Ghosh et al., 2020)

The TTF model links the task requirements, individual abilities, and the functionality of technology (Goodhue & Thompson, 1995). TTF theory focuses on the application and the general reliance on technologies and does not recommend any task or technology pairings that could produce a strong effect (Howard & Rose, 2019). The participants explained that the manual redundant tasks were identified first and then the automation solution that matched the tasks and the constraints was selected to ensure that the automation initiative was a success. Therefore, the TTF conceptual framework provided the correct lens for exploring strategies used by the PV systems managers to successfully automate AE case processing.

Theme 2: Business Operational Model Changes

The second key theme that emerged from the data was business operational model changes. This theme referred to the outcome of implementing the automation solution. Initial analysis of the word cloud created by ATLAS.ti included AEs also called *cases, system, automation, change, implementation,* and *automatically* as the key words as shown in Figure 6.

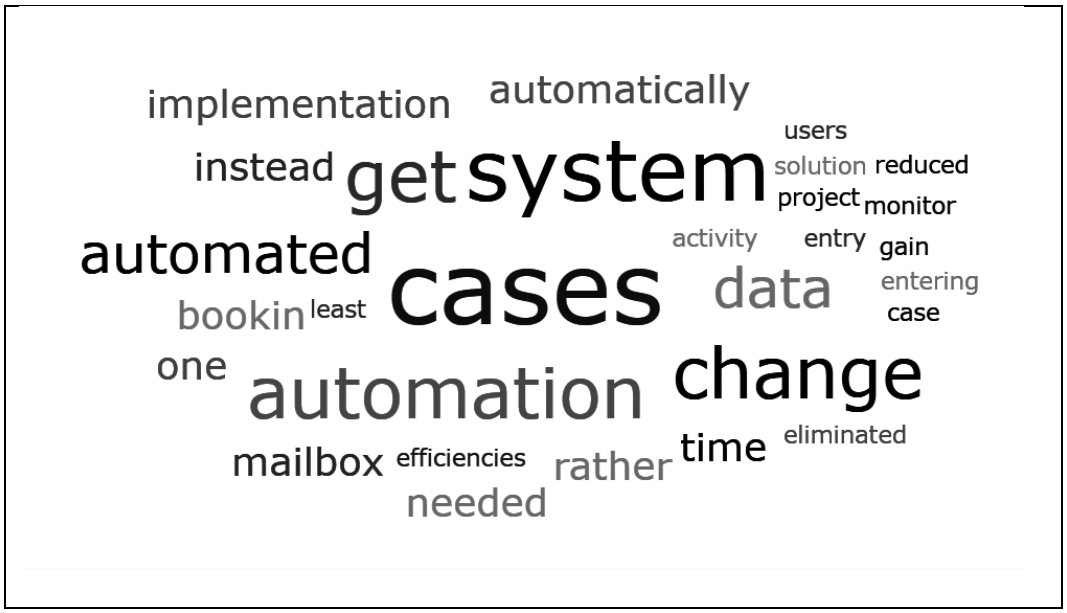

Figure 6. Word cloud for business operational model changes in the interview data. Created from ATLAS.ti.

Business operational model changes theme included the following two strategies:

Simplified, standardized, and efficient business processes by supplementing and reducing operational workforce. All participants stated that the introduction of the automation solution simplified and standardized the business processes and assisted in building efficiencies, as intended. P1 and P2 noted that although reduction of workforce was not the primary intention, the managers were able to successfully supplement the

manual, redundant tasks like double data entry to free up and repurpose the workforce to focus on more value-added tasks. P4 indicated that the PV operations team could reduce the number of full-time employees.

Changes to organizational structure and job profiles. The introduction of automation solution led to changes in the way the AE case processing employees performed their jobs. P1 indicated that the AE case processor now only has to read the data on the screen as opposed to having to type or enter it manually. P2 and P3 noted that the mailbox that had to be monitored for new AEs need not be monitored because the AEs were automatically created in the database and the task was eliminated.

Review of the documents provided by the participants showed process improvements and elimination of nonvalue-added activities as key objectives for automation. One of the challenges that the PV organization targeted to resolve was manual, time consuming, and inefficient processes. Ever increasing AE case volume, derivative operational cost, and resources were the other key challenges that the PV leadership decided to mitigate.

The findings for business operational model changes matched previous studies in this regard. Stergiopoulos et al. (2019) noted that all PV leaders believed implementing AI-based solutions will decrease costs for PV operations including simplifying AE detection and processing. Mishra et al. (2019) summarized that business process simplification, standardization, and re-engineering are the critical factors for a successful automation strategy. Routray et al. (2020) confirmed that human intervention and review of AE seriousness will be required, and that automation can augment human review by

increasing efficiencies and consistency, thereby enabling reporting compliance. Beninger (2018) emphasized on the new skillsets, which will define the roles of the next generation of professionals who perform PV activities. Tomita (2019) added that organizations must expect to supplement the human workforce with expert systems.

The TTF model matches the tasks as the events occur with the ability of a technology to address these events. TTF focuses on the application of technology (Howard & Rose, 2019). As concluded by Wang et al. (2020), the results of this study indicated that the automation technology implementation resulted in business process re-engineering. The results also indicated that if the automation solution fits the business processes to successfully complete the tasks and enables employees' personal fulfillment (Wang et al., 2020), then the managers can expect enhanced adoption of the technologies from the employees and a favorable attitude toward their jobs.

Theme 3: Communication and Training Strategies

The third key theme that emerged from the data was communication and training strategies. This theme included change management-related strategies. Initial analysis of the word cloud created by ATLAS.ti included *communication, vendor, training, project, team,* and *management* as the key words as shown in Figure 7.

Figure 7. Word cloud for communication and training strategies in the interview data. Created from ATLAS.ti.

Effective communication and training strategies played a key role in successful change management and adoption of the innovative technology solution within the PV organization. Communication and training strategies theme included the following two strategies:

Open communication, collaboration, and engagement with stakeholders including end users and the vendor. Considering the high priority and ranking of the AE automation project, the project team maintained open communication and collaboration channels to ensure all the relevant stakeholders stayed engaged throughout the implementation. All participants indicated that communication was key and that introducing automation was viewed as a welcome change for the AE processing operational activities. P2 noted that the end users were made an integral part of the project, which made change management effortless. Managing the vendor using open

communication and collaboration was critical. Multiple touch points like steering committee and core team meetings were built to ensure the information is flowing through the organization and timely escalation and resolution of issues. P1 and P2 also indicated collaborating externally with other companies to explore the opportunities for automation, which can be practically implemented.

Training. Since the introduction of automation changed the way certain business processes were managed, training was a critical aspect. The participants noted that multiple cycles of training were provided to the end users and the impacted third-party call center vendor. P2 and P3 explained that the end users were engaged in the implementation project and were trained multiple times.

Review of the documents shared by the participants revealed that open communication and collaboration were key to set up an optimum governance structure during implementation. Lack of efficient collaboration tools was a key challenge in the initial stages of the project. Considering varied stakeholders, both internal and external, and the vendor implementation team located remotely added to the communication challenges. The team used online collaboration tools like Google and Smart Sheets to help track tasks and keep the teams aligned.

Findings regarding communication and training strategies matched previous studies. Training and re-learning initiatives assist in preparing and guiding the in-house staff for digital transformation (Mishra et al., 2019). The human and technology relationship should also include user training, interaction, and collaboration sub-goals in order to be effective (Oyekan et al., 2017). PV systems managers realized the importance

of communication and collaboration early during the implementation project and ensured adequate measures were included to create open communication channels assisting in timely escalations and change management. Ghosh et al (2020) also recommended collaboration across the pharmaceutical industry between regulators and companies to build a generic process flow to fuel third-party innovations.

In the TTF model, Goodhue and Thompson (1995) linked the technology solution with individual performance. Wang et al. (2020) used the user task technology fit model to summarize that the technology solutions alter business processes and existing work patterns leading to re-training and re-learning, which could increase employees' work-related stress (Wang et al., 2020). The study results showed that engaging the users early during the technology implementation led to easier change management and enhanced adoption of the solution and possibly job satisfaction, since the solution was fit for purpose.

I included the researcher biases and assumptions that I had identified during data analysis. My biases and assumptions were confirmed to be a practical reality. PV systems managers I interviewed confirmed that they made the decisions to identify and implement innovative technology solutions. Participant P1 confirmed that among the many strategies available the PV organization managers decided to pursue the few above mentioned strategies for successful implementation. All participants confirmed that PV business operational model had an impact of introducing automation. And finally, the participants confirmed that innovative automation technology was used by their organization to

automatically read and create database entries, thereby eliminating redundant manual tasks, improving efficiencies, and over a period, achieving cost savings at the same time.

Applications to Professional Practice

Processing of an AE is an expensive resource-intensive process, which includes high risk of errors and operational inefficiencies (Ghosh et al., 2020). A detailed review of literature concluded that innovative technology such as data mining, machine learning, AI, and robotics could result in new operating models for PV (Beninger & Ibara, 2016; Lai, 2017), improve efficiencies and reduce PV operations costs (Karimi et al., 2015; Lu, 2009; Schmider et al., 2018), better allocation of resources, and improve patient outcomes (Lewis & McCallum, 2019). In this doctoral study, I explored the strategies that PV systems managers in the pharmaceutical industry use to implement innovative technology solutions to automate AE processing.

The single case that I selected to study was the implementation of an innovative technology solution to automate AE processing. The organization had a larger vision to automate PV business operations and this project was a part of that vision. Leaders and managers in the PV function decided to partner with a vendor to source and implement the solution, having realized that the organization lacked the necessary expertise on the technology. Multiple internal drivers such as objectives, timelines, cost, and compliance shaped the strategies the PV systems managers used to execute the project. Considering this being their first automation solution, the team ensured that the solution is fit for purpose, both task (functionality) and technology (architecture) perspectives. Strong project leadership and steering committee were established for robust governance and

monitoring. The managers established an open communication, collaboration, and training model to engage with the relevant stakeholders across multiple functions within the organization and the vendor. Measures were established to capture metrics in terms of volume, time, and quality of the business AE processing tasks before and after automation. Regular project governance and monitoring measures ensured the automation solution was implemented on time. The metrics defined the successful outcome of this implementation.

The results showed that implementing the automation solution impacted the PV business operational model in a favorable manner. Business processes are now more simplified, standardized, and efficient. The metrics revealed major savings in terms of time and effort, which led to reduction in operational workforce and better allocation of the resources. The organization has started reallocating the savings from the manual labor toward more value-added tasks. By successfully implementing the automation solution, the PV organization managers have started defining a sustainable model for PV business operations. Other pharmaceutical companies can use the strategies identified in this study to realize the benefits of implementing innovative automation technology solutions to build a resilient and sustainable PV business operations organization.

Implications for Social Change

The successful strategies identified in this study can be used by organizations to adopt a digitized PV future. The study findings show a positive outcome and realization of savings from PV business operations because of strategically implementing and embedding automation. PV leaders can redirect the savings from PV operations toward

investing in the actual PV tasks like benefit-risk assessments of products, thereby improving patient outcomes and making the products more efficacious and safer for human use.

The challenges on the pharmaceutical industry's perspective include the management of the high volume of AEs, globally diverse and changing regulations, complex and evolving systems, and sparse PV expertise and talent (Price, 2018). Automation technologies can detect, database, and report AEs quicker, and manage high volume of AEs, which can help in protecting patients from unnecessary harm. The implications for positive social change include the identification of strategies to assist in making pharmaceutical medicines safer for human consumption. The savings from PV operations could also be used to help or assist with community projects that could bring about social change. Companies can also use the savings to offer scholarships to students pursuing courses and majoring in PV, thereby contributing to increase PV expertise and talent.

Recommendations for Action

This study revealed multiple strategies used by PV managers to implement AE case processing automation solution. The three themes that emerged included automation solution selection and implementation strategies, business operational model changes, and communication and training strategies. The results revealed that the PV systems managers can follow their company's internal processes for solution selection and implementation, while paying close attention to the strategies identified in this study. By

successfully implementing automation technology for AE case processing, PV managers can realize time and effort savings and improve efficiencies with PV operations.

Other stakeholders in the pharmaceutical industry who could benefit from this study include PV organization leaders and PV system database vendors. PV organization leaders can include the strategies identified in this study as they start defining their PV automation vision and objectives. PV system database vendors can build automation solutions which fit the demand from the end users and build a mutually benefitting, strategic partnership with the pharmaceutical industry. The findings of this study could also provide valuable insights to researchers interested in further research in PV AE management automation. I will share the findings of this study with the research participants. Additionally, I will disseminate the results through scholarly journals.

Recommendations for Further Research

This qualitative study focused on a single case. I interviewed PV systems managers employed in one pharmaceutical company. This study can be extended in a future research to include additional perspectives like end user feedback and IT technology strategies. Due to the ever-increasing volume of AE cases to be detected, processed, and reported, more companies are building visions for digitalization and sustainability by incorporating more automation for their PV business operations and case management. This opens multiple avenues for future research. This study can be replicated with other study population to explore additional successful strategies. This study focused on successful strategies to implement automation and not on the actual automation solution that was implemented. A future study can delve deeper into the

technology that was used in addition to exploring successful implementation strategies. One of the participants stated that their implementation was a success and that many others are not. A future study can explore strategies that were unsuccessful, which can serve as learnings for other companies starting on this journey.

Reflections

I work in the pharmaceutical industry and have extensive experience with technology solutions and implementations. I selected this research topic based on an exploration project I conducted for the company I work for as the PV leaders were exploring the PV landscape with an automation lens. Since I was close to the topic, I had assumptions and preconceived thoughts regarding automation solution implementation strategies. Therefore, mitigating personal bias was crucial for my study. I made a list of my potential bias and included them during data analysis. The results showed that my biases and assumptions were practical realities.

The doctoral study process seemed a daunting task when I started. Soon, I started enjoying the process of conceptualizing the research, conducting, and concluding it. I did not face any challenges with the selection of participants and interviewing them. The participants took pride in their successful implementation as they are seeing the benefits now. I conducted my doctoral study as the small-scale project in the DBA Qualitative Research process course. I could effectively use the learnings from the pilot run for my study.

I decided to use innovative technology as a part of the study data analysis process. I used an application on my mobile phone for the initial transcript of the interviews. The

application audio recorded the interview and converted it into a transcript output, which saved many hours of transcribing effort. I proof-read the entire output, paraphrased as needed, and subjected it to member checking process for confirming accuracy.

Conclusion

Processing of an AE is an expensive resource-intensive process, which includes high risk of errors and operational inefficiencies (Ghosh et al., 2020). As deducted in multiple previous research, technology can accelerate efficiencies and can be used to identify and process AEs faster and contribute to reduction of costs (Beninger, 2018; Donzanti, 2018; Karimi et al., 2015; Kusch et al., 2020; Lewis & McCullum, 2019; Schmider et al., 2018; Stergiopoulos et al., 2019). Organizations must internalize digitalization and incorporate in the operations methodology and structure in order to select the most suitable technological solutions and reap the maximum benefits (Buyukozkan & Gocer, 2018). Many pharmaceutical organizations are experimenting, and some are implementing automation technology solutions for AE case processing.

This study focused on one such company whose PV organization managers have implemented an automation solution for AE case processing. The results of the study are in line with previous research. By prudently executing automation solution selection and implementation strategies and establishing communication and training strategies, the organization is now benefitting from simplified and efficient AE case processing business operations. Multiple factors such as internal drivers like cost and timelines, functionality of the automation solution, strong project leadership, stakeholder partnerships and engagement, including the size of the organization play an important role in shaping the

outcome of the digitalization initiative. With careful planning and execution, intelligent AE case processing automation initiative can be a success and be sustained over the long term.

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Appendix A: Interview Protocol

Interview introduction:

1. Introduce the topic and objectives.
2. Explain the purpose and scope of the study.
3. Assure participants that their name and organization information will be kept confidential.
4. Ask to record the interview and let the participant know that the materials will be stored for a maximum of 5 years.
5. Let participants know they can stop if they do not wish to proceed.

Strategic research questions Reminders to do during the interview: Watch for nonverbal cues. Paraphrase as needed. Ask follow-up probing questions to get more in-depth, rich data.	1. What strategies did you use to identify automation solutions for AE case processing? 2. What strategies did you use for implementing the identified automation solution? 3. What, if any, kinds of operational changes did the automation solution require to your PV business operations model? 4. What communication strategies were used to manage regulatory obligations and employee's expectations to enable employee's adoption of the automation solution? 5. What key difficulties did your organization face when implementing the automation technology

	solution? 6. How did your organization overcome the key difficulties to implementing automation technology solution? 7. How did your organization assess the implementation strategies' effectiveness? 8. What additional information can you add about the development and implementation of the strategies your organization used for automating AE case processing?
Wrap up interview	Thank the participant for their time and information. Schedule a follow-up interview for member checking.
Follow-up member checking interview Reminders to do during the interview: Watch for nonverbal cues. Paraphrase as needed. Ask follow-up probing questions to get more in-	Introduction: 1. Reiterate and refresh the topic and objectives. 2. Introduction for follow-up. 3. Assure participants that their name and organization information will be kept confidential. 4. Ask to record the follow-up interview. 5. Let participants know they can stop if they do not wish to proceed. Follow-up Interview:

depth, rich data.	1. Share a copy of the interpretation and synthesis of answers for each question. 2. Walk through each question including the interpretation of answers to ensure information was not missed and include any additional information. 3. Ask any additional questions related to the initial interview to add clarity to the research topic. 4. Wrap up follow-up interview by thanking the participant.