Spring 2023

A Digital Transformation Framework for Biopharma Manufacturing

Frederick K. Johnson

A Digital Transformation Framework for Biopharma Manufacturing

By
Frederick K. Johnson

Claremont Graduate University
2022

Approval of the Dissertation Committee

This dissertation has been duly read, reviewed, and critiqued by the Committee listed below, which hereby approves the manuscript of Frederick K. Johnson as fulfilling the scope and quality requirements for meriting the degree of Doctor of Philosophy in Information Systems & Technology.

Chinazunwa Uwaoma, Chair

Claremont Graduate University

Research Assistant Professor of Information Systems & Technology

Lorne Olfman

Claremont Graduate University

Professor Emeritus

Samir Chatterjee

Claremont Graduate University

Fletcher Jones Chair of Technology Design & Management

Abstract

A Digital Transformation Framework for Biopharma Manufacturing

By

Frederick K. Johnson

Claremont Graduate University: 2022

In the current climate of economic uncertainty and social unrest, biopharmaceutical (biopharma) companies face the challenges of changes in consumer behavior, cyber threats, and technological advancement. At the same time, their top priorities are global market growth, strengthening R&D, and undergoing digital transformation (Dx). Given these developments, biopharma organizations must choose a Dx framework as they engage in the digital transformation of their businesses in this high-stakes environment. However, there are significant problems with existing Dx frameworks. Most models are generalized frameworks designed to sell consulting services. Some focus on the enterprise or the manufacturing operations, but not both, and emphasize technology over strategies to address patient needs. However, the biggest problem is that the most commonly used frameworks are high-level models that need to provide guiding pathways for practitioners to follow. This study explores the evolution of the life science industry and explicitly addresses the challenges of adopting effective Dx frameworks in the biopharma manufacturing sector. Using a design science research (DSR) approach combined with Kumar's (2012) seven modes of the design innovation process, the study leverages existing research to determine the critical dimensions of any Dx process. After cross-referencing up-to-date research, the study offers a novel DSR Dx framework covering the enterprise and manufacturing landscapes to provide IT leaders with tools to assist in their Dx process.

Dedication

With love and sincere gratitude, I dedicate this work to my beloved daughters, Malia and Meta Johnson. Thank you for your unconditional love, support, and patience in my pursuit to achieve the illustrious status of “Professor Daddy.”

Acknowledgments

Completing a dissertation is a significant milestone in anyone's academic career. As I look back on my educational journey, success was not a linear trajectory; rather, it was built on a foundation of mistakes and failures spanning Europe, Asia, and the US. However, with loss came personal and cultural insight into how the world viewed me, and with that insight came an erupting but vivid understanding of the path I had to take to achieve success. The only comparison I can make is akin to seeing the path to checkmate while your opponent believes you have lost the game.

Still, standing where I am now, I understand that some people never achieve that level clearly in their lives; therefore, I count myself blessed. Moreover, throughout that process of self-discovery, several people supported and guided me, and I would not be where I am today without them. With this in mind, I must thank my high school counselor, Ms. Peggy Berg, who is no longer with us, for believing in me, counseling me, and showing me that going to college was not like going to the moon. I also want to thank Mr. Art Mayberry, Sandy Robison, Dr. Mira J. George, and the entire EOP staff at Marquette University for giving me the foundation for success and academic excellence despite my adversity.

Furthermore, I would like to thank Dr. Lorne Olfman, Dr. Wallace Chipidza, and Dr. Samir Chatterjee for creating one of the best educational experiences I have ever had in my academic career. I sincerely appreciate your wisdom, patience, and ability to convey knowledge and understanding. I would also like to acknowledge all the faculty and staff members at the Center for Information Systems & Technology. Finally, thank you to my dissertation advisor, Dr. Chinazunwa Uwaoma, for your guidance, patience, and continued perseverance in supporting me throughout this process.

Table of Contents

List of Tables

List of Figures

List of Appendices

Chapter 1: Introduction

Operating within an ever-changing and fast-moving global economy is no easy task, especially in the life sciences. The industry comprises businesses and research organizations with missions to improve and enhance people's lives by developing life-saving drugs and treatments. The most common life sciences areas include pharmaceuticals, biotechnology, biomedicine, cell biology, and biopharmaceuticals (Preclinical, 2021). In recent years, pharmaceuticals, biotechnology, and biopharmaceuticals (biopharma) have gained much attention due to the spread of numerous infectious diseases. In early 2009, the H1N1 influenza virus, which causes Swine Flu, infected over 60 million people and resulted in over 12,000 fatalities in the US alone. Scientists warned of an impending pandemic and urged the development of a universal flu vaccine decades before the SARS-CoV-2 (i.e., COVID-19 virus) pandemic in the spring of 2020 (Osterholm, 2007). Even though the COVID-19 virus had a catastrophic impact on the world, it paled compared to its predecessors. Figure 1 is a visualization comparing the COVID-19 virus to HIV/AIDS (1981 to present), the Spanish Flu (1818 to 1819), the Third Plague (1855), Smallpox (1820), and the Black Death (1347 to 1351) (LePan & Schell, 2022).

As we reflect on the history of pandemics, several factors have undoubtedly changed as human society has evolved. SARS, MERS, Ebola, and Swine Flu proved to be very serious infectious diseases in the past twenty years. Any one of these viruses could have signaled an extinction-level event (ELE). However, advances in pharmaceuticals, biopharmaceuticals, virology, and gene mapping immensely diminished the impact of infectious diseases on the world.

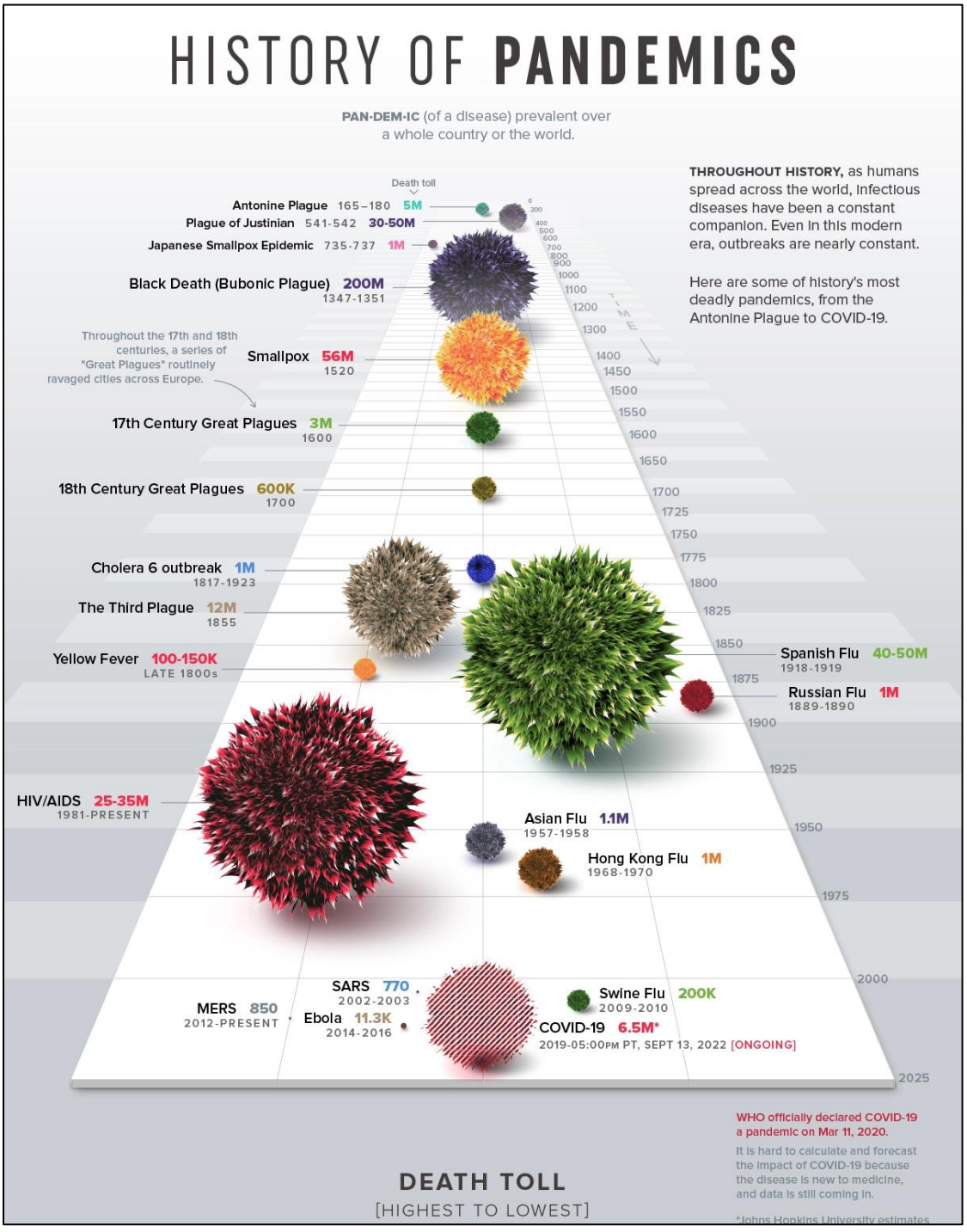


Figure 1: LePan and Schell, 2020 - History of Pandemics, www.visualcapitalist.com

COVID-19 was no different. Yet, despite the pandemic and other changes in the business environment, the life sciences industry is transforming in multiple ways. This study discusses the drivers behind these changes by presenting a Dx framework to assist biopharma manufacturing IT leaders and practitioners in transforming their manufacturing processes.

1.1 Background

As a brief preface to understanding the biopharma industry in the wake of the 2020 COVID-19 pandemic, we must take a few steps back. Manufacturing within a global economy seems nearly impossible, given the emergence of disruptive technologies that can unhinge entire industries, global markets, and value networks. With disruptive technology and increased international competition, manufacturing leaders in the life sciences have sought strategic ways to maintain or increase their competitive positions. Although gene therapy and preventive medicine still present business opportunities despite the COVID-19 pandemic, the life sciences industry was long overdue for disruption (Narain, 2016)

According to Irwin (2021: 4), during the COVID-19 pandemic, biopharma manufacturing organizations focused on three "types of COVID-19 vaccine: viral vector; whole virus; and messenger RNA (mRNA). mRNA vaccines are made from strands of genetic material that code for a protein on the virus that elicits an immune response." Companies such as Moderna, Johnson & Johnson, and AstraZeneca used mRNA-based vaccines and non-replicating viral vectors to produce high-efficacy COVID-19 vaccines (Craven, 2021). Manufacturing mRNA-based COVID-19 vaccines was a relatively simple but highly controlled process; however, manufacturers could not produce enough vaccines to supply the exponential demand (Irwin, 2021). Managing drug

product volume has generally not been an issue in the pharmaceutical industry since the production of blockbuster drugs focused on one disease affecting many people is the norm (Yang, 2020). The spread of COVID-19 has changed that. During the pandemic, most biopharma companies producing FDA-approved COVID-19 vaccines did not have the business capabilities within their manufacturing plants, capacity, or digital ecosystems to meet global demand (Ford, 2020). The Global Health Innovation Center at Duke University estimated that 12 billion COVID-19 vaccine doses would be needed by the end of 2021 (Irwin, 2021).

As a result, some of the largest names in the pharmaceutical industry, including BioNTech, began working together to meet global demand within the drug substance and drug formulation space, which included the manufacture of COVID-19 vaccines and the drug product space which completed the COVID-19 vaccine fill and packing process (Irwin, 2021). In early 2022, BioNTech unveiled an effective solution of small module laboratories to help offset African countries' capacity issues. The solution serves as a means to quickly "jump-start" the COVID-19 vaccine manufacturing process in parts of the world where the vaccines are most needed (Fletcher, 2022). The drug substance and product formulation manufacturing process can be conducted within the BioNtainer and packaged through local partnerships.

The BioNtainer addresses two central questions. First, how can biopharma manufacturers quickly increase their manufacturing capacity? Second, what innovation is required to produce high-quality drug products with short lead times and lower relative costs than their predecessors? The BioNTech BioNtainer is, in theory, the answer to both questions. At its core, the BioNtainer

is a modular pop-up smart factory and the perfect example of what many of the largest biopharma manufacturers plan to accomplish, but on much larger scales across different drug product lines.

1.2 Relevance

Undoubtedly, manufacturing COVID-19 vaccines is only one part of the equation. The pandemic also ushered in a new era within the biopharma sub-sector geared towards preventive treatments and cures rather than treating symptoms. The future of medicine sees biopharma companies working hand-in-hand with doctors and patients to produce personalized treatments (Yang, 2020). The ideal future solution is to build or transform existing facilities into smart factories like the BioNtainer. The biomanufacturing plants of the future will be digital and built on Pharma 4.0 principles that fully integrate and connect the digital ecosystem of their value chains to their shop floor manufacturing processes (Yue, 2020).

At their core, biopharma manufacturing facilities of the future will have intelligent operational technology (OT), including Manufacturing Operating Management Systems (MOMS), Manufacturing Execution Systems (MES), and Control Systems that leverage automated control processes (ACP), process analytical technology (PAT), and other advanced data analytics to automate continuous batch process times for vaccines (Hozdić, 20215). PAT and ACP technologies are essential to decreasing drug (i.e., vaccine) batch processing times from months to days, supporting the promise of Pharma 4.0 (Manufacturing Chemist, 2019). Therefore, if we consider the BioNtainer as a pop-up smart factor with the same business capabilities as a "connected plant" which can produce high-quality drug products at lower relative costs, then the life sciences industry is in a race towards adaptive manufacturing. Figure 5 describes the

generalized business capabilities at each plant's digital maturity level, where an adaptive plant is fully integrated from supplies to patients (Attonen et al., 2017).

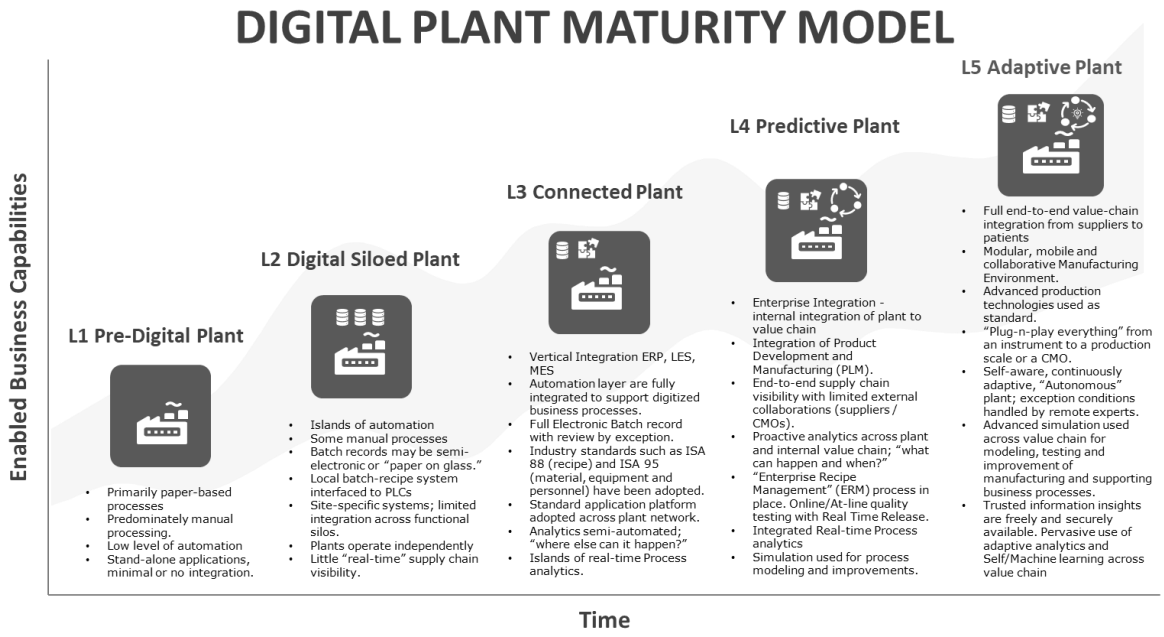


Figure 2: Digital Plant Maturity Model (Attonen et al., 2017)

In addition, having ACP and PAT business capabilities is the foundation of Pharma 4.0 because biomanufacturers plan to move from reactive MOM behavior to predictive and ultimately adaptive MOM behavior (Dutton, 2019). It isn't easy to achieve predictive and adaptive manufacturing capabilities as it requires transforming the entire business across multiple dimensions. Most biopharma manufacturing organizations are betting on Dx and Pharma 4.0 strategic efforts. By 2022, expenditure or Dx efforts will hit US$2 trillion worldwide, a 60% increase in expenditure in 2016 (Menear, 2020). As innovative and proactive as this may seem, IT leaders face immense demands, high risks, and formidable obstacles. Organizations face challenging questions, such as where the business should start achieving its desired digital maturity

level and how the organization will get there. Adopting a Dx framework can answer these questions. In practice, a Dx framework provides a governing set of processes, tools, and guidelines to map how organizations will achieve higher levels of digital maturity over time. Given its importance, selecting which Dx framework to adopt is critical. Therefore, this study addresses IT leaders' and practitioners' selection problems when determining which factors are important in choosing a biopharma manufacturing Dx framework.

1.3 Study Objectives

As a means to support life-saving pharmaceutical products and personalized treatments, this research focuses on conducting a DSR analysis to develop a Dx framework proof of concept for biopharma manufacturing. The proposed DSR artifact will support a Pharma 4.0 Operating Model to help transform an organization and allow biopharma IT leaders to achieve their organizational priorities while addressing their businesses' challenges.

Moreover, life in a post-pandemic world is highly dependent on the success of biopharma companies in digitally transforming their organizations in response to the changing business environment, including the prospect of another pandemic. Given this, any functional Dx model should span the enterprise and the plant manufacturing operations while addressing the critical functional areas, technologies, and business capabilities that support digital maturity. With this in mind, this study is broken into three objectives, as shown in Figure 6.

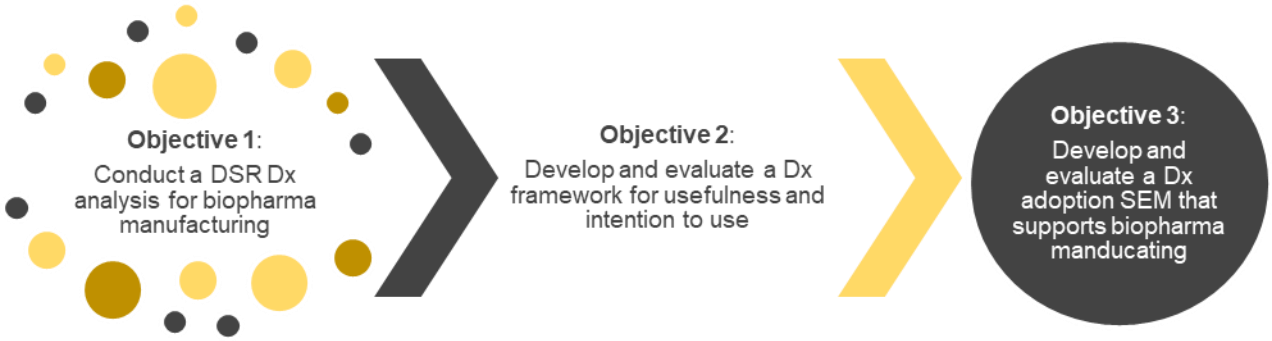


Figure 3: Study Objectives Flow

Objective 1: Conduct a DSR Dx analysis that supports the development of a Dx framework proof of concept for biopharma manufacturing which (1) places patients and their doctors as the primary focus; (2) supports a responsive and efficient supply chain; (3) demonstrates hallmark attributes of top Dx frameworks; (4) supports implementing Pharma 4.0 programs and transformations across key business dimensions, including resources, information systems, culture, and organization and processes; and (5) provides tools, including a strategic road map to guide IT leaders and practitioners through the Dx process.

Objective 2: Develop and evaluate a Dx framework by collecting data through an online survey of a sample population of biopharma IT leaders and practitioners actively involved in Pharma 4.0 and Dx activities. This study will evaluate the framework's usefulness (i.e., the artifact's usability) and participants' intentions to use it.

If the evaluation results demonstrate that respondents find the proposed framework useful and provide evidence of their intention for adoption, future research will focus on objective three.

Objective 3: Use the collected survey data in future research to (1) develop a Dx adoption structural equation model (SEM) specifically for use in biopharma manufacturing; (2) evaluate the proposed Dx adoption SEM using the partial least squares (PLS) analysis to determine which factors influence biopharma IT leaders' decisions to adopt a framework; (3) introduce a novel Dx adoption SEM for biopharma manufacturing with a high explanation of variance in surrounding perceived ease of use and ease of use while having high power of prediction of intention to use.

1.4 Chapter Summary

In summary, understanding the drivers changing the life sciences industry provides a strong monetary incentive and business case for biopharma companies worldwide to transform, retool, and build smart factor business capabilities that integrate with responsive supply chains for increased business agility (Ford, 2020). A Dx framework specifically designed to support Pharma 4.0 initiatives provides tools and a strategic roadmap for IT leaders and practitioners to follow would be an invaluable tool in assisting IT leaders to achieve SmartFactory business capabilities and, ultimately, Dx success.

The next chapter will focus on laying the foundation and providing a basis for understanding biopharma manufacturing as it relates to the challenges and priorities of the industry as a whole. The subsequent sections contrast the differences between Industry 4.0 and Pharma 4.0 and connect these concepts and principles to the broader context of Dx and, ultimately, to manufacturing capabilities. Chapter 2 presents a theoretical literature review that explores the biopharma industry's challenges and priorities, including the concepts and principles of Industry 4.0 and Pharma 4.0, the broad context of Dx, manufacturing capability, and Dx-related work.

Chapter 3 presents the research method and discusses the tools, techniques, and procedures used to support the study. It also outlines the DSR method and the design evaluation process. Chapter 4 will introduce the proposed Dx framework and detail the two artifacts the study will evaluate. Chapter 5 summarizes the results of the evaluation process conducted in Chapter 3 and provides a disposition on the proposed hypotheses. The study concludes in Chapter 6 with a summary of the findings, a discussion on the theoretical and practical implications, contributions to the literature, and plans for future research.

Chapter 2: Literature Review

In biopharma, much of what the public sees as customers or recipients of life-saving products and treatments come via a culture focused on scientific innovation rather than customer service. For decades, biopharma companies enjoyed substantial profit margins by developing drugs, treatments, and therapies that offered few incentives for innovation beyond product development (Narain, 2016). Now, however, everything is changing. The current challenge is how a company can transition to meet future realities meaning that the biopharma field is experiencing nothing short of an evolution.

Monumental innovations and increased competition are apparent across the entire life sciences landscape, especially in medical devices and equipment and in biotechnology and its subsector, biopharmaceuticals (biopharma), which combines biotechnology and pharmaceuticals in the process of product development (CB Insights Research, 2018). Despite fears of product and technology disruptions, biopharma organizations worldwide are consolidating, rethinking their business models, restructuring, and learning how to leverage informatics and artificial intelligence in their drug development processes. The most exciting goals that the industry hopes to reach by 2024 are (1) creating an outcome-driven, patient-centric corporate culture, (2) transforming from mass generalization to mass customization, (3) adapting to new digital ecosystems, and (4) market entrants that disrupt healthcare delivery (Yang, 2020).

Significant changes are taking place in response to culture, business practices, and technology transformations. In the past, the life sciences industry was focused on innovation in science, with little regard for innovation in personalized medicines, treatments, and therapies. Underlying trends have supported progressive changes in the universal business model to focus on "outcome-based health solutions that meet the needs of empowered health consumers" (Ernst & Young, 2017:1).

Apple and Amazon pride themselves on their agile business models, flexible work environments, and customer-centric approaches to developing new products and services. Big tech companies, namely Apple, have forged operating models and organizational structures that make innovation a cornerstone of their culture while controlling the entire user experience (Tian, 2022). Unlike outdated business models primarily focused on product development, large technology companies now operate according to customer-centric business models with corporate surveillance capabilities that seamlessly market and conveniently deliver digital products based on individual preferences (Foroohar, 2019). Most of us now expect an Amazon- or Apple-like experience as an unstated but universal standard. New market entrants are what the biopharma industry fears most. "Pharma's competitive positioning and pricing power will be challenged by new, fast-moving market entrants and by the expectations of empowered consumers" (Ernst & Young, 2017:1).

2.1 Challenges and Priorities in the Biopharma Industry

The experience most people have come to expect from companies such as Apple and Amazon involves a complex, evolved, and transparent ecosystem orchestrated by processes and technologies rooted in Industry 4.0 concepts and principles. In 2020, the Deloitte Center for Health

Solutions (DCHS) surveyed top executives at 60 leading mid-sized biopharma companies. It analyzed investment statements for the pharma companies posting the largest revenues from the fourth quarter of 2019 to the first quarter of 2020. The survey found that biopharma executives saw "changing consumer behavior, cyber threats, and accelerated technology advances as the top challenges" and global market growth, strengthening R&D and Dx as the top priorities (Ford, 2020: 1). The DCHS suggested that biopharma companies are unable to meet the changing behaviors and expectations of customers. Respondents supported a more responsive approach to market changes, given customer needs. Future successful biopharma companies will not only use technologies to respond to their patient's unique needs; they will further curate and manage the overall digital experience of the patient, seeing them first as customers.

Still, research and development will always comprise the cornerstone of biopharma. A solid and viable pipeline must be supported by establishing R&D global markets to maintain competitive dominance (Ford, 2020). Several key market factors will undoubtedly change the biopharma business over the next two decades, drawing resources away from traditional blockbuster drug research (Yang, 2020). The Biopharma business of the future will primarily focus on preventive care and early detection, personalized medicine, and curative therapies. In preventive care and early detection, the opportunities are immense as genetic sequencing and vaccines assist in detecting and curing life-threatening diseases. Personalized medicine provides patients with the most effective treatments, with genetic sequencing and testing through which medical professionals can determine dosages and drug regimens based on each patient's genetic biomarkers.

Curative therapies are, no doubt, the future of medicine overall. Gene editing has given rise to gene and cell therapies that can cure and correct genetic diseases. With discoveries in genetics and gene editing tools such as CRISPR, augmenting the human genome is now a reality (Nemudryi et al., 2014). As society adopts wellness activities that support preventive care, the healthcare paradigm is shifting through digital therapeutics. Trends in this area help patients to manage illness through wearable devices that provide real-time biofeedback. Doctors and other medical professionals can track, monitor, and coach patients on their behavior to help reduce the need for prescription medicines. The application of digital therapeutics ranges from prescription dosing to clinical research (Yang, 2020).

Precision intervention, whether through robotic surgery, nanotechnology, or printed products and engineered organic materials, is at the forefront of the biopharma field (Yang, 2020). These biopharma trends require a different but specific business strategy that places patients' needs at the center of any new business biopharma model. Over the next five years, 52% of biopharma companies plan to prioritize Dx (Yang, 2020). Therefore, the continued success of any biopharma manufacturing organization over the next five-to-ten years depends on (1) drug and product development, (2) globalization, and (3) maintaining high levels of business agility. Strategic success is based on building a digitally mature enterprise through a Dx process. As a competitive means of ensuring business continuity, smart factories and smart manufacturing provide unparalleled capabilities that leverage Industry 4.0 technologies to meet these priorities.

2.2 Understanding Industry 4.0 and Pharma 4.0

Over the years, scholars and futurists have predicted the arrival of highly sophisticated, digitally connected, and automated manufacturing entities (ISPE, 2018). Today, these entities are known as smart factories, the physical manufacturing assets of smart manufacturing, and the processes connected to those assets by specific Industry 4.0 technologies. The primary objective of a smart factory is ideally the same as any other factory – to optimize costs. The only difference between Henry Ford's manufacturing plants and the smart factories of today is that Ford used money and politics to maximize his manufacturing facilities.

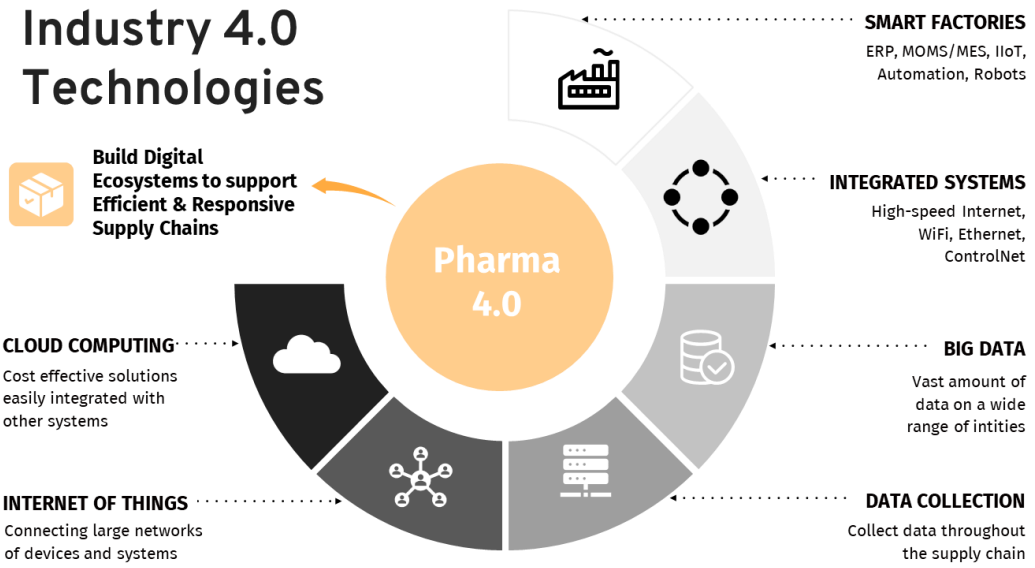


Figure 4: Industry 4.0 Technologies and Pharma 4.0 Relationship

In contrast, Figure 7 demonstrates how smart factories take an entirely different approach. Future factories will adopt cloud computing, the Internet of Things, data collection, big data, high-speed internet, industrial networks, computers, machine modeling, and other automation to improve manufacturing efficiency by predicting and adjusting operations (ISPE, 2018). With these

capabilities, biopharma manufacturers build digital ecosystems that support efficient and responsive supply chains that are agile enough to respond to market trends and changes in consumer behavior. This response-based business approach constitutes a significant paradigm shift, placing business agility at the center of business continuity (Hugos, 2018).

Without an effective business strategy, it would be overly speculative to predict what will happen and how a biopharma organization can succeed (Menear, 2020). Given this, Industry 4.0 represents an evolution into the Fourth Industrial Revolution, which expands manufacturing capabilities by interconnecting islands of technology through the Industrial Internet of Things (IIoT). The Fourth Industrial Revolution supports smart manufacturing models by contextualizing manufacturing as digital objects that produce and consume real-time data. Many of these systems are highly automated and utilize robots, automatic guided vehicles (AGVs), and sensors based on the IIoT that provide real-time data collection coupled with predictive and adaptive functions (Chen et al., 2018). Industry 4.0 takes manufacturing to a higher level of responsiveness, from suppliers to customers.

Industry 4.0 combines people, processes, and technology to increase quality, productivity, and profit margins by leveraging real-time data analytics (Markarian, 2018). Many of the biggest life science organizations plan to implement Pharma 4.0 programs. Initiatives like these translate into corporate Dx strategies dedicated to increasing manufacturing digital maturity through data integrity by design, offering greater capability at enterprise and plant levels (Ford, 2020). The differences in Figure 7 place Pharma 4.0 at the center of digital manufacturing strategies regarding data integrity and collection, automated process control, pharma analytics, and resource

management. At the same time, Industry 4.0 technologies enable the supply chain by connecting it to the manufacturing shop floor (ISPE, 2018).

The differences and similarities between the two frameworks stem from the fact that Pharma 4.0 is a derivative of Industry 4.0 and is highly tailored to support predictive and adaptive manufacturing. In many cases, Pharma 4.0 facilities are deeply rooted in automation that requires minimal human interaction. Automated production equipment monitors critical process parameters (CPP), essential manufacturing variables that impact product quality. The equipment shares real-time feedback about its state and status to allow preventive maintenance (Chen et al., 2018). Value comes from practices such as review by exception, automatic batch release, and product lifecycle management, achieved through advanced data analytics (Markarian, 2018).

Herein lie the real benefits and incentives driving the adoption of Pharma 4.0 concepts and principles in the biopharma industry. As described in Figure 8, the key aims of Pharma 4.0 include finding a balance between resources, organization, and process, on the one hand, and information systems, on the other, while changing the manufacturing culture through communication and decision-making (ISPE, 2018). The real challenge is understanding how any biopharma company can transform itself by shifting to a new paradigm based on the current business environment. The Pharma 4.0 framework represents a generalized path toward meeting that challenge. The idea is that a life sciences company can transform its organization around four dimensions: resources, information systems, organization and process, and culture (Ford, 2020).

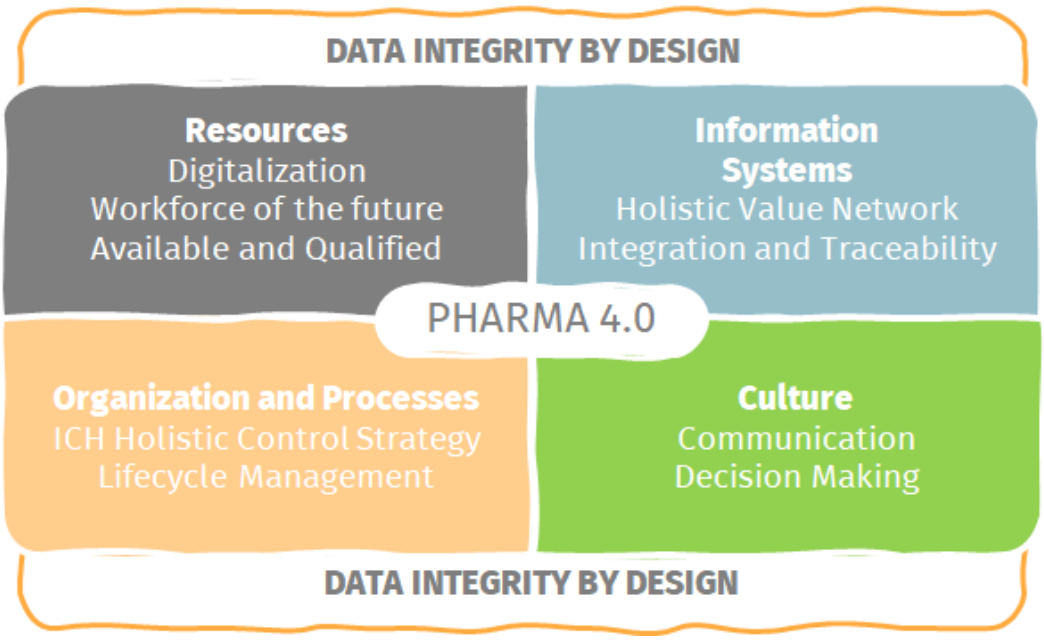


Figure 5: ISPE, 2018 – Pharma 4.0 Digital Maturity Model

However, there is minimal direction on how to achieve, track, or determine the success of these dimensions regarding digital maturity, which, in this context, is ideally limited to the manufacturing facility, although an enterprise-level transformation is most likely required. The central issues regarding resources, digitalization, and whether the future workforce will be qualified are new to the biopharma field, although they have already taken hold in other industries. The central perspective must include creating agile work environments, networks of teams, and paperless workspaces. Companies such as Google and Salesforce have established their foundation on collaborative models (CB Insights, 2018).

Likewise, organizational changes and processes support International Council for Harmonization (ICH) holistic control strategies and lifecycle management. The key takeaway is that Pharma 4.0 will provide much tighter levels of batch processing control than those mandated

by the ICH regarding the technical requirements for pharmaceuticals for human use, which will define process control standards and lifecycle management (ISPE, 2018). Therefore, what Pharma 4.0 offers biopharma manufacturing over Industry 4.0 is a more sophisticated means of driving efficiency and reducing costs and time while maximizing overall product quality (ISPE, 2021).

Changing an organization's typical top-down culture of communication and decision-making is no easy task. Hence, if Pharma 4.0 is seen as digital maturity through data integrity by design, senior leaders can now access computerized systems that provide visibility and transparency to their manufacturing processes (ISPE, 2018). Advanced facilities will not only have prediction capabilities; they will also be able to adapt. Shifting to a Pharma 4.0 paradigm is quite different from manufacturing plants of the past. Still, manufacturing leaders are better off with a company culture that supports power over information, control, and adaptability.

2.3 Digital Maturity Relativity

Although ‘digital maturity’ is often used when referring to Industry 4.0 and Pharma 4.0, its meaning is applied in two different ways. For Pharma 4.0, digital maturity means having substantial control of, access to, and visibility over continuous batch manufacturing processes, with automation and manufacturing agility (ISP, 2018). The digital maturity of Industry 4.0 is much broader, including the control of continuous batch processes, manufacturing operations, the enterprise, the supply chain network, and customer responses (Colli, 2019). Digital maturity, in this sense, means having the ability across an organization to capitalize and respond quickly to changes in the supply chain network. Digital maturity may be similar within each framework, but the phrase carries specific meanings across two dimensions.

2.4 The Broader Context of Digital Transformation

By definition, digital maturity addresses an organization's ability to capitalize on market fluctuations resulting from changes in consumer tastes and preferences or technological trends. The net effect of digital maturity can lead to a company’s rapid evolution based on innovation that fosters competitive advantage by establishing deeper connections with customer needs. Dx supports adopting and implementing digital technologies designed to transform a business or its services by replacing obsolete and ineffective technologies and procedures with new and emerging ones (Dilmegani, 2021). The fruits of any Dx are digital maturity and increased business agility, ultimately providing a business with enhanced manufacturing capabilities.

2.5 Defining Manufacturing Capabilities

From a manufacturing perspective, the expected benefits of a Dx strategy are that it will enable or enhance specific business and manufacturing capabilities. However, there are many Dx models from which business leaders can choose. Many are flexible and address specific areas and types of business models; the fundamental difference between Dx models comes down to the business application and industry sector. Although most Dx frameworks take a generalized approach, frameworks supporting Pharma 4.0 initiatives will incorporate items listed in Table 1:

Table 1: Supporting Manufacturing Theories, Concepts, and Principles

Manufacturing Focus Area	Related Theories and Principles	Sources
Supply Chain Management Theories	• Collaborative Manufacturing • Responsive Supply Chains	• (McClellan, 2002) • (Hugo, 2018)
Leading Manufacturing Principles	• Manufacturing Excellence • Operational Excellence • Manufacturing Operation Management	• (Tjahjono, 2016), (Hitomi, 1996) • Operational Excellence • (Filipov & Vasilev, 2016)
Manufacturing IT Standards	• ANSI/ISA 95 • ANSI/ISA 88	• (ISA, 2021) • (ISA, 2021)
MOMS/MES System Architectures	• The Seven Lives of MOMS/MES	• (Hughes, 2017)
Pharma 4.0 Concepts and Principles	• Digital Transformation • Plant Digital Maturity Levels • Smart Factories	• (ISPE, 2021) • (ISPE, 2021) • (ISPE, 2018)

Given the current level of innovation and the importance of change in the biopharma industry, IT leaders and practitioners must have a viable Dx framework. This study supports the entire Dx journey across a manufacturing enterprise.

2.6 Related Work

The concept of Dx has a long history, dating back to Claude Shannon's 1948 article "A Mathematical Theory of Communication" (Menear, 2020). Since then, strategy has been placed over technology as the key driver, and as a major element of business strategy, Dx is a critical driver of growth (Menear, 2020). Nonetheless, this study builds its artifacts on the transformation of three areas of business: customer experience, operational processes, and business models (Westerman et al., 2014).

2.6.1 The Six Dimensions of Digital Transformation

Bumann and Peter (2019) evaluated 18 Dx and digital maturity models in use during their study. They consolidated the key dimensions in each model to support a final overall conceptual model. The study compared all 18 models across 26 dimensions. The consolidated results, depicted in Figure 9, were based on a 40% threshold, meaning that the dimension had been at least 40% of the group total. Therefore, any dimension greater than or equal to 40% was deemed a relativity dimension (Bumann & Peter, 2019). Other researchers have used more rigorous methods to corroborate their findings despite their simplified research methodology. Morakanyane et al. (2020) examined the success factors of a Dx process, exploring the paths that organizations take to enable Dx success. Using 10 case studies classified as exemplars, those scholars selected 16 articles from a group of 89, coded selected case studies with specialized software (NVivo), and used the "asking the questions" analytical procedure (Morakanyane et al., 2020).

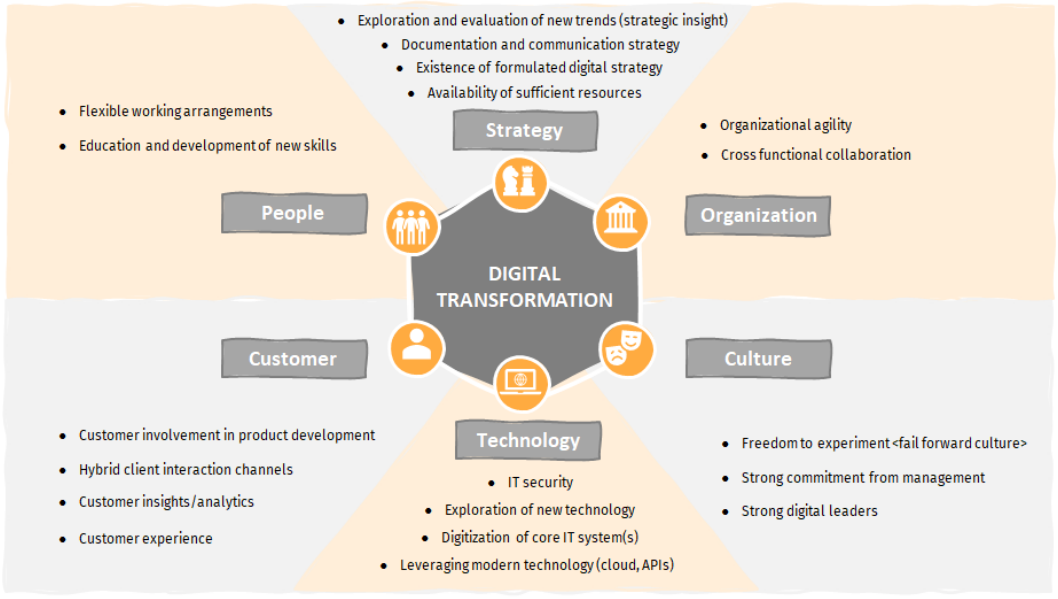


Figure 6: Bumann and Peter, 2018 – Digital Transformation Dimensions and Model

Bumann and Peter's findings suggest that the most frequently occurring dimensions are the Dx and maturity models. Morakanyane et al. (2020) found that classifying the factors and subfactors supports Bumann and Peter's Dx dimensions and model in five of the seven elements providing empirical evidence for the validity and relevance of Bumann and Peter's consolidated dimensions. One of the most important factors highlighted by Morakanyane et al. (2020) is the determination of the digital trigger related to behavior associated with achieving Dx success.

Gurbaxani and Dunkle (2019) align with Bumann and Peter in three categories. Having examined companies operating in different industrial sectors, Bumann and Peter established a framework for business leaders to assess their organization's progress based on six critical dimensions for Dx success. However, this tool is not as helpful in executing strategies. Another notable study is that of Nwaiwu (2018), who provided some ancillary support for comparing and evaluating detailed transformation frameworks. Using a credible framework proposed by Kavadias et al. (2016), Nwaiwu's research takes an academic approach to relevance. Although Kavadias et al.'s (2016) study are well argued, it focuses more on offering recommendations than on providing viable Dx tools to assist IT leaders and practitioners.

The results of Morakanyane et al.'s (2020) research reveal six classified dimensions (referred to as factors) and 23 subcategories (referred to as subfactors). Bumann and Peter's (2019) findings suggest that there are most frequently six dimensions to Dx and maturity models. Morakanyane et al.'s (2020) key conclusion are that the classification of factors and subfactors supports five of the seven factors in Bumann and Peter's Dx dimensions and model, thus empirically validating Bumann and Peter's consolidated dimensions. One of the most important

factors that Morakanyane et al. (2020) bring to light is the determination of the digital trigger, which relates to a specific behavior associated with achieving Dx success.

2.6.2 Theory of the Business

Another approach is to assume that Dx is iterative, as businesses change from the inside out. For this process to occur, the business must engage in activity over its life course that allows for self-assessment of its needs and environment (Aguilar, 1967). As monitoring or assessment processes occur, senior leaders constantly evaluate the strategies in need of change or the business areas that no longer support the objectives or continuity of the business, as described by Drucker (1994). Drucker's theory is based on four assumptions. The first is that the "environment of the organization: society and its structure, the market, the customer, and technology" are consistent with reality (Drucker, 1994: 4). The second is the first assumption that fits together.

2.7 Chapter Summary

In contrast, the third assumes the theory of the business is widely known throughout the organization. The fourth is that "the theory of the business must be constantly tested" (Drucker, 1994: 5). Although several theories support the use of a scanning process, the view of the business is more appropriate as the foundation for the strategic roadmap artifact. Drucker's theory perfectly depicts the iterative and metamorphic approach successful leaders take in transforming their businesses (Drucker, 1994).

The contents of this chapter serve as the conceptual and theoretical building blocks for the design of the proposed Dx framework in Chapter 3. The proposed framework's core is based on ISPE Pharma 4.0 principles and concepts. Similarly, Bumann and Peter's (2019) six dimensions of Dx account for the primary activities for Dx success. Finally, Drucker's (1994) theory of business offers the last component for putting a guideline and process in place for the continual self-assessment of a business and the business environment over the life course of a company. The remaining aspects are the outcomes of a successful Dx program, such as plant digital maturity and manufacturing capabilities.

Chapter 3 presents the overall research methodology, utilizing Männistö's (2020) generalized DSR methodology and Peffers et al.'s (2007) DSRM process model combined with Kumar's (2012) seven modes of the design innovation process. The chapter also outlines the DSR guidelines, applies the supporting research reviewed in Chapter 2, defines the artifact according to contemporary theory, and discusses the design evaluation process and tools used during each phase.

Chapter 3: Research Methodology

Designing and building an innovative Dx framework dedicated to supporting IT leaders and practitioners in the biopharma industry is rooted in design research that systematically addresses business-related problems, solves design issues, and offers overall utility. The methodology used to achieve success in this space combines four leading design methods, design science kernel theories, and concepts as the foundation for both the approach and method. Therefore, this study's generalized DRS approach follows a solution-oriented path described in Figure 10 (Männistö, 2020).

Figure 7: Männistö, 2020 – Generalized Design Science Research Approach

This generalized approach has several components supported by leading DSR theories. DSR is defined by Hevner et al. (2004: 75) as a design-science paradigm that "seeks to extend the boundaries of human and organizational capabilities by creating new and innovative artifacts." The components are defined as follows:

- **Rationale**: The reason or objective behind the proposed research project.
- **Artifact**: "Design-science research must produce a viable artifact in the form of a construct, a model, a method, or an instantiation" (Hevner et al., 2004: 83).
- **Evaluation (utility)**: Stakeholders' value or satisfaction with achieving the desired goal (Hevner et al., 2004).
- **Prescription**: "A special case of prediction exists where the theory provides a description of the method or structure or both for the construction of an artifact (akin to a recipe)" (Gregor, 2006: 619).

3.1 Tools, Techniques, and Procedures

The DSR model (Figure 10) provides the generalized context to Hevner et al.'s (2004) design science research guidelines. Therefore, this study proceeds based on principles from DSR theories presented by Peffers et al. (2007). Kumar's (2012) seven modes approach to design innovation and Gregor's (2006) eight components of information systems design theory will address the key research problem. These theories, concepts, and principles of design science research are presented, and the fundamental approach is defined in Table 2.

Table 2: The Research Method Based on Hevner et al.'s (2004) DSR Guidelines

Hevner et al.'s Guideline	Description	Selected Method & Description
Guideline 1: Design as an Artifact	Design-science research must produce a viable artifact in the form of a construct, a model, a method, or an instantiation.	➔**Model & Method**: The objective is to develop a digital transformation framework that provides a model and methods to IT leaders and practitioners within the biopharma industry.
Guideline 2: Problem Relevance	Design-science research aims to develop technology-based solutions to important and relevant business problems.	➔**Relevance**: Digital transformation through adopting Pharma 4.0 technology is the highest priority in the biopharma industry (Ford, 2020).
Guideline 3: Design Evaluation	The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via well-executed evaluation methods.	➔**Experimental**: Using an online survey to evaluate the utility of the constructed artifacts based on the analysis of the recent Dx theories. ➔**Controlled Experiment:** Study the artifact in a controlled environment for usability (Hevner et al., 2004).
Guideline 4: Research Contributions	Effective design-science research must provide clear and verifiable contributions in the dressing artifact, design foundation, and design methodologies.	➔**Objective 1:** DSR Theory Type: "I Analysis - Says what is. The theory does not extend beyond analysis and description. No causal relationships among phenomena are specified and no predictions are made." (Gregor, 2006).
Guideline 5: Research Rigor	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact.	➔**Peffers et al.'s (2007) DSRM Process Model**: As a DSR method to construct and evaluate the design artifact. ➔**Seven Modes of the Design Innovation Process**: Utilize design innovation process Modes 1–7 to support Peffers et al.'s DSRM Process Model (Kumar, 2012).
Guideline 6: Design as a Search Process	The search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.	➔**Seven Modes of the Design Innovation Process**: The study will use Kumar's (2012) Mode **1: Sense Intent** to design the search process.
Guideline 7: Communication of Research	Design-science research must be presented effectively to both technology-oriented as well as management-oriented audiences.	➔**Functional Framework**: The subsequent artifact will provide an activity-centered model and a method for IT leaders and practitioners within a biopharma manufacturing environment (Hevner et al., 2004).

Source: Hevner et al., 2004

Following a DSR approach is the most effective way to achieve this study's goal of providing a functional set of tools within an integrated framework. DSR methodology supports

this effort as it performs four key functions: (1) it insists on relevance; (2) it provides methods to demonstrate rigor; (3) it defines the key aspects of what constitutes a research contribution; and (4) it provides evaluation methods to demonstrate an artifact's utility (Hevner et al., 2004). Following Hevner et al.'s DSR guidelines, the design evaluation method, Gregor's (2006) information systems theory types, and DSR contribution types can help a study meet or exceed standards of repeatable and plausible research that contribute to a broader information system knowledge base (Gregor, 2006).

3.2 Design Science Research Methodology

Therefore, a DSR approach is suitable for designing, constructing, and evaluating an artifact for its intended use in a business environment. The approach aims to demonstrate usefulness by solving specific business-related problems. As previously stated, Hevner et al.'s guideline 5, research rigor, suggests applying Peffers et al.'s (2007) DSRM process model as a DSR method to construct and evaluate the design artifact (Figure 11). This six-step DSRM process model includes (a) non-linear possible research entry points, (b) an interactive approach to developing the artifact, (c) supports previous theories, and (d) alignment with Männistö's (2020) DSR approach and Hevner et al.'s (2004) DSR guidelines (Peffers et al., 2007).

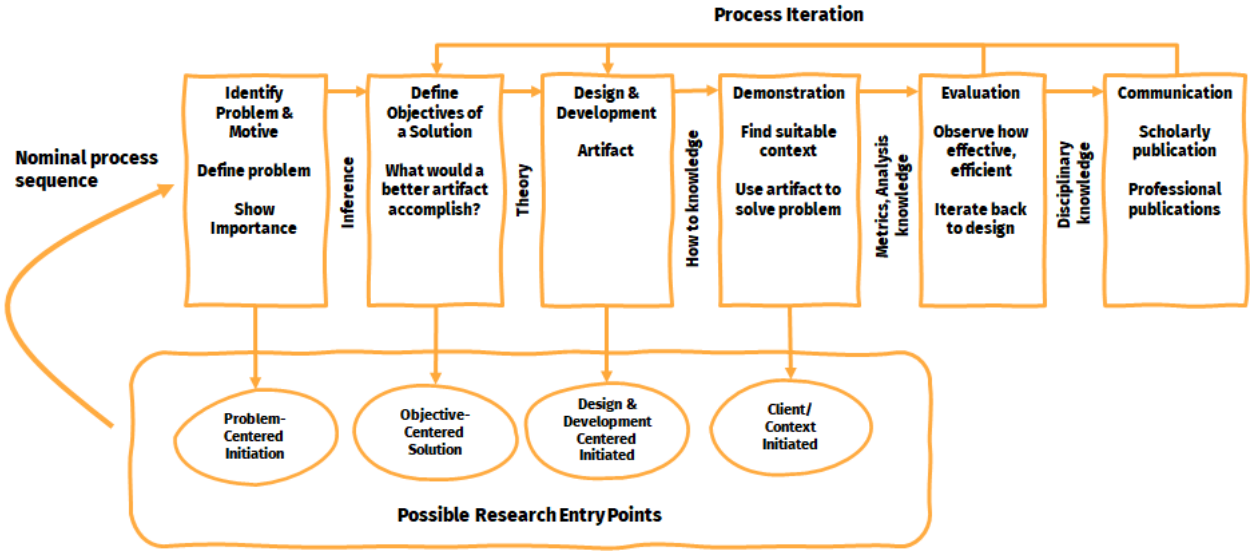


Figure 8: Peffers et al., 2007 – DSRM Process Model

The study takes an activity-centered design innovation perspective by leveraging Kumar's (2012) seven modes of the design innovation process concerning research rigor. The final DSR approach merges Kumar's design innovation process, modes 1–7, with Peffers et al.'s (2007) DSRM process model to create a methodology that simultaneously considers design innovation and the DSR process. The novelty of the merger allows for more details and specific references to design innovation while following the DSR methodology. While Peffers et al.'s (2007) approach is quite useful, Kumar's (2012) design innovation process adds more levels of flexibility and greater detail to each DSR phase dedicated to innovation.

Although there are several DSR methods to select, the Peffers et al. (2007) model aligns well with Kumar's (2012) seven modes of the design innovation process. The result is that each innovation mode (1–7) is placed into the Peffers et al. process model, adding instructional depth to the DSR guidelines defined in that model. Hevner et al. (2004: 83) guideline 6 suggests that "the search for an effective artifact requires utilizing available means to reach desired ends while

satisfying laws in the problem environment" when addressing design as a search process. As a result, the current study uses Kumar's seven modes of the design innovation process (Figure 12). The entire process begins once both methodologies are merged into one process model.

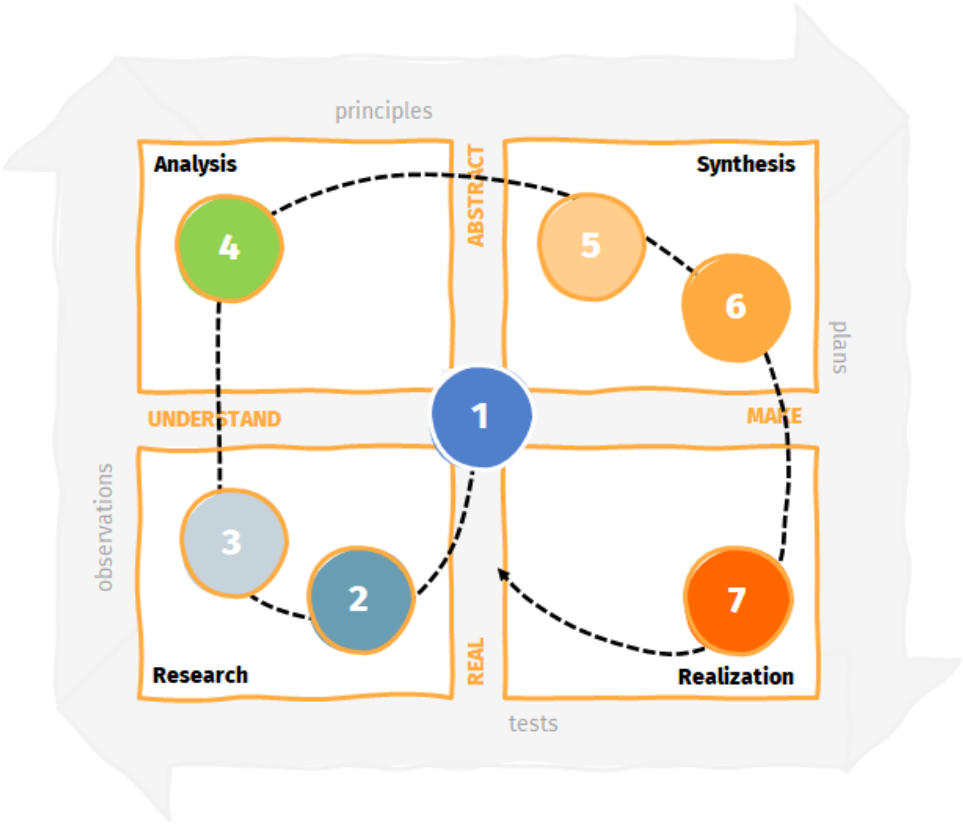


Figure 9: Kumar, 2012 – Seven Modes of the Design Innovation Process

Mode 1, sense intent, focuses on figuring out where to start. Innovation is the goal, but changes across other dimensions must be considered. Mode 2, knowing the context, involves understanding the circumstances or events that affect the environment in which the innovation offerings (products, services, experiences, brands, etc.) exist or will exist. Mode 3, know people, furthers the investigation by strengthening the understanding of end-users and other stakeholders involved. Mode 4, frame insights, adds structure to what has been found in the previous three research modes. Mode 5 explores concepts and generates ideas using insights and principles

framed in the earlier modes. Mode 6, frame solutions, combines concepts resulting from the previous mode to form systems of concepts or solutions. Mode 7, realize offerings, involves testing, evaluating, and implementing prototypes (Bingham, 2017).

A key aspect of Kumar's (2012) model is that it takes a design innovation perspective that can be interactive or non-linear. In addition to the model's completeness and flexibility, Kumar's modes are innovative in creating a DSR artifact when aligned with Peffer et al.'s (2007) DSRM process model.

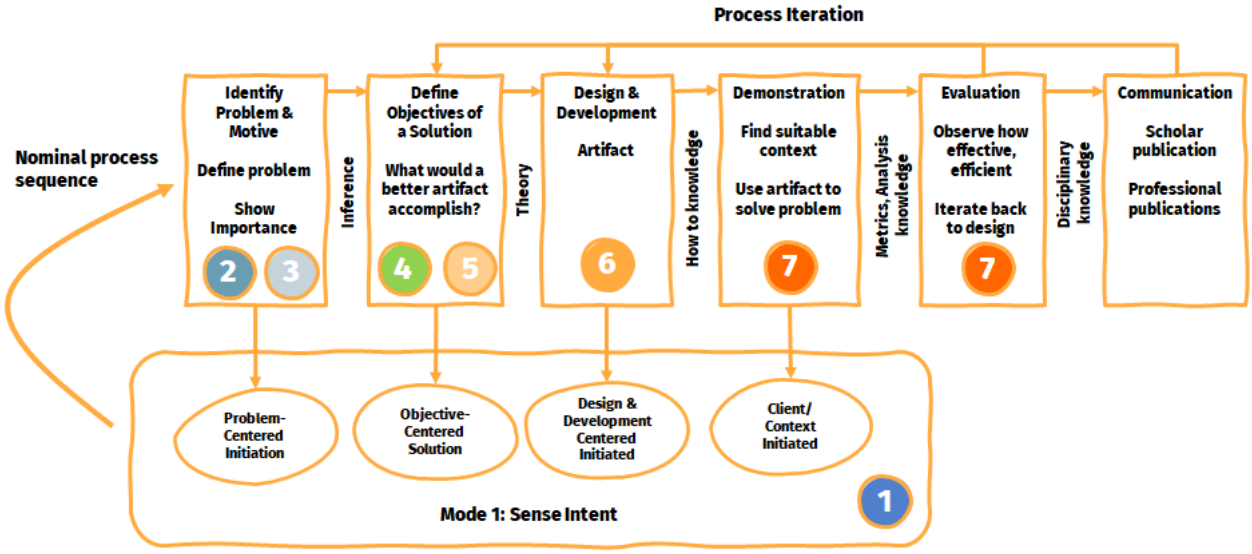


Figure 10: Modified DSRM Process Model

Figure 13 shows how Kumar's modes are aligned with Peffers et al.'s DSRM process model. The fundamental idea is to conduct a DSR project based on an established model while following effective design innovation guidelines with principles that yield meaningful artifacts.

3.3 Supporting Research and Theories

Bumann and Peter's (2019) consolidated dimensions and the work of Morakanyane et al. (2020) and Gurbaxani and Dunkle (2019) underpin the framework of this study and serve as the foundation for the key dimensions for the evaluation of Dx success. Other manufacturing concepts, principles, and theories also support the construction of the artifacts in this study. Multiple Dx dimensions are examined in the framework overview, and the framework supports various dimensions of the plant information model and strategy. This study uses the results of three recent Dx studies as input for data collection, classification, and cross-referencing, listed in Table 3.

Table 3: Supporting Research and Theories

Studies	Details of Study	Resulting Dimensions
Bumann & Peter, 2019	"In a comparative analysis of over one hundred described dimensions, the most often cited dimensions were identified, namely strategy, the organization, corporate culture, technology, the customer and people (employees). The six identified dimensions/action fields provide an important framework for businesses to succeed in digital transformations" (Bumann & Peter 2019: 13).	• **Strategy** • **Organization** • **Culture** • **Technology** • **Customer** • **People**
Gurbaxani & Dunkle, 2019	"The benchmarks were created through a survey of senior executives at 129 U.S. public companies and 18 large private companies over the three-month period December 2016 to February 2017" (Gurbaxani & Dunkle, 2019: 211). • "To identify the items in each of the six categories, we first drew up a list of potential characteristics for each dimension and generated a potential survey question. • We then drafted the entire survey and met with more than a dozen business and IT executives to obtain their feedback. • Through an iterative process, resulting in the addition and deletion of many questions, we arrived at the final version of the survey" (Gurbaxani & Dunkle, 2019: 212).	• **Strategy Vision** • **Culture of Innovation** • **Know-How and Intellectual Property** • Digital Capabilities • Strategic Alignment • **Technology Assets**
Morakanyane et al., 2020	"From a total of 89 articles, 16 single-case articles which sufficiently documented end-to-end DX success stories of 10 exemplar organizations were selected. Within case content analysis and asking the questions analytical procedure were employed to code each exemplar case, where a total of 174 attributes were found. Making the comparisons procedure was employed to build thematic higher-level categories by grouping similar attributes. Cross case content analysis was employed to determine presence strength of attributes in the category groupings. A list of 7 success factors and 23 subfactors emerged from the thematic groupings. These success factors constitute the initial steps towards building a DX framework which organizations seeking to embark on successful digital transformation journeys can adopt." (Morakanyane et al. 2020: 4356).	• Determine Digital Trigger • **Cultivate Digital Culture** • **Develop Digital Vision** • Determine Digital Drivers • **Establish Digital Organization** • Determine Transformed Areas • Determine Impacts

Note: The bold dimensions were used as the foundation of the DRS analysis in developing the proposed Dx framework.

Moreover, Bumann and Peter (2018) conducted a comparative analysis of the 18 most widely used Dx frameworks and maturity models to consolidate their dimensions, Gurbaxani and Dunkle (2019: 211) conducted an online "survey of senior executives at 129 U.S. public companies and 18 large private companies over the three-month period December 2016 to February 2017", and Morakanyane et al. (2020) used 89 published articles including 16 case articles documenting Dx success for ten exemplary companies. Although Bumann and Peter's (2018) model had some deficiencies, it is the foundation for the proposed framework.

Research by Morakanyane et al. (2020) and Gurbaxani and Dunkle (2019) demonstrates a level of empirical rigor that serves to support Bumann and Peter's (2018) findings. Morakanyane et al. (2020) focused on the Dx success factors of companies, while Gurbaxani and Dunkle (2019: 219) concentrate on creating a framework for business leaders to evaluate their "company's progress based on six dimensions critical to successful digital transformation." They conclude that culture, technology, strategy, organization, customers, and employees are reliable key dimensions for any Dx framework. Their method for evaluating success is also a major tool used in the framework proposed in this study. Based on this, Bumann and Peter's (2018) model was chosen as the basis for designing and constructing the conceptual overview artifact since Gurbaxani and Dunkle (2019) and Morakanyane et al. (2020) support Bumann and Peter (2018).

3.4 Design Evaluation & Tools

This study takes a DSR approach by following Peffers et al.'s (2007) DSRM process model in conjunction with Kumar's (2012) seven modes of the design innovation process. Hevner et al.'s

(2004) DSR guidelines provide five options to evaluate any DSR artifact. The study used specific tools, as described in Table 4.

Table 4: Research Tools

Tools	Description and Use
High-end micro-computer, high-speed Internet	Workstation to conduct and develop the study.
Amazon Mechanical Turk	Pre-experiment: This crowdsourcing solution allows businesses to hire remote workers to complete tasks that computers cannot perform. The study hired 50 remote MTurk workers with manufacturing experience from around the world to complete the pre-experiment online survey.
Qualtrics	An online survey tool allowed the study to build surveys, distribute surveys and analyze responses.
Centiment	Experiment: Centiment is an all-in-one research platform enterprise used by academics to build advanced surveys and reach targeted audiences. This study used Centiment to recruit survey participants from the biopharma and pharmaceutical industries.
MS PowerPoint, Excel, Access, Notepad	Desktop presentation, spreadsheet, and database applications were used to review, organize and convert the survey data from Qualtrics and import it into SmartPLS.

The resulting artifact is an analysis using Dx-supporting research that will leverage the proposed artifact as a baseline to develop a Dx adoption model. However, the study will only expand beyond further analysis and theoretical description. In addition, the proposed artifact will not denote or express any causal relationships concerning adoption predictions. (Gregor, 2006). Moreover, the study will assess the submitted artifacts based on the design theory through controlled experiments conducted across two phases. Within the second phase, the study will evaluate the conceptual overview and the strategic roadmap artifacts, as shown in Tables 5 and 6. The strategic roadmap supports the other half of Tiersky's (2017) argument concerning transformational vision using a sequential process with drill-down capabilities to describe how

biopharma organizations can meet the changes impacting their business. This tool offers IT leaders tasks tied to objectives that execute iterative transformation strategies.

3.4.1 Phase 1: Pre-Experiment Testing

In Phase 1, a pre-test was conducted using the Amazon Mechanical Turk platform as an online survey to evaluate the effectiveness of specific survey questions, the type of evaluation scales, and the quality of responses to establish that the most appropriate methods were being used to ensure the quality of the collected data. The results demonstrated that 1) the Amazon Mechanical Turk platform was not an acceptable tool, 2) the sample population was too generalized, and 3) the responses had varying levels of quality. The output of this phase was then the input to the second phase. Complete details are listed in Appendix A.

3.4.2 Phase 2: Experiment – Hallmark Functional and Structural Elements

This phase evaluated elements of the best Dx frameworks. Tables 5 and 6 list indicators and their descriptions.

Table 5: Hallmark Functional Elements (HFE)

Indicator	Evaluation	Description and Use
HFE1	With this framework, I can see the big picture and the digital transformation ideals (Coundouris, 2020).	One of the most important aspects of any digital transformation framework is conveying the overall vision to provide an ideal for senior leaders.
HFE2	With this framework, I can see different layers that drill-down to a set of tasks and sequences (Coundouris, 2020).	Gives practitioners the ability to construct leveled relationships between tasks and sequences.
HFE3	This concept offers the flexibility to transform front and back office functions (Coundouris, 2020).	The key to transformation is flexibility within a framework to change both front and back-office business processes.
HFE4	I can customize this concept to suit different biopharma manufacturing circumstances (Coundouris, 2020).	Any digital transformation framework must suit the practitioner's needs and business model.

Source: Coundouris, 2020

Table 6: Hallmark Structural Elements (HSE)

Indicator	Evaluation	Description and Use
HSE1	This framework is customer- or patient-centric (Coundouris, 2020).	The primary reason any digital transformation effort occurs is to increase business agility to meet the customer's (i.e., patient's) needs.
HSE2	This framework demonstrates the potential opportunities and constraints within a biopharma manufacturing environment (Coundouris, 2020).	These define areas of improvement and challenges associated with change.
HSE3	This framework emphasizes company culture (Coundouris, 2020).	Transforming any business relates to a cultural transformation, which lies at the heart of change.
HSE4	The framework is simple to apply (Coundouris, 2020).	The digital transformation framework must be easy to understand and apply.

Source: Coundouris, 2020.

3.4.3 Phase 3: Experiment Evaluation

The third part considers elements and relationships within the technology acceptance model (TAM2) developed by Venkatesh and Davis (2000) to evaluate the utility of the proposed artifacts. The study primarily focuses on surveying respondents' perceived ease of use (EU), perceived usefulness (PU), behavioral intention (BU), intention to use (IU), subjective norms (SN), image (IM), job relevance (JR), output quality (OQ), and results demonstrability (RD) for each artifact (Venkatesh & Davis, 2000). Even though behavioral intention is a better predictor of actual use than perceived ease of use and perceived usefulness, this study uses perceived usefulness and intention to use as the only determinants for evaluating the overall utility of the proposed artifacts for a few reasons.

First, one of the main objectives of any DSR study is to evaluate the artifacts' utility. Of course, perceived usefulness does not equate to utility or satisfaction. According to Davis, perceived usefulness addresses "the degree to which a person believes that using a particular system would enhance his/her job performance" (Davis, 1989). Although Davis is assessing the

perceived usefulness of software within his Technology Acceptance Model, as long as Ajzen's theory of planned behavior holds, the decision-making process will be the same for the proposed artifact. Second, the perceived usefulness indicator will also support the third objective of the studying in developing a Dx Adoption Model. Therefore, the study must consider the respondents' wants (utility) and needs (usefulness). Even though determining utility is the primary goal, perceived usefulness and intention to use are required to ensure the artifact is useful and demonstrates utility to the respondents to complete the current and future research objectives. Tables 7 and 8 describe each indicator.

Table 7: Perceived Usefulness (PU)

Indicators	Description and Use
PU1	Using the framework would help my academic writing or my organization to reach our research or digital transformation goals more quickly.
PU2	Using this framework would improve the relevance of my research or the performance of my organization's digital transformation execution.
PU3	Using this framework would be useful in not overlooking critical steps within the organization's digital transformation or Pharma 4.0 process.
PU4	Using this framework would enhance my research or my organization's effectiveness throughout our digital transformation process.
PU5	Using this framework would make it easier for people executing digital transformation programs and projects to succeed within their roles.
PU6	I would find this framework useful in communicating a digital transformation or Pharma 4.0 business strategy.

Table 8: Intention to Use (IU)

Indicator	Description and Use
IU1	I intend to use this digital transformation framework.
IU2	I would use this digital transformation framework.
IU3	I plan to use this digital transformation framework.

3.5 Chapter Summary

Chapter 3 detailed the overall research methodology using Männistö's (2020) generalized DSR approach. From a high-level perspective, Männistö's method leads to a theory or a prescription. However, Hevner et al.'s (2004) DSR guidelines provide the structural details and checkpoints by which to execute the study. The study used Peffers et al.'s (2007) DSRM process model for scaffolding the DRS's process modeling while integrating Kumar's (2012) seven modes of the design innovation process as a means to develop the proposed artifacts. Although Peffers et al.'s DSRM process model is well established within the broader information system community, Kumar's design innovation process offers a more creative direction for innovation. Furthermore, the supporting research discussed in Chapter 2 was refined to three studies—Bumann and Peter (2018), Gurbaxani and Dunkle (2019), and Morakanyane et al. (2020) —as inputs to the design of the proposed artifacts.

Finally, the design evaluation process discussion included brief accounts of the pretest, a description of the sample population, a complete list of tools used during each experiment phase, and clear definitions of each indicator associated with hallmark functional elements (HFE), hallmark structural elements (HSE), perceived usefulness (PU) and intention to use (IU). The goal is to determine whether or not respondents frequently "agree" that the proposed artifacts demonstrate hallmark Dx characteristics, are useful, and are tools that would intend to use. This phase of the stud is extremely important since a successful evaluation will result in respondents affirming the proposed utility and intention to use.

Chapter 4 introduces and discusses the proposed artifact designed in Chapter 3 using Männistö's (2020) generalized method, Hevner et al.'s (2004) DSR guidelines, and Peffers et al.'s (2007) modified DSR process model. The chapter provides visualizations and step-by-step descriptions of each artifact presented to the sample population during the evaluation process.

Chapter 4: Design and Development

The stated DSR guidelines and the DRSM process model, in conjunction with Kumar's (2012) design innovation process modes 1–7, led to the following preliminary results after the first iteration of the Dx framework overview diagram.

4.1 Introduction of a Dx Framework for Biopharma Manufacturing

Building the proposed Dx framework artifacts involved incorporating supply chain management theories, leading manufacturing principles, manufacturing IT standards, leading MOMS and MES systems architecture, and Pharma 4.0 concepts and principles, as shown in Table 1 on page 22. This study presents the Conceptual Overview and the Strategic Roadmap, which accounts for two of the nine tools that comprise the completed Dx framework (Figure 14).

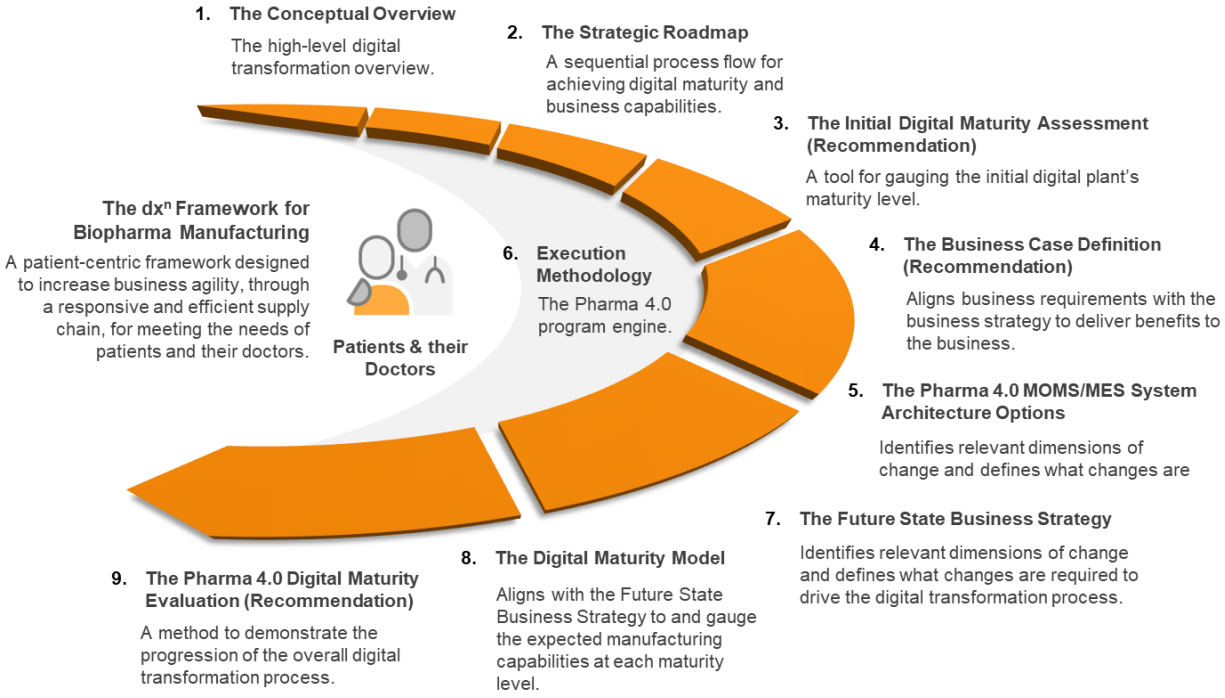


Figure 11: The Proposed Dx Framework for Biopharma Manufacturing

The framework consists of the following tools: (1) conceptual overview, (2) strategic roadmap, (3) initial digital maturity assessment, (4) digital transformation business case definition, (5) Pharma 4.0 MOMS/MES system architecture options, (6) execution methodology, (7) future state business strategy, (8) digital maturity model, and (9) Pharma 4.0 digital maturity evaluation tool. The framework will provide IT leaders and practitioners with tools to support their Dx efforts from initial assessment and conceptualization to program execution and tracking digital maturity achievements.

4.2 The Conceptual Overview

The conceptual overview and the strategic roadmap are the most important aspects of the framework and the primary focus of this study. Each artifact provides a high-level conceptual explanation of the model, with Pharma 4.0 principles as its foundation, overlaid by four of the six dimensions of Bumann and Peter's (2018) Dx dimensions (see Figure 16). The ANSI /ISA 95 manufacturing standards structure is inherent within the model. Level 0 is shop floor equipment communicating through an Industry Internet of Things (IIoT) platform, and Level 4 represents the Internet of Things (IoT) communicating in a cloud-based digital ecosystem (He et al., 2021).

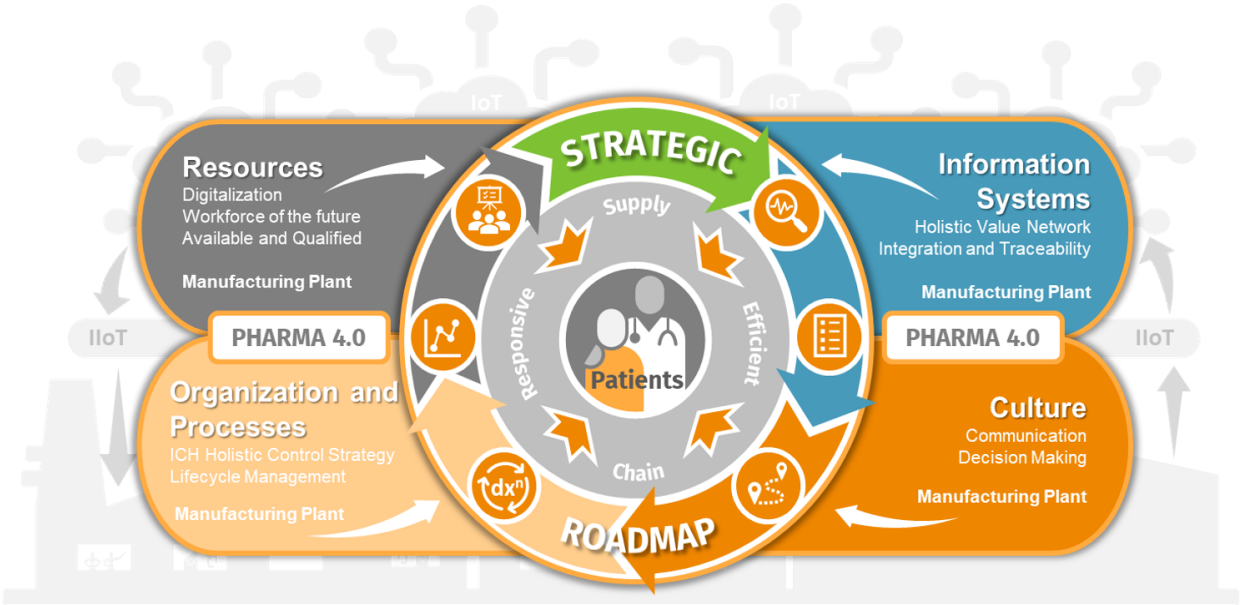


Figure 12: The Proposed Dx Conceptual Overview

Bumann and Peter's (2018) strategy dimension is the strategic roadmap of this study, as defined by Gurbaxani and Dunkle (2019) and Morakanyane et al. (2020). Finally, Bumann and Peter's customer dimension was translated into a patient dimension, which lies at the model's heart and assumes an efficient and responsive supply chain (Hugos, 2018).

- **Patients**: This framework is patient-focused and aimed at providing a responsive and efficient supply chain required to meet the needs of patients in a changing business environment. The purpose is to increase business agility.

- **Responsive and efficient supply chain**: All other dimensions should be directed toward building a manufacturing plant that operates with a responsive and efficient supply chain, and that has the personnel, technology, organization, and culture to support patient needs.

- **Strategic roadmap**: Bumann and Peter (2018) argue that strategy is equal to the other five dimensions. Evidence shows that strategy, or what is called here the "strategic roadmap," is a key driver that supersedes the different dimensions. The process through which the biopharma business checks its strategies is based on Drucker's (1994a, 1994b) theory of the business.

- **People, technology, culture, and organization**: All aspects of the transformation related to people, technology, culture, and organization are supported by the strategic roadmap.

- **Pharma 4.0**: Bumann and Peter's (2018) six dimensions represent lower-level connections to the corresponding Pharma 4.0 framework dimension resources, information systems, culture, and organization and processes.

4.3 The Strategic Roadmap

The strategic roadmap (Figure 16) represents a step-by-step process based on Drucker's (1994a, 1994b) theory of business that links the framework's tools to key steps in the entire transformation process. The stud will be discussed in greater detail in Chapter 5.

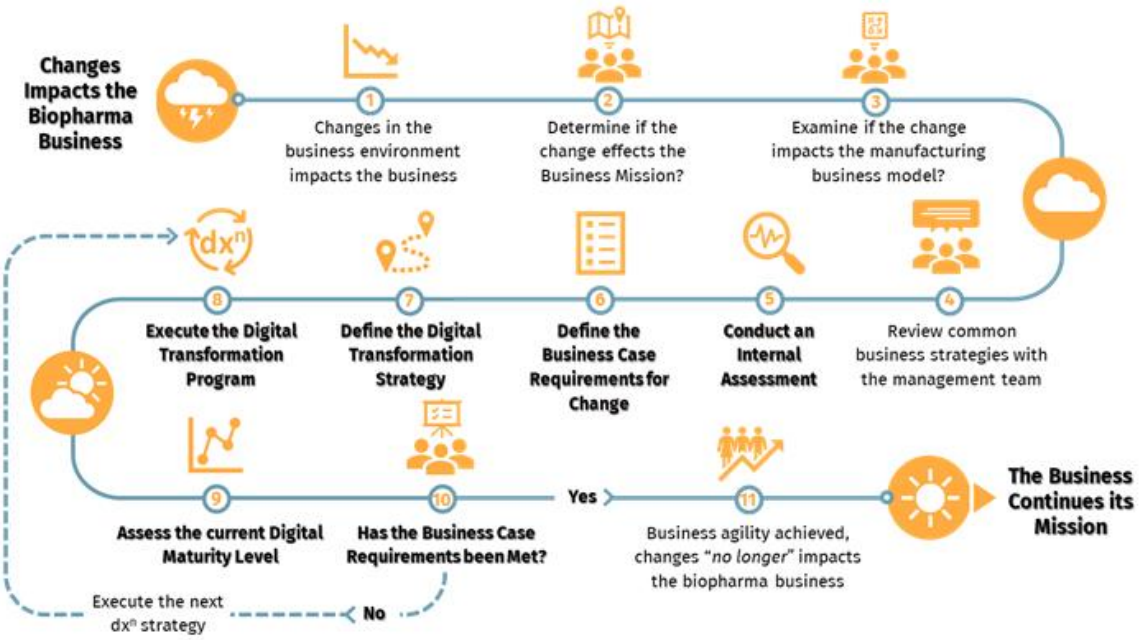


Figure 13: The Proposed Dx Strategic Roadmap

- **Step 1**: Something within the biopharma business environment has changed or will change, which impacts or will impact the continuity of the business (e.g., pharma's competitive positioning and pricing power are challenged by new, fast-moving market entrants and the expectations of empowered consumers) (Ernst & Young, 2017).
- **Step 2**: Leadership in the biopharma company meet to discuss how the change affects the manufacturing business model at the corporate level.
- **Step 3**: The management team meets with manufacturing leadership to determine how this change affects the business mission at the manufacturing plant level.
- **Step 4**: Given the magnitude, the area of impact, and the timeframe of the change, the management team reviews common business strategies for addressing the change.
- **Step 5**: In this scenario, the impact on the business is related to the digital maturity of the corporation, specifically the manufacturing facility. As a result, the company should

partner with external industry experts to conduct an internal assessment to gauge the facility's current digital maturity and how advanced this maturity should be in the future.

- **Step 7**: A decision is made to build a specific Dx strategy and an IT roadmap to guide the organization through its transformation efforts. The business will undoubtedly bring in consultants and advisors to suggest means and methods, including frameworks that define an approach and dimension of focus to support a series of portfolios, programs, and projects that will move the company forward.
- **Step 8**: The company executes a multi-phase Dx strategy to achieve digital maturity for the manufacturing plant, as defined by the Pharma 4.0 framework.
- **Step 9**: The first phase of the Dx strategy is checked against the business cases to determine whether the high-level requirements were achieved.
- **Step 10**: The company reviews and evaluates Pharma 4.0 and the success criteria and continues its Dx until its desired business agility is achieved.
- **Step 11**: Once the desired level of business agility is achieved and the changes in the business environment no longer impact the biopharma company, the business proceeds on its mission. However, it must continue to scan its environment and test its business theory.

4.4 Chapter Summary

Chapter 4 introduced the proposed Dx Framework for biopharma manufacturing composed of nine tools; however, the study only evaluated two. The proposed conceptual overview diagram provides a high-level view of the complete Dx process, which details the digital ecosystems of the manufacturing plant and value chain. This artifact exhibits all the hallmark characteristics of an exemplary Dx framework by incorporating patients, a responsive and efficient supply chain,

embedded strategic roadmap elements, and the Pharma 4.0 dimensions of change, including people, technology, culture, and organization. As the conceptual overview diagram, this artifact uses its embedded strategic roadmap elements to connect to the proposed strategic roadmap. This artifact focuses on guiding IT leaders and practitioners through the eleven-step iterative Dx process. Drucker's (1994a, 1994b) theory of business is the driving force behind the process. When used together, IT leaders can develop and communicate their Dx strategies.

Chapter 5 discusses the data analysis and results. The chapter begins by focusing on the demographics of the sample population to confirm that the most appropriate participants were targeted and selected. There is further discussion of the four variables: HFE, HSE, perceived usefulness (PU), and intention to use (IU). Since a seven-point Likert scale was used during the evaluation process, the analysis will use the mode or (the most frequent response) to determine the results.

Chapter 5: Results and Data Analysis

An online Qualtrics survey, conducted from October 19 to November 1, 2021, collected feedback from 210 executives and managers working in the biotech and pharmaceutical industries, including industry consultants and academic professionals. Respondents assessed the conceptual overview and the strategic roadmap artifacts and answered questions based on a seven-point Likert scale ranging from “Strongly agree” to “Strongly disagree.” The survey applied elements from the technology adoption model 2 (TAM2) and Coundouris’ (2020) hallmarks of a top Dx framework, presenting questions covering different areas.

5.1 Sample Population and Demographics

Two questions supported Coundouris' (2020) structural recommendations and functional Dx hallmarks. The first gauged the quality of the response by testing respondents' attention and disqualifying those respondents who did not answer the question correctly. The second supported demographics, active projects, and specific segments of the TAM2 model by exploring the social influence and cognitive instrumental components to capture perceived usefulness and intention to use precisely. The results reveal very positive responses. Table 9 displays the relevant sample population, with 57.62% of all respondents currently involved in research or Dx or in implementing Pharma 4.0 programs and projects.

Table 9 Respondents’ Current Digital Transformation Activity

Involved in Digital Transformation Efforts	Frequency	Percent
Yes	121	57.62
No	89	42.38
Total	**210**	**100.0**

Managers and above in non-IT roles accounted for 35.25% of the total sample population, executives accounted for 30.48%, managers or IT leaders for 19.05%, academics for 8.10%, and consultants for 7.14% (see Table 10). These results demonstrate that the study successfully targeted the correct sample population based on relevance, respondents' job functions, and industries.

Table 10: Respondent's Demographics

Respondents Categories	Frequency	Percent
Executives	64	30.48
Managers and above in non-IT roles	74	35.24
Managers or IT leaders	40	19.05
Academics	17	8.10
Consultants	15	7.14
Total	**210**	**100.0**

5.2 Results and Analysis

The study collected data on eleven constructs and forty-two indicators; however, the results and analysis in this section will only focus on four constructs: perceived usefulness, intention to use, HFE, and hallmark structural elements. A complete review of the survey and results for the remaining constructs and their indicators can be found in **Appendix C**.

With this in mind, Tables 7 and 8 list respondents' feedback regarding Coundouris' (2020) functional and structural hallmarks of top Dx frameworks. The analysis demonstrates that the most frequent response (i.e., the mode) was "agree" for each hallmark element. Both artifacts were valued more strongly on the functional side, even though opportunities for structural improvements were noted, including the need for clarity on how the framework is patient-centric, easy to apply, and that it depicts culture as the primary agent of change.

Table 11: Survey Results for HFE (n =210)

Indicator	Description	Strongly Agree	Agree	Somewhat Agree	Neither agree nor disagree	Somewhat Disagree	Disagree	Strongly disagree
HFE1	Vision of the big picture, ideal for executives	32.38%	**46.67%**	11.43%	5.71%	2.86%	0.95%	0.00%
HFE2	Drill-down to a set of tasks and sequences	34.76%	**40.00%**	15.71%	7.14%	1.90%	0.48%	0.00%
HFE3	Flexibility to transform front and back office	24.76%	**36.62%**	26.76%	9.52%	0.95%	0.00%	0.48%
HFE4	Customize to suit circumstances	29.05%	**40.00%**	17.14%	10.48%	2.86%	0.00%	0.48%

Note: The values in red list the value of the mode percentage for the most selected responses.

Table 12: Survey Results for HSE (n =210)

Indicator	Description	Strongly Agree	Agree	Somewhat Agree	Neither agree nor disagree	Somewhat Disagree	Disagree	Strongly disagree
HSE1	Patient-centric	27.62%	**33.81%**	21.43%	9.05%	6.19%	1.43%	0.48%
HSE2	Opportunities and constraints	19.52%	**45.71%**	25.24%	5.71%	2.86%	0.48%	0.48%
HSE3	Emphasizes culture	19.07%	**34.76%**	20.00%	12.86%	7.62%	2.38%	0.95%
HSE4	Easy to apply	22.86%	**27.14%**	21.90%	16.75%	6.67%	3.33%	1.43%

Note: The values in red list the value of the mode percentage for the most selected responses.

Each artifact scored highest in demonstrating a vision of the big picture, their suitability for executives, and their ability to depict opportunities and constraints.

Moreover, it is one thing to demonstrate the hallmarks of a leading Dx framework; providing evidence that its utility leads to intention to use is quite another. In this regard, aspects of the TAM2 model concerning social influence and cognitive instrumental components were examined to gain insight into the perceived usefulness (PU) and Intention to Use (IU) of the

conceptual overview and the strategic roadmap artifacts. Tables 13 and 14 summarize respondents' feedback.

Table 13: Survey Results for Perceived Usefulness (PU) Variables (n =210)

Indicator	Perceived Usefulness	Strongly Agree	Agree	Somewhat Agree	Neither agree nor disagree	Somewhat Disagree	Disagree	Strongly disagree
PU1	Would help reach goals...	22.86%	**32.86%**	18.10%	14.76%	7.14%	3.33%	0.95%
PU2	Would improve...	23.81%	**30.00%**	21.43%	17.62%	4.76%	1.90%	0.48%
PU3	Useful in not overlooking critical…	26.67%	**36.19%**	18.57%	14.29%	3.33%	0.95%	0.00%
PU4	Would enhance...	21.90%	**39.05%**	18.10%	15.71%	3.81%	1.43%	0.00%
PU5	Make it easier for people...	22.38%	**37.62%**	20.00%	16.19%	1.90%	1.90%	0.00%
PU6	Useful in communicating...	25.24%	**38.10%**	18.10%	12.86%	2.86%	2.38%	0.48%

Note: The values in red list the value of the mode percentage for the most selected responses.

Table 14: Survey Results for Intention to Use (IU) Variables (n =210)

Indicator	Perceived Usefulness	Strongly Agree	Agree	Somewhat Agree	Neither agree nor disagree	Somewhat Disagree	Disagree	Strongly disagree
IU1	I intend to use...	22.86%	**30.00%**	11.43%	22.86%	4.29%	6.67%	1.90%
IU2	I would use...	26.67%	**30.00%**	20.00%	14.76%	3.33%	4.29%	0.95%
IU3	I plan to use...	23.81%	**28.10%**	10.48%	23.33%	5.71%	7.62%	0.95%

Note: The values in red list the value of the mode percentage for the most selected responses.

The most frequent response is "agree," demonstrating the usefulness of the purpose and function of the conceptual overview and the strategic roadmap. As a result, respondents agreed that each artifact is useful. Notably, more respondents agreed that the tools could enhance their organization's transformation process, communicate, make program execution easier, and not overlook critical steps. Therefore, the study can conclude that the proposed artifacts serve the functions of a Dx framework.

Feedback on intention to use was also conclusive, with some minor reservations, revealing some structural errors in the survey. Questions related to the wording of variables IU1 and IU3 were similar, and both values were nearly identical, causing collinearity issues during the statistical analysis process. Nonetheless, 30% of respondents "agreed" that they intend or plan to use these artifacts. Even though the respondents perceived the artifact as useful, over 20% were somewhat neutral about using the tools.

5.3 Chapter Summary

The results and analysis outlined in Chapter 5 support the study's primary objectives listed in Chapter 1 by demonstrating that the proposed artifacts are useful and that respondents intend to use the framework. Chapter 6 will conclude the study with a summary of the findings, a discussion of the implications for theory and practice, the literature contributions, the limitations of the study, and future research directions.

Chapter 6: Conclusion and Future Work

Worldwide trends at the time of the study show that the life sciences industry is undergoing major evolutionary change (Ford, 2020). Much progress has resulted from technological advancements and medical breakthroughs with genetic tools such as CRISPR/Cas9 and TALEN (Nemudryi et al., 2014). Other challenges stem from the entry of Big Tech into the healthcare market through purchases and acquisitions, which has forced life sciences companies to reset their priorities for global market growth, strengthen their R&D, and engage in Dx. The net effect is that many organizations in the biopharma industry have embarked on or will embark on a Dx journey. These organizations must adopt a Dx framework and transition to a paradigm that supports outcome-based health solutions that satisfy empowered patients (Yang, 2020).

Of course, implementing transformation strategies across global organizations is a challenging task. The biggest question hinges on determining the type of Dx framework biopharma manufacturing industries can adopt to implement a Pharma 4.0 operating model effectively. Success in this space will allow biopharma leaders to achieve their organizational priorities and address business challenges. With monumental changes occurring in the biopharma industry, there is a need for a more comprehensive Dx framework designed explicitly for that industry.

With this in mind, this study executed controlled experiments to examine the key characteristics and usefulness of the conceptual overview and the strategic roadmap artifacts based on a DSR analysis. A panel of 210 executives and managers working in the biotech and

pharmaceutical industries, including industry consultants, completed a survey. Nearly 60% of participants were involved in research or Dx efforts to implement Pharma 4.0 projects. Respondents were asked to evaluate the artifacts in two phases using an online survey based on a six-point Likert scale. In the first phase, participants were asked to determine if the artifacts demonstrated functional and structural hallmark characteristics of an ideal Dx framework. In the second phase, they were asked to evaluate the perceived usefulness and the intention to use the artifacts. Based on the results, the relics met the first objective of developing a Dx framework that (1) places patients and their doctors as the primary focus, (2) supports a supply chain that is both responsive and efficient, (3) demonstrates hallmarks attributes of exemplary Dx frameworks, (4) supports the implementation of a Pharma 4.0 program and transformation across key business dimensions, including resources, information systems, culture, and organization and processes, and (5) provides tools, including a step-by-step strategic road map, to guide IT leaders and practitioners through the Dx process.

In addition, the study also achieved its second objective by successfully evaluating the proposed Dx framework and collecting data from a sample population through an online survey. The results successfully supported the usefulness of the artifact and respondents' intentions to use them. Since the results affirmed the usability of the proof of concept, the study can progress with its third objective as future research to develop a PLS-SEM Dx adoption model for biopharma manufacturing.

6.1 Summary of Findings

The underlying findings support three significant points. First, the results agree with Coundouris (2020) regarding the importance of the hallmark elements of leading Dx frameworks. Over half of the respondents were interested in leading Dx frameworks' HSE and the HFE. However, there was a greater preference for HFE, indicating support for job functions and related tasks, including a Dx framework that provides a vision of the big picture, is ideal for executives, can drill down to a set of functions and sequences, is flexible enough to transform the front and back office, and is customizable to suit circumstances within this order.

Conversely, HSE is essential to a Dx framework that can address opportunities and constraints within the respondent's company. Second, more respondents found the proposed framework useful across the four areas of (1) enhancing research or organization effectiveness, (2) communicating business strategies, (3) making it easier for people to succeed within their roles, and (4) not overlooking critical steps within the Dx process. Third, from a general perspective, these four areas may seem obscure; nevertheless, each site details what constructs are important to IT leaders and practitioners and how they plan to use a Dx framework.

6.2 Theoretical Implications

The theoretical implications are potentially substantial. Many respondents working within the biopharma industry found Coundouris' (2020) hallmark elements useful. Therefore, constructs of this nature have theoretical merit when attempting to understand the factors that drive technology adoption or intention to use Dx frameworks within the biopharma industry. The results demonstrate that hallmark elements will undoubtedly be factors linked to perceived usefulness, in

addition to data collected about other constructs such as subjective norms, behavioral intentions, perceived ease of use, image, job relevance, results demonstrability, and output quality. Another issue is determining whether or not any of the TAM and TAM2 constructs are also key factors. However, suppose the theory of planned behavior (TPB) holds (Ajzen, 1991). In that case, IT leaders and practitioners should exhibit the same behavioral intention for selecting tools such as a Dx framework as they would for any other technology, including software. Given the overwhelmingly positive results of the data analysis, building a Dx adoption model for a biopharma manufacturing environment should be possible.

6.3 Practical Implications

The results of the data analysis provide insight into what IT leaders and practitioners want and what factors influence their adoption decisions. IT leaders and practitioners are interested in achieving their transformation goals while facilitating a process that makes it easier for others to succeed. There is a demand for frameworks that are easy to learn, create pathways to enlightenment, and transform based on need while addressing each Dx step. The findings suggest that IT leaders and practitioners place more utility on the functional hallmark elements of an exemplary Dx framework, which is certainly reasonable. Despite this, we must question whether respondents' behavioral intentions are based on sound judgment. For example, a 'want' and a 'need' come from two entirely different perspectives, which any effective Dx framework should functionally and structurally address.

However, best practices from expert opinions regarding successful Dxs emphasize the value of structural elements over those of functional features. Experts agree that IT leaders and

practitioners must know their organizations' challenges and understand the drivers behind Dx to determine where to focus the best company resources, effort, and time (Rogers, 2016). Leading thinkers identify changes in culture as the secret to Dx's success. Therefore, changing an organization's behavior is essential through shifting the way people within the organization think, interact and work with one another on a collaborative basis (Rogers, 2016:1). Rogers goes on to argue that companies must spend time changing employee behaviors company culture, and how decisions are made (Rogers, 2016). In practice, which the data in this study supports, users are more likely to focus on adopting functional tools to help them succeed in their jobs and job-related tasks. Of course, Dx best practices will encourage users to focus first on structural elements, such as culture and identifying opportunities and constraints, rather than job-relevant functional elements.

6.4 Contributions to Literature

This study's research contributions are supported by Hevner et al.'s (2004: 83) Guideline 4, which states that "Effective design-science research must provide clear and verifiable contributions in the area of the dressing artifact, design foundation, and design methodologies." The study verified the contribution of the "dressing artifact" by assessing and providing clear evidence of the proposed artifact's utility by surveying a sample population based on relevant activities, job functions, and industries. In addition, Gregor (2006) takes Hevner et al.'s guidelines further through a nature of theory classification in which she classifies the dressing artifact as DSR theory Type I analysis. "The theory does not extend beyond analysis and description. No causal relationships among phenomena are specified, and no predictions are made." (Gregor, 2006: 620). This definition is precisely what the study's first objective was to accomplish.

6.5 Limitations

Despite its contribution to the literature, this study has several specific and potential limitations. Based on the survey feedback, the proposed artifacts require refinement to demonstrate how the framework is patient-centric, simple in application, and that it depicts culture as the primary agent of change. This requires restructuring the framework where these aspects are clear. Other potential limitations relate to collinearity issues and a lack of moderating variables. For example, the resulting values for indicators IU1 and IU3 for the IU construct are nearly identical. Indicators in these cases may cause collinearity issues during the statistical analysis process. Finally, the Centiment research platform could not provide data to support moderating variables, such as age and gender data; therefore, these variables were not included in the analysis.

6.6 Future Research

Despite these limitations, setting out on a Dx journey requires massive time, money, and effort for any organization. Over 80% of companies that start a Dx process never reach the end of the process (Rogers, 2016). Companies fail to transform their businesses for many reasons, including lack of vision, project failure, and focusing on technological rather than cultural transformation (Andriole, 2021). There are many tools, techniques, and methods leading to success. Among the most vital decisions leading to transformation success is determining where to start, what to focus on from the beginning, and what the journey's outcome should look like. However, the findings of this study demonstrate that IT leaders and partitioners want an effective Dx framework that supports their job functions and tasks. Of course, experts have different opinions, and problems remain, despite what users wish and what experts deem they need. Still,

determining which framework to select and which can best support a biopharma manufacturing environment is essential.

Using SmartPLS 4, future research will combine a partial least squares structural equation model (PLS-SEM) (Venkatesh et al., 2003) with the hallmark element of the leading Dx framework constructs. The goal is first to develop a stable Dx adoption model and evaluate the model using the data collected from the first objective to determine which factors impact perceived usefulness (PU), perceived ease of use (EU), and intention to use (IU). The future research will test and quantify the impact of (PU), and (EU) on the intention to use (IU) including HFE and HSE, in addition to the remaining TAM2 constructs associated with perceived usefulness and perceived ease of use, as external variables, as seen in figure 14.

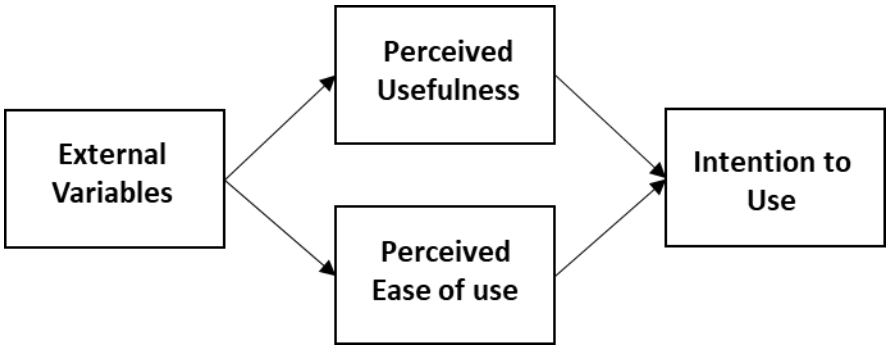


Figure 14: The Future Research Dx Adoption Model - Venkatesh & Davis 2000.

The resulting artifact will be a novel PSL-SEM adoption model that is specifically relevant to the biopharma manufacturing environment and will hopefully demonstrate a high predictive power of intention to use for any prospective Dx framework. In practice, the artifact will help IT leaders and practitioners to address their selection problem by identifying key factors that influence

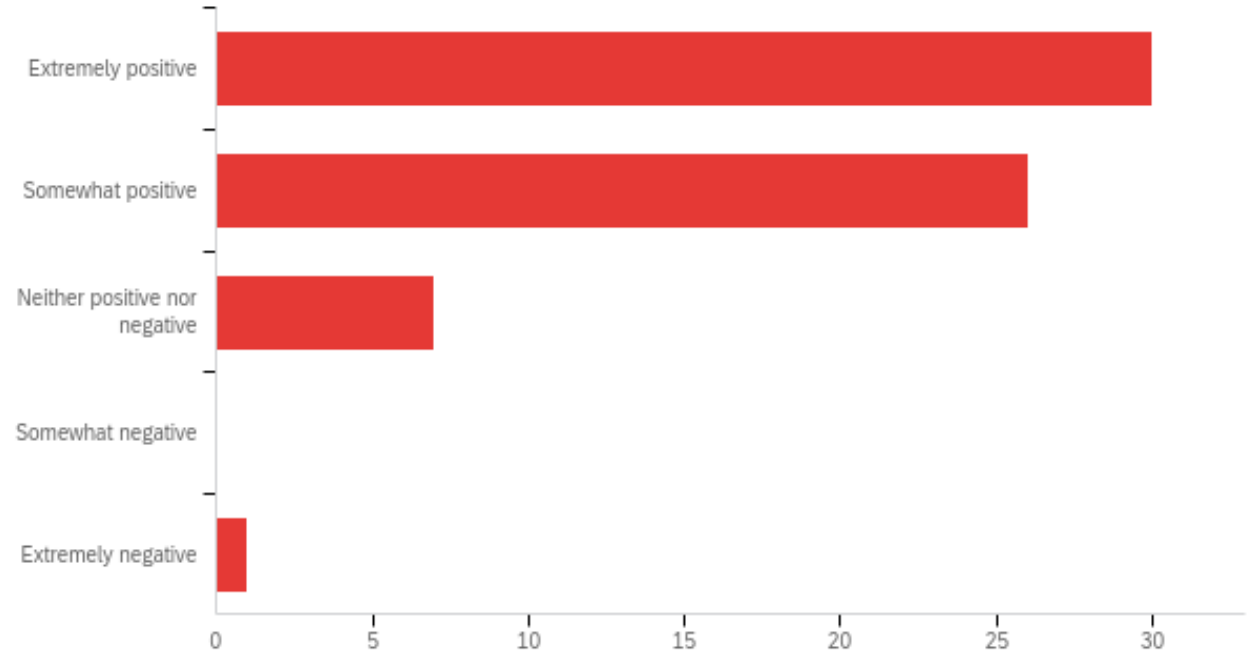
the adoption of a Dx framework. By focusing on influential factors, IT leaders and practitioners can select the Dx framework best suited to their company's needs.

Appendices

Appendix A: Phase 1 – Pre-Experiment Testing Survey Instrument and Results

Biopharma Manufacturing Digital Transformation Framework

Q2 – What is your initial reaction this concept?

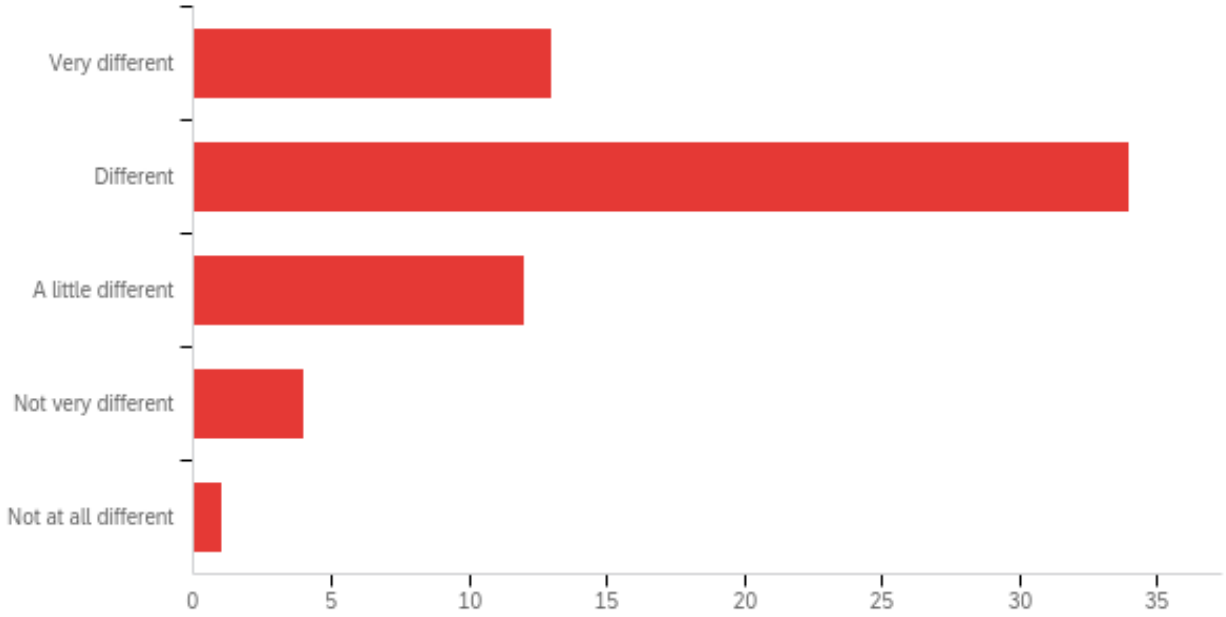


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – What is your initial reaction this concept?	1.00	5.00	1.69	0.79	0.62	64

#	Answer	%	Count
1	Extremely positive	46.88%	30
2	Somewhat positive	40.63%	26

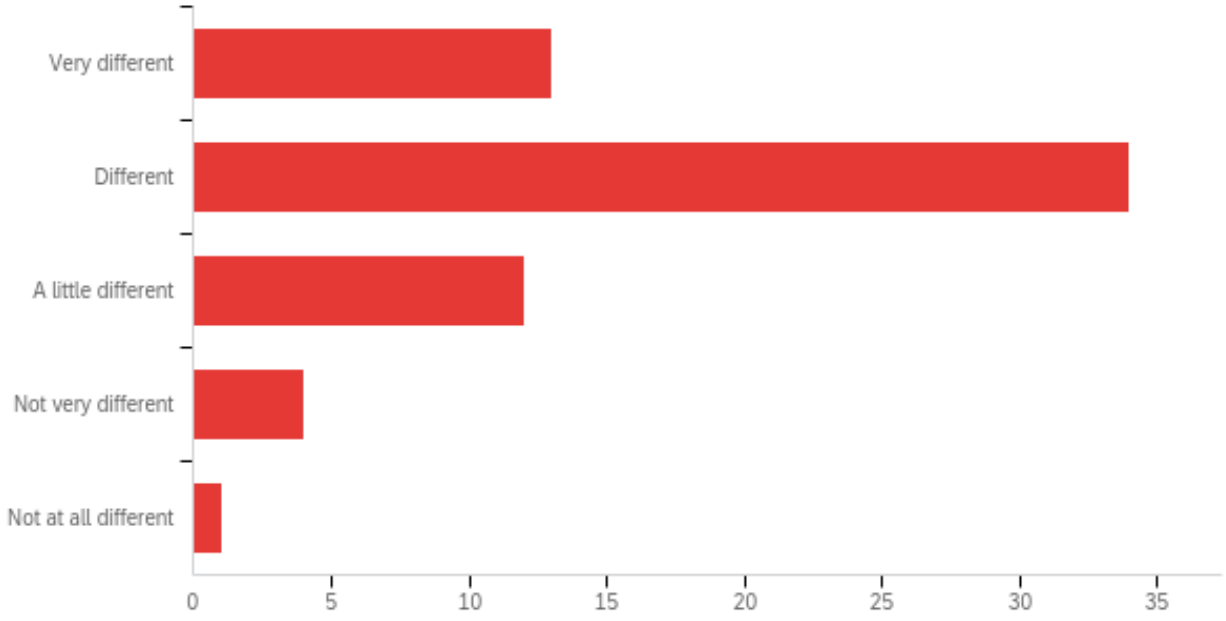
3	Neither positive nor negative	10.94%	7
4	Somewhat negative	0.00%	0
5	Extremely negative	1.56%	1
	Total	100%	64

Q3 – How different is this concept from other frameworks currently available?

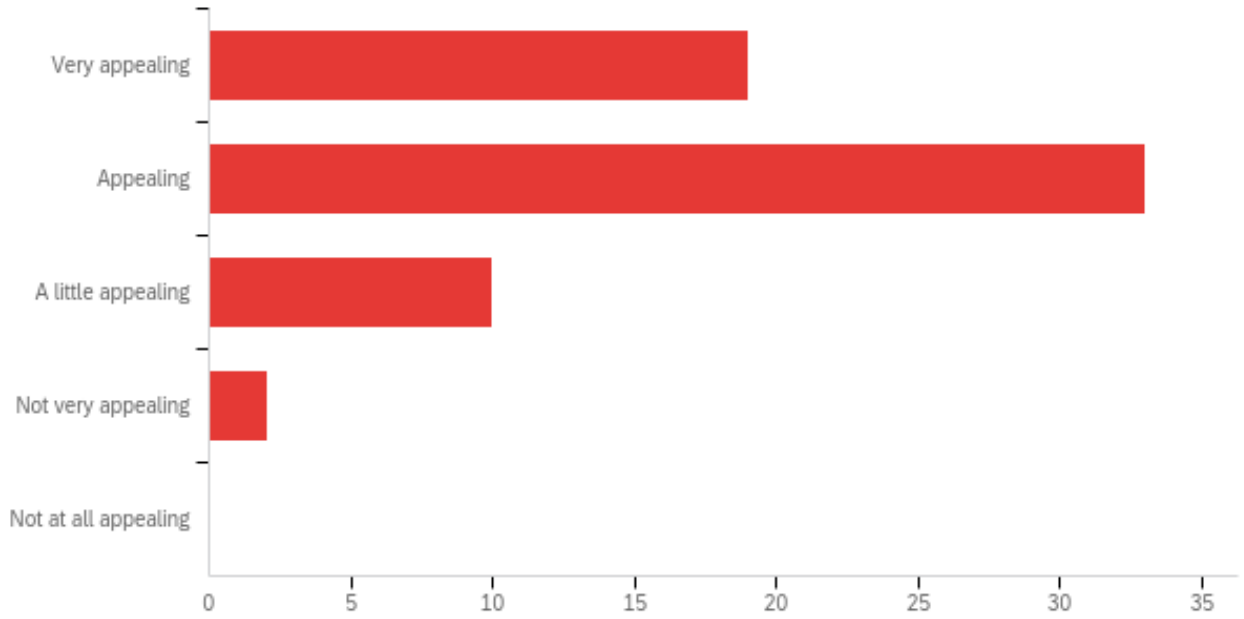


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – How different is this concept from other frameworks currently available?	1.00	5.00	2.16	0.87	0.76	64

#	Answer	%	Count
1	Very different	20.31%	13
2	Different	53.13%	34
3	A little different	18.75%	12
4	Not very different	6.25%	4
5	Not at all different	1.56%	1
	Total	100%	64


Very different
Different
A little different
Not very different
Not at all different
0
5
10
15
20
25
30
35

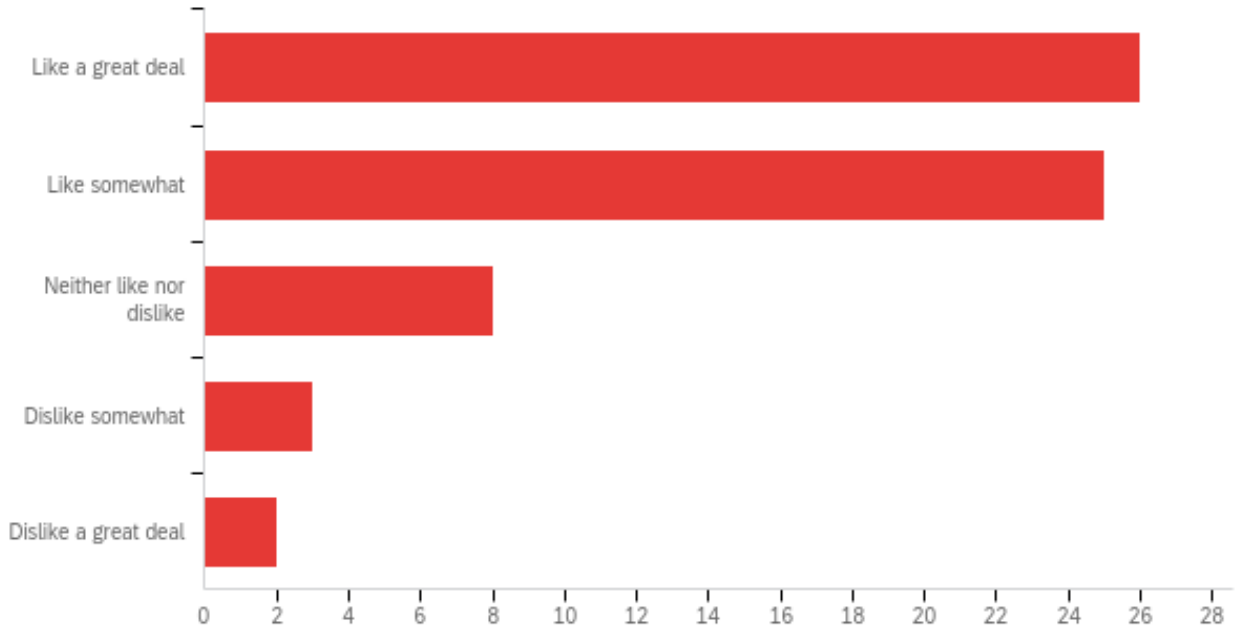
Q4 – How appealing is this concept compared to other frameworks currently available?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – How appealing is this concept compared to other frameworks currently available?	1.00	4.00	1.92	0.76	0.57	64

#	Answer	%	Count
1	Very appealing	29.69%	19
2	Appealing	51.56%	33
3	A little appealing	15.63%	10
4	Not very appealing	3.13%	2
5	Not at all appealing	0.00%	0
	Total	100%	64

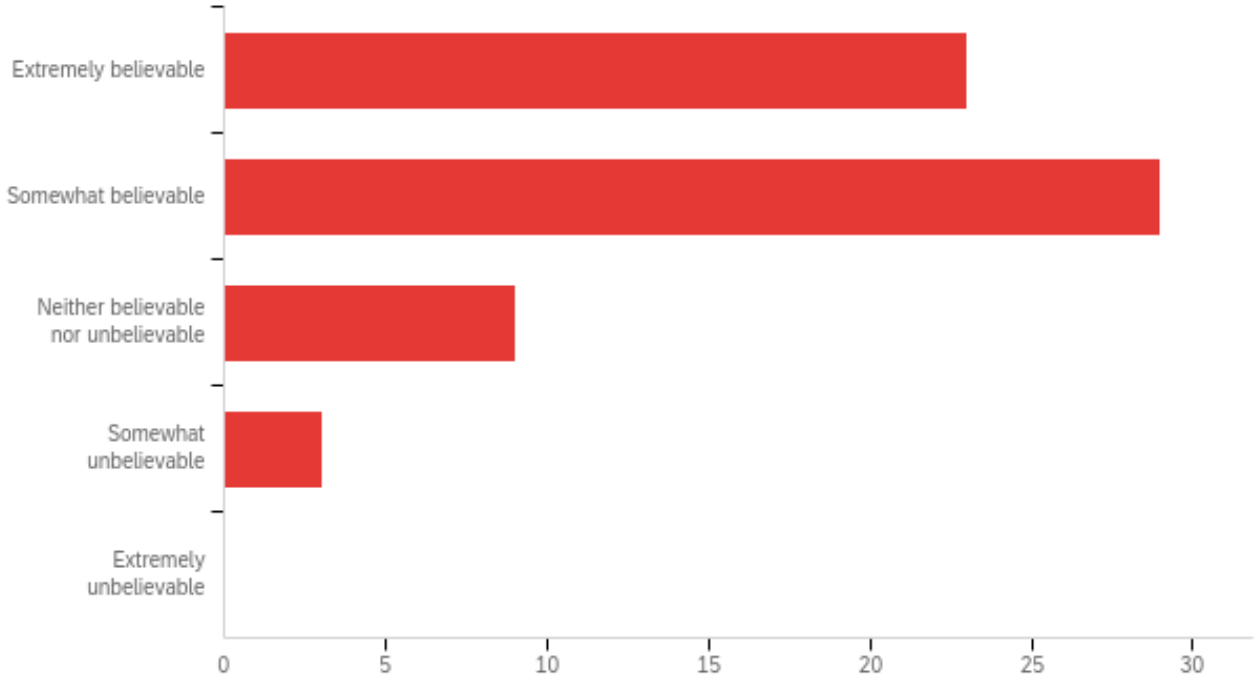
Q5 – How much do you like or dislike this concept?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – How much do you like or dislike this concept?	1.00	5.00	1.91	1.00	0.99	64

#	Answer	%	Count
1	Like a great deal	40.63%	26
2	Like somewhat	39.06%	25
3	Neither like nor dislike	12.50%	8
4	Dislike somewhat	4.69%	3
5	Dislike a great deal	3.13%	2
	Total	100%	64

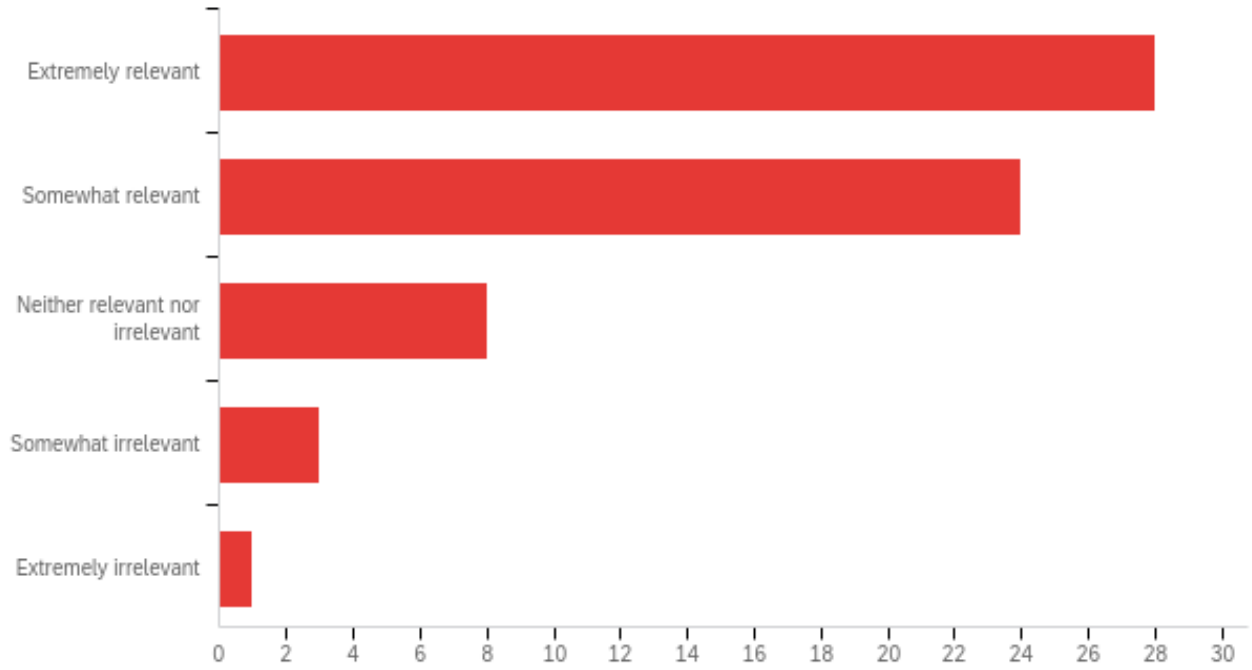
Q6 – How believable is this concept?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – How believable is this concept?	1.00	4.00	1.88	0.82	0.67	64

#	Answer	%	Count
1	Extremely believable	35.94%	23
2	Somewhat believable	45.31%	29
3	Neither believable nor unbelievable	14.06%	9
4	Somewhat unbelievable	4.69%	3
5	Extremely unbelievable	0.00%	0
	Total	100%	64

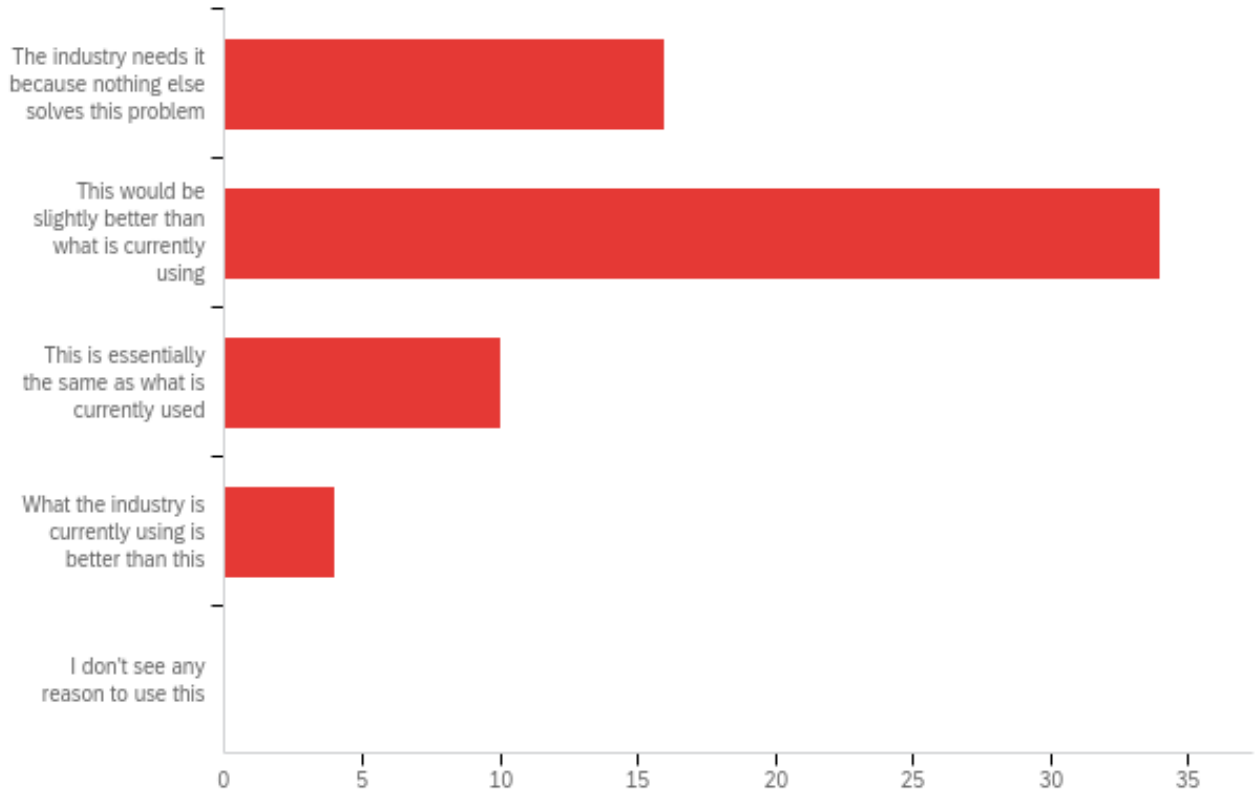
Q7 – How relevant do you think this concept is to biopharma manufacturing?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – How relevant do you think this concept is to biopharma manufacturing?	1.00	5.00	1.83	0.93	0.86	64

#	Answer	%	Count
1	Extremely relevant	43.75%	28
2	Somewhat relevant	37.50%	24
3	Neither relevant nor irrelevant	12.50%	8
4	Somewhat irrelevant	4.69%	3
5	Extremely irrelevant	1.56%	1
	Total	100%	64

Q8 – From the list below, which best describes the need for this concept?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Dx – From the list below, which best describes the need for this concept?	1.00	4.00	2.03	0.81	0.66	64

#	Answer	%	Count
1	The industry needs it because nothing else solves this problem	25.00%	16
2	This would be slightly better than what is currently using	53.13%	34
3	This is essentially the same as what is currently used	15.63%	10
4	What the industry is currently using is better than this	6.25%	4
5	I don't see any reason to use this	0.00%	0
	Total	100%	64

Q10 – What do you like MOST about this concept?

Dx – What do you like MOST about this concept?
chart was good
culture industry
CHART WAS GOOD
2
The Chart Describes in full detail about pharma manufacturing and responsibility
A Criterial Framework for Understanding. Concept Formation in the Social Sciences.
The chart look like good
culture
A growth-oriented Autonomous Digital Enterprise delivers value with competitive differentiation enabled by agility, customer centricity, and actionable insights. To be successful, organizations must develop new operating models enabled by key technologies that: Deliver a transcendent customer experience Apply automation everywhere Support enterprise DevOps Drive data-based business outcomes Safeguard the organization through adaptive cyber security
I THINK IT IS GOOD TO USE.
I THINK THIS IS GOOD FOR ALL.
Resources
culture
culture and industry
Good to the future time line is my thought. I think about the biopharma manufacturing plant level establish very well to all.
resource concept is good
medicen
good concept
good
Biopharma Manufacturing Digital
I like the content of the graph
The content about this chart really useful and good.
Organizations and Processes
Test

culture industry
N/A
yes
yes
frame work
more reliable and easy to understand.
MORE RELIABLE AND EASY TO UNDERSTAND
more reliable and easy to understand
mostly cycle type
Contribution from every sector
chart was good
I like this chart because it was colorful
I like this creative chart
It look more reliable and easy to understand.
pharma
GOOD
A great way to find out more about yourself is to ask people you like, trust and respect what they think you're best at
It's Unique concept and I like this
culture
the design concept
concept
This is helpful.
Resources
IT HAS ITS UNIQUE CONCEPT
Adoption of a standard eData platform accelerates and facilitates sharing of raw material quality data and enables the end user to integrate data directly into internal knowledge management systems and process analytical tools. This allows for improved monitoring
Resources, Culture
Resources, Culture

culture and industry

culture

I like the digital ecosystem

The concept seems to be promising and should be a good idea for the people.

The Dx is the good product and likely this concept.

THIS FRAME WORK IS VERY GOOD QUALITY AND REACHABLE

Q11 – What do you like LEAST about this concept?

Dx – What do you like LEAST about this concept?

poor content

ppartners industry

POR CONTENT

Colours the used in chart, its not catchy

The best way to answer what you liked least about a recent job is to approach the question with a positive, casual tone and name one thing that you felt could have been better, but then name some positive aspects about the job, too.

content was poor

partners

Give customers and employees what they need by making technology feel more human: Enable rich do-it-yourself experiences backed by human expertise Recognize mobile devices as the primary channel for interaction Leverage analytics and orchestration for a frictionless experience.

SOWEWHAT AFRAID TO THIS WHILE GETTING SIDE EFFECT LIKE THAT.

SOMEWHAT IT MAY AFRAID OF GETTING SIDE EFFECT.

Culture

partners

resources

It good all following generation. At least is not declared it is very useful concept.

i like it

useful mediceine

nuice

good
Biopharma Manufacturing Digital
even the graph is everything the information is less.
Even this content is useful and something missing.
culture
Test
partners industry
N/A
yes
yes i like it
none
nope
NOPE
nope
good one
Will this replace the existing
poor content
the chart content was doesn't understand easily
This chart is little distract
nope.
i like me
Nice
Talk about tasks and situations when highlighting your dislikes
I like this more
partners
the colours used
confused
This is bad.

Culture
IT'S LITTLE DIFFICULT TO DO IT IN PRACTICAL
Standard file structure and data format providing consistency, reliability, and flexibility
Organization
Organization
resources
resources
nothing least , I like everything
I find anything that i least like about the concept, I agreed with the entire concept.
Not in least about this concept.
THIS IS DIFFERENT TYPE OF MANUFACTURING

Appendix B: Phase 3 – Experiment Survey Instrument

Construct	Indicator	Survey Questions
Actual Use	IU1	I intend to use this digital transformation framework.
	IU2	I would use this digital transformation framework.
	IU3	I plan to use this digital transformation framework.
Behavioral Intentions	BI1	I believe a framework is required for any organization that plans to take on any digital transformation effort.
	BI2	Using a digital transformation framework to express the big picture and generalize ideas is a positive idea.
	BI3	Giving and receiving feedback through the use of a digital transformation framework is a good idea.
Perceived Ease of Use	EU1	Learning to use this framework would be easy for me.
	EU2	I would find it easy to transform this framework to do what I wanted it to represent.
	EU3	Using this framework would be clear and understandable.
	EU4	I find this framework to be flexible to use.
	EU5	It would be easy for me to become skillful at using this framework.
	EU6	I would find this framework easy to use.
Hallmark Functional Elements	HFE1	With this framework, I can see the big picture and the digital transformation ideals.
	HFE2	With this framework, I can see different layers that drill-down to a set of tasks and sequences.
	HFE3	This concept offers the flexibility to transform front and back office functions.
	HFE4	I can customize this concept to suit different biopharma manufacturing circumstances.
Hallmark Structural Elements	HSE1	This framework is customer or patient-centric.
	HSE2	This framework demonstrates the potential opportunities and constraints within a biopharma manufacturing environment.
	HSE3	This framework emphasizes company culture.
	HSE4	I would find this framework simple to apply.
Image	IM1	People within my organization who leverage tools like this seem to have more prestige and success than those who do not.
	IM2	High profile people within my organization use these frameworks to communication their ideas.
	IM3	Using frameworks and tools symbolizes competence and expertise within my organization.
Job Relevant	JB1	In my role, using digital transformation framework is important.
	JB2	In my role, it is relevant to use digital transformation frameworks and strategic roadmaps.

	JB3	Using digital transformation frameworks and strategic roadmaps is pertinent to my job-related tasks.
Output Quality	OQ1	The quality of output I get from using this framework is high.
	OQ2	I have no problem with the quality of output I would get from using this framework.
	OQ3	I would rate the results I would get from this using this framework as excellent.
Perceived Usefulness	PU1	Using the framework would help my academic writing or my organization to reach our research or digital transformation goals more quickly.
	PU2	Using this framework would improve the relevancy of my research or the performance of my organization's digital transformation execution.
	PU3	Using this framework would be useful in not overlooking critical steps within the organization's digital transformation or Pharma 4.0 process.
	PU4	Using this framework would enhance my research or my organization's effectiveness throughout our digital transformation process.
	PU5	Using this framework would make it easier for people executing digital transformation programs and projects to succeed within their roles.
	PU6	I would find this framework useful in communicating a Digital Transformation or Pharma 4.0 business strategy.
Result Demonstrability	RD1	I have no problem sharing the results of using this framework.
	RD2	I believe I could communicate the consequences of using this framework.
	RD3	The results of using this framework are apparent to me.
	RD4	I would have a hard time explaining why or why no using this framework is beneficial.
Subjective Norms	SN1	People who influence my behavior believe that I should use a framework in communicating my organization's digital transformation strategy.
	SN2	People who are important to me think that I should use a framework in building my organization's digital transformation strategy.
	SN3	Senior Management within my organization supports using tools like this.

Source: Venkatesh & Davis, 2000.

Appendix C: Phase 3 – Experiment Survey Questions and Results

Survey Instrument Report
SME Survey Concept (Framework) - ID6337719824
September 18th 2022, 9:30 am MDT

Q0 – The Anatomy of a Digital Transformation Framework for Biopharma Manufacturing

Thank you for taking the time to participate in our study.

We designed this survey to help understand how you, as Academic Researchers, Consultants, Executives, Managers & IT Leaders, and Practitioners, would respond to our digital transformation concepts.

This survey will present a framework that has two conceptual diagrams for you to review. We will then ask you a few questions about each conceptual diagram. The survey will include questions regarding each diagram's expressiveness, functionality, usefulness, and overall ease of use within a biopharma manufacturing environment or for future academic research. We end the survey by asking questions regarding the framework as a whole. Your participation in this research study is voluntary. You have the right to withdraw at any point during the study.

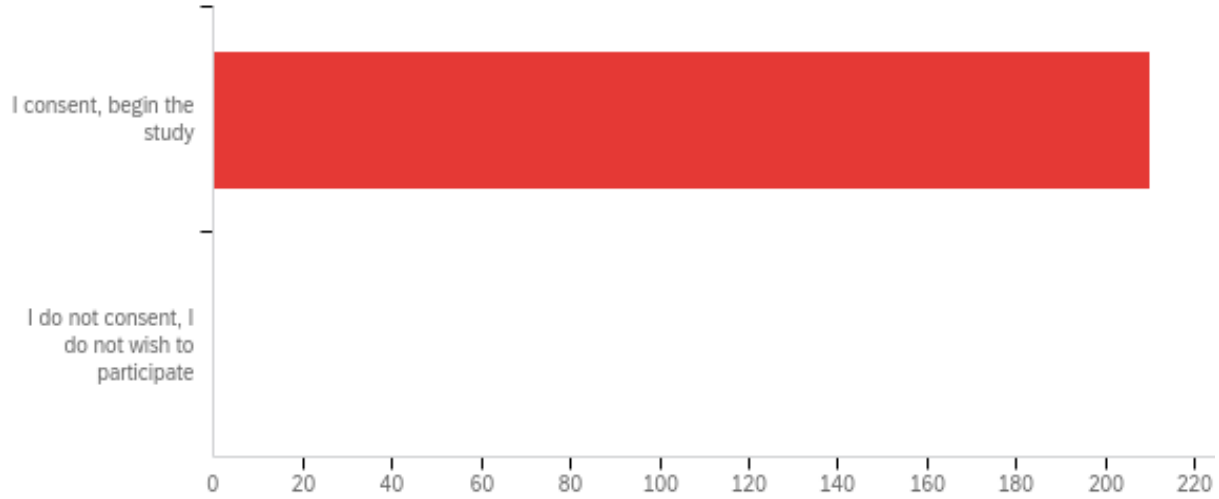
By clicking the button below, you acknowledge:

Your participation in the study is voluntary.
You are 18 years of age.
You may choose to terminate your participation at any time for any reason.

Again, thank you for your participation. Please feel free to take as much time as your need.

Best regards,

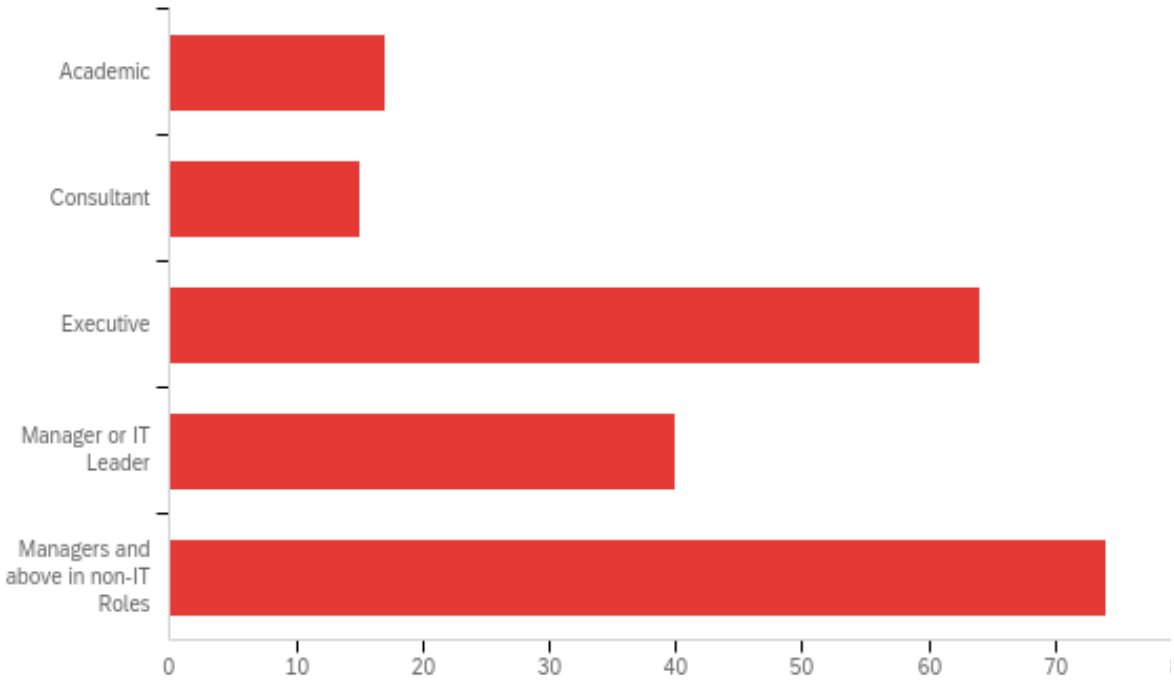
Frederick K. Johnson
Center for Information Systems & Technology



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	The Anatomy of a Digital Transformation Framework for Biopharma Manufacturing. Thank you for taking the time to participate in our study. We designed this survey to help understand how you, as Academic Researchers, Consultants, Executives, Managers & IT Leaders, and Practitioners, would respond to our digital transformation concepts. This survey will present a framework that has two conceptual diagrams for you to review. We will then ask you a few questions about each conceptual diagram. The survey will include questions regarding each diagram's expressiveness, functionality, usefulness, and overall ease of use within a biopharma manufacturing environment or for future academic research. We end the survey by asking questions regarding the framework as a whole. Your participation in this research study is voluntary. You have the right to withdraw at any point during the study. By clicking the button below, you acknowledge: Your participation in the study is voluntary. You are 18 years of age. You may choose to terminate your participation at any time for any reason. Again, thank you for your participation. Please feel free to take as much time as your need. Best regards, Frederick K. Johnson, Center for Information Systems & Technology	1.00	1.00	1.00	0.00	0.00	210

#	Answer	%	Count
1	I consent, begin the study	100.00%	210
2	I do not consent; I do not wish to participate	0.00%	0
	Total	100%	210

Q1 – How would you categorize your functional area of expertise?

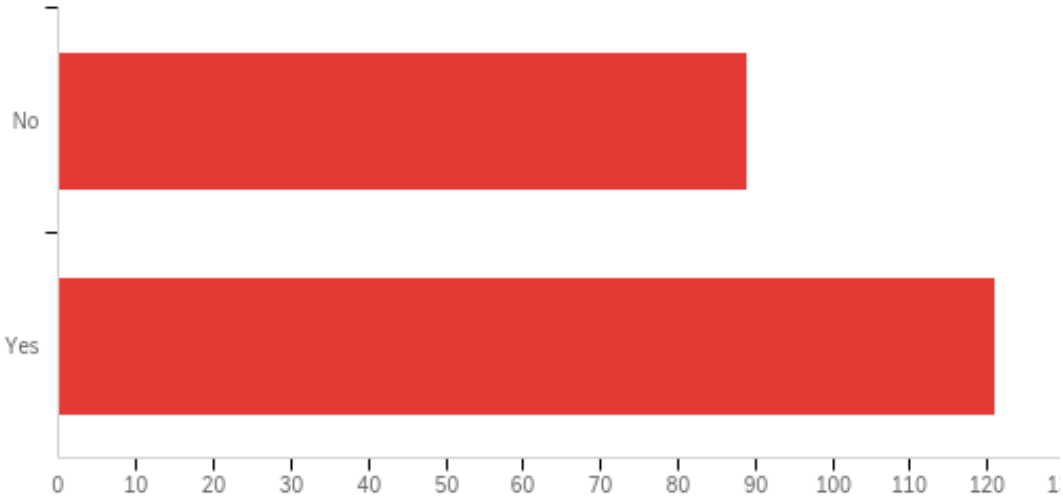


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	How would you categorize your functional area of expertise?	1.00	5.00	3.66	1.25	1.56	210

#	Answer	%	Count
1	Academic	8.10%	17
2	Consultant	7.14%	15
3	Executive	30.48%	64
4	Manager or IT Leader	19.05%	40
5	Managers and above in non-IT Roles	35.24%	74

	Total	100%	210

Q3 – Based on your current role, are you currently or will you be involved in research, or work dealing with digital transformation or implementing Pharma 4.0 programs and projects?

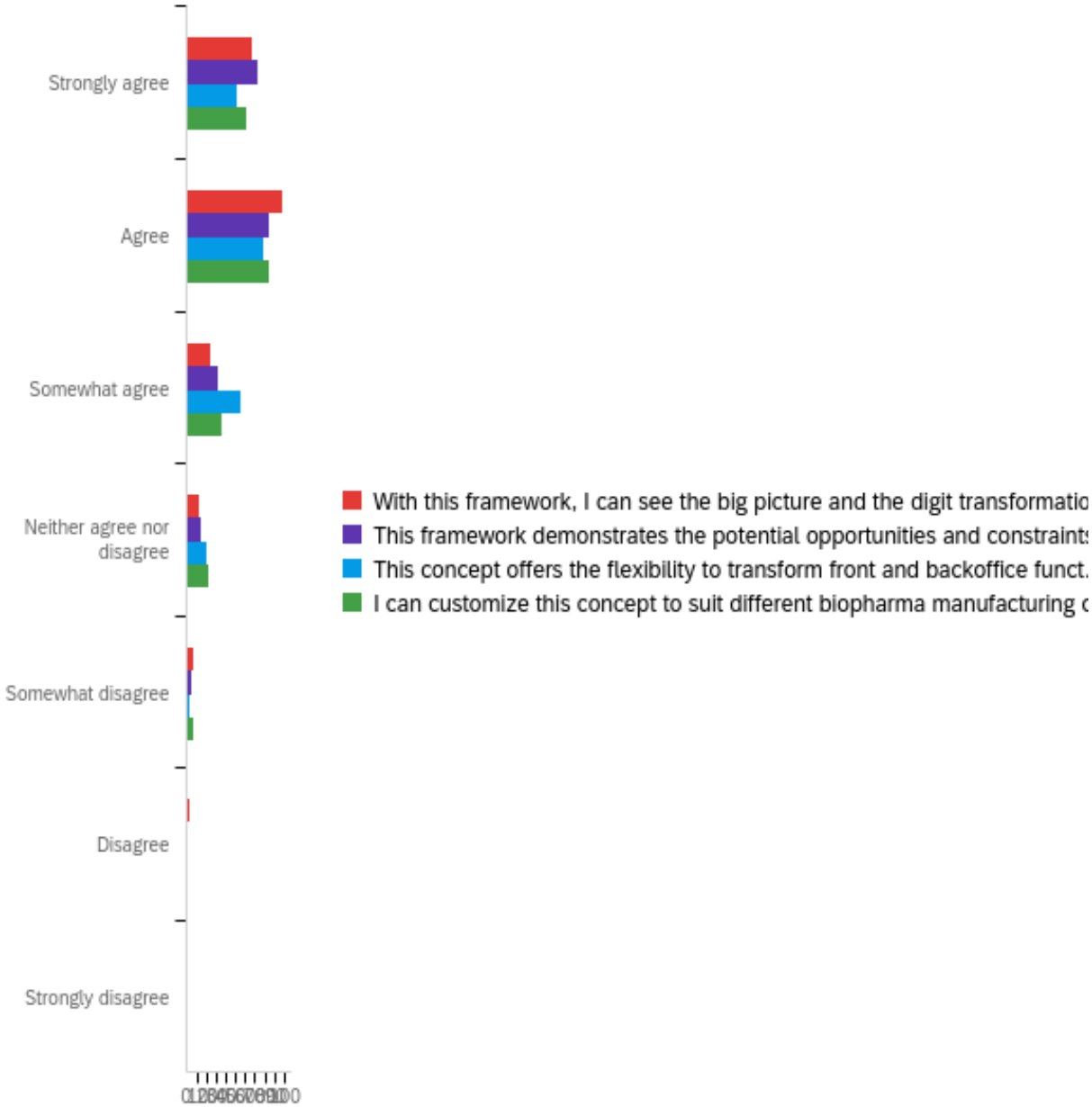


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Based on your current role, are you currently or will you be involved in research, or work dealing with digital transformation or implementing Pharma 4.0 programs and projects?	1.00	2.00	1.58	0.49	0.24	210

#	Answer	%	Count

1	No	42.38%	89
2	Yes	57.62%	121
	Total	100%	210

Q3 – Please select the option that represents your response to each question.

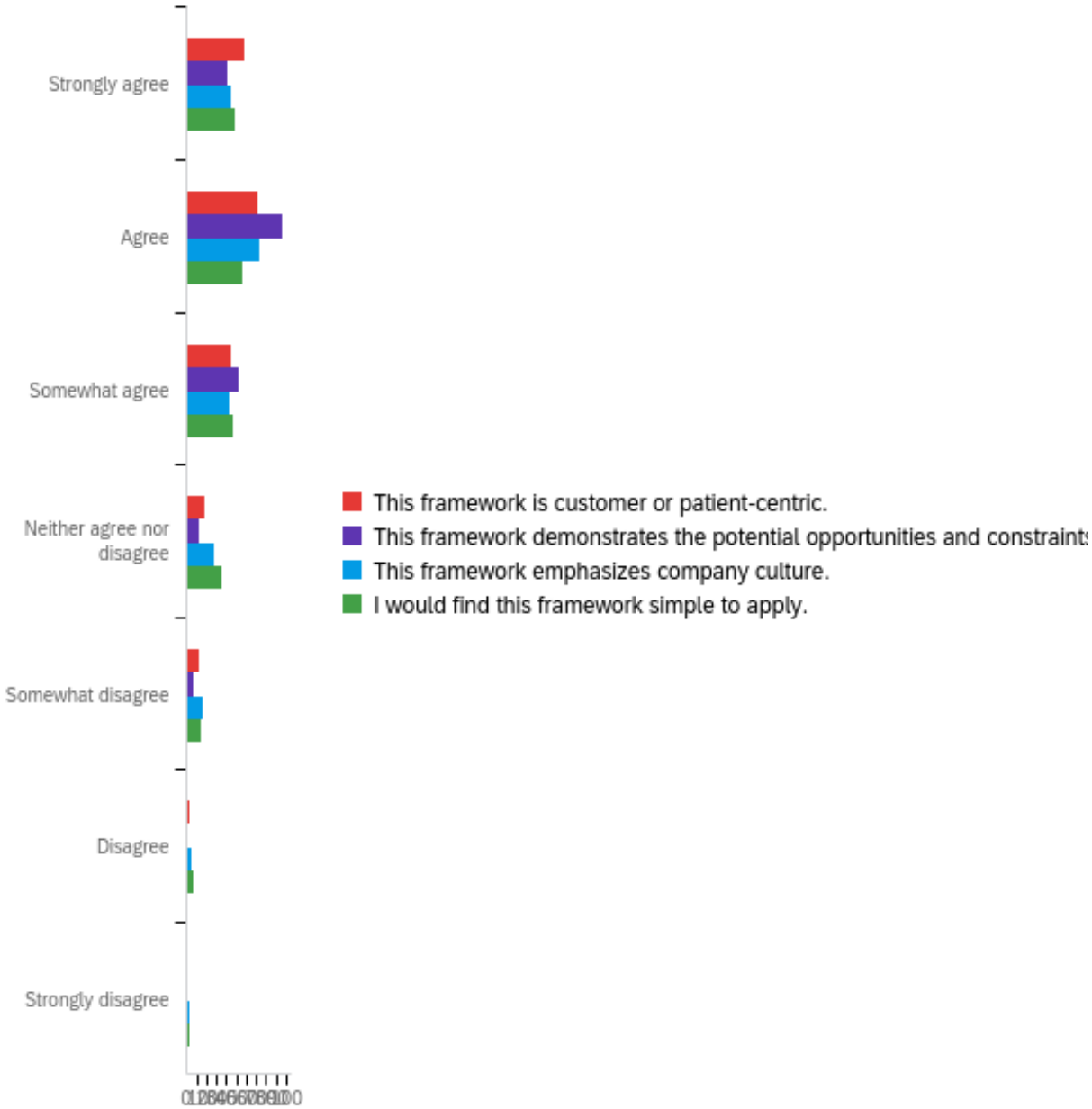


#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	With this framework, I can see the big picture and the digit transformation ideals.	32.38%	68	46.67%	98	11.43%	24	5.71%	12	2.86%	6	0.95%	2	0.00%	0	210
2	This framework demonstrates the potential opportunities and constraints within a biopharma manufacturing environment.	34.76%	73	40.00%	84	15.71%	33	7.14%	15	1.90%	4	0.48%	1	0.00%	0	210
3	This concept offers the flexibility to transform front and back office functions.	24.76%	52	37.62%	79	26.67%	56	9.52%	20	0.95%	2	0.00%	0	0.48%	1	210
4	I can customize this concept to suit different biopharma manufacturing circumstances.	29.05%	61	40.00%	84	17.14%	36	10.48%	22	2.86%	6	0.00%	0	0.48%	1	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor		Somewhat disagree		Disagree		Strongly disagree		Total

								disagree							
1	With this framework, I can see the big picture and the digit transformation ideals.	32.38%	68	46.67%	98	11.43%	24	5.71%	12	2.86%	6	0.95%	2	0.00%	0	210
2	c	34.76%	73	40.00%	84	15.71%	33	7.14%	15	1.90%	4	0.48%	1	0.00%	0	210
3	This concept offers the flexibility to transform front and back office functions.	24.76%	52	37.62%	79	26.67%	56	9.52%	20	0.95%	2	0.00%	0	0.48%	1	210
4	I can customize this concept to suit different biopharma manufacturing circumstances.	29.05%	61	40.00%	84	17.14%	36	10.48%	22	2.86%	6	0.00%	0	0.48%	1	210

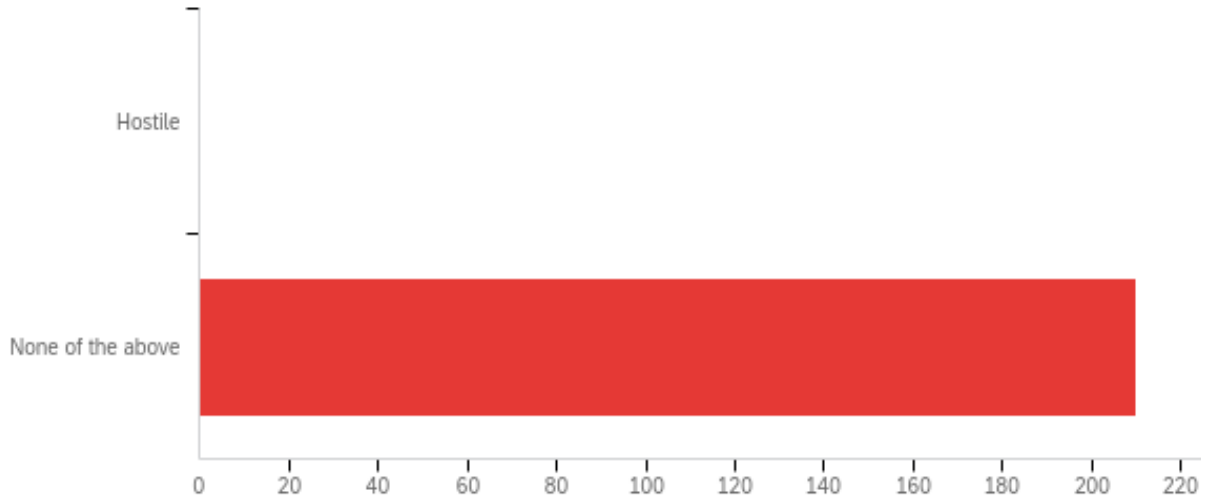
Q3 – Please select the option that represents your response to each question.



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	This framework is customer- or patient-centric.	1.00	7.00	2.39	1.27	1.61	210
2	This framework demonstrates the potential opportunities and constraints within a biopharma manufacturing environment.	1.00	7.00	2.30	1.02	1.04	210
3	This framework emphasizes company culture.	1.00	7.00	2.61	1.36	1.86	210
4	I would find this framework simple to apply.	1.00	7.00	2.73	1.44	2.07	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	This framework is customer- or patient-centric.	27.62%	58	33.81%	71	21.43%	45	9.05%	19	6.19%	13	1.43%	3	0.48%	1	210
2	This framework demonstrates the potential opportunities and constraints within a biopharma manufacturing environment.	19.52%	41	45.71%	96	25.24%	53	5.71%	12	2.86%	6	0.48%	1	0.48%	1	210
3	This framework emphasizes company culture.	21.43%	45	34.76%	73	20.00%	42	12.86%	27	7.62%	16	2.38%	5	0.95%	2	210
4	I would find this framework simple to apply.	22.86%	48	27.14%	57	21.90%	46	16.67%	35	6.67%	14	3.33%	7	1.43%	3	210

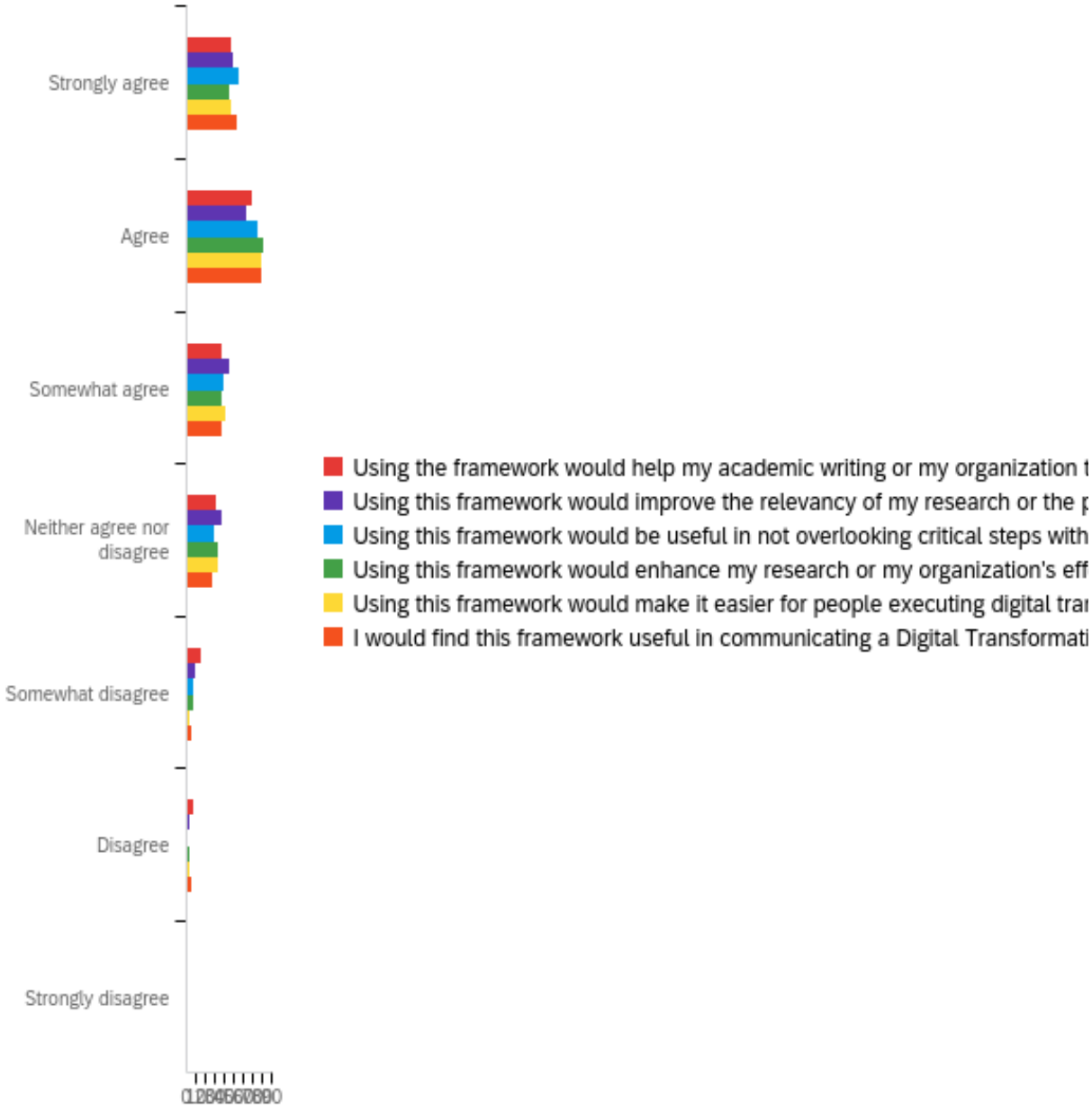
Q14 – Please select the "None of the above" option as your answer.



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Please select the “None of the above” option as your answer.	1.00	1.00	1.00	0.00	0.00	210

#	Answer	%	Count
1	None of the above	100.00%	210
0	Hostile	0.00%	0
	Total	100%	210

Perceived Usefulness – Please select the option that accurately represents your response to each question.

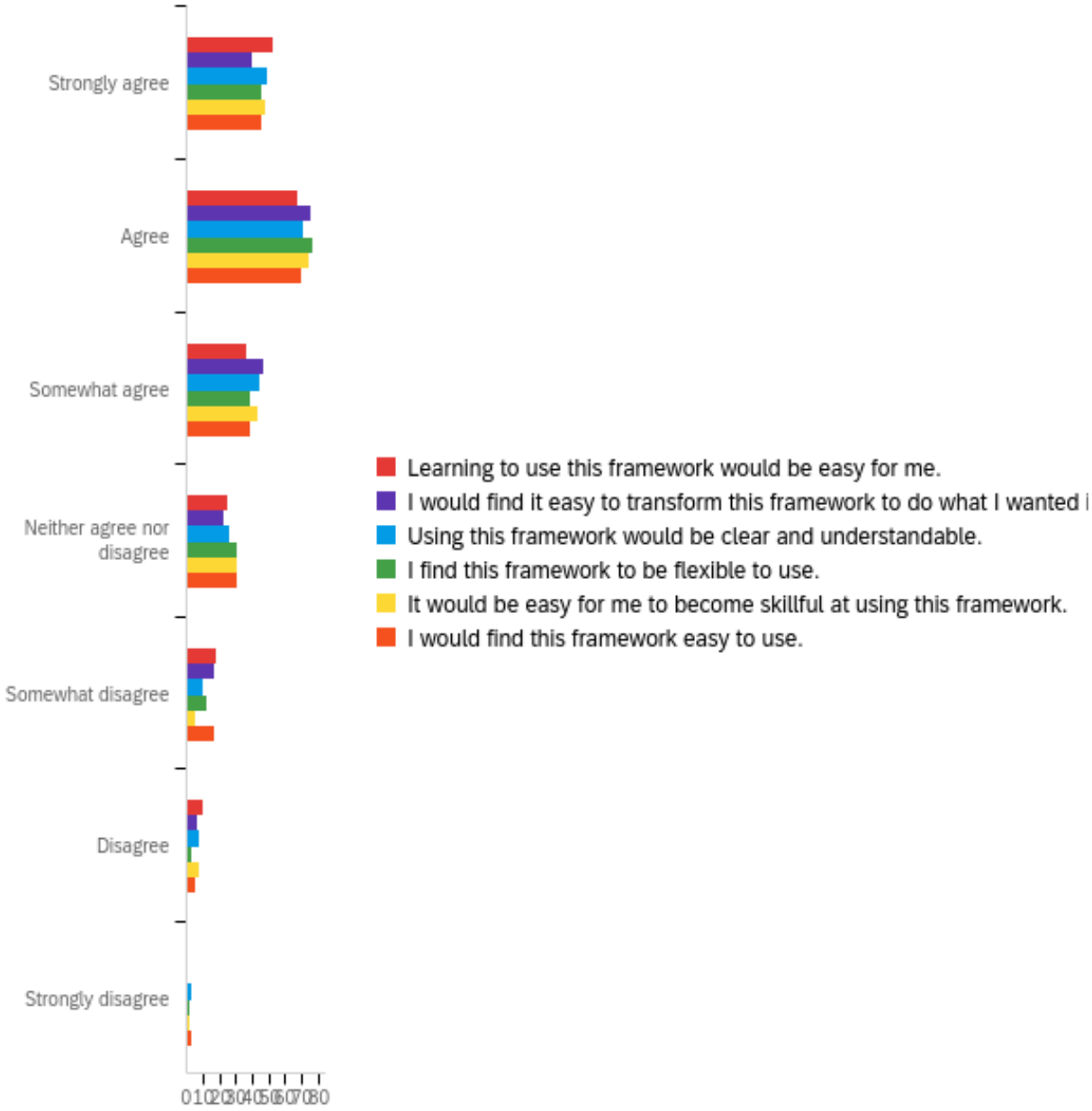


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Using the framework would help my academic writing or my organization to reach our research or digital transformation goals more quickly.	1.00	7.00	2.64	1.41	2.00	210
2	Using this framework would improve the relevancy of my research or the performance of my organization's digital transformation execution.	1.00	7.00	2.57	1.30	1.68	210
3	Using this framework would be useful in not overlooking critical steps within the organization's digital transformation or Pharma 4.0 process.	1.00	6.00	2.34	1.17	1.36	210
4	Using this framework would enhance my research or my organization's effectiveness throughout our digital transformation process.	1.00	6.00	2.45	1.18	1.40	210
5	Using this framework would make it easier for people executing digital transformation programs and projects to succeed within their roles.	1.00	6.00	2.43	1.17	1.36	210
6	I would find this framework useful in communicating a Digital Transformation or Pharma 4.0 business strategy.	1.00	7.00	2.39	1.25	1.55	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	Using the framework would help my academic writing or my organization to reach our research or digital transformation goals more quickly.	22.86%	48	32.86%	69	18.10%	38	14.76%	31	7.14%	15	3.33%	7	0.95%	2	210
2	Using this framework would improve the relevancy of my research or the performance of my organization's digital transformation execution.	23.81%	50	30.00%	63	21.43%	45	17.62%	37	4.76%	10	1.90%	4	0.48%	1	210
3	Using this framework	26.67%	56	36.19%	76	18.57%	39	14.29%	30	3.33%	7	0.95%	2	0.00%	0	210

	would be useful in not overlooking critical steps within the organization's digital transformation or Pharma 4.0 process.															
4	Using this framework would enhance my research or my organization's effectiveness throughout our digital transformation process.	21.90%	46	39.05%	82	18.10%	38	15.71%	33	3.81%	8	1.43%	3	0.00%	0	210
5	Using this framework would make it easier for people executing digital transformation programs and projects to succeed within their roles.	22.38%	47	37.62%	79	20.00%	42	16.19%	34	1.90%	4	1.90%	4	0.00%	0	210
6	I would find this framework useful in communicating a digital transformation or Pharma 4.0 business strategy.	25.24%	53	38.10%	80	18.10%	38	12.86%	27	2.86%	6	2.38%	5	0.48%	1	210

Q5 – Please select the option that accurately represents your response to each question.

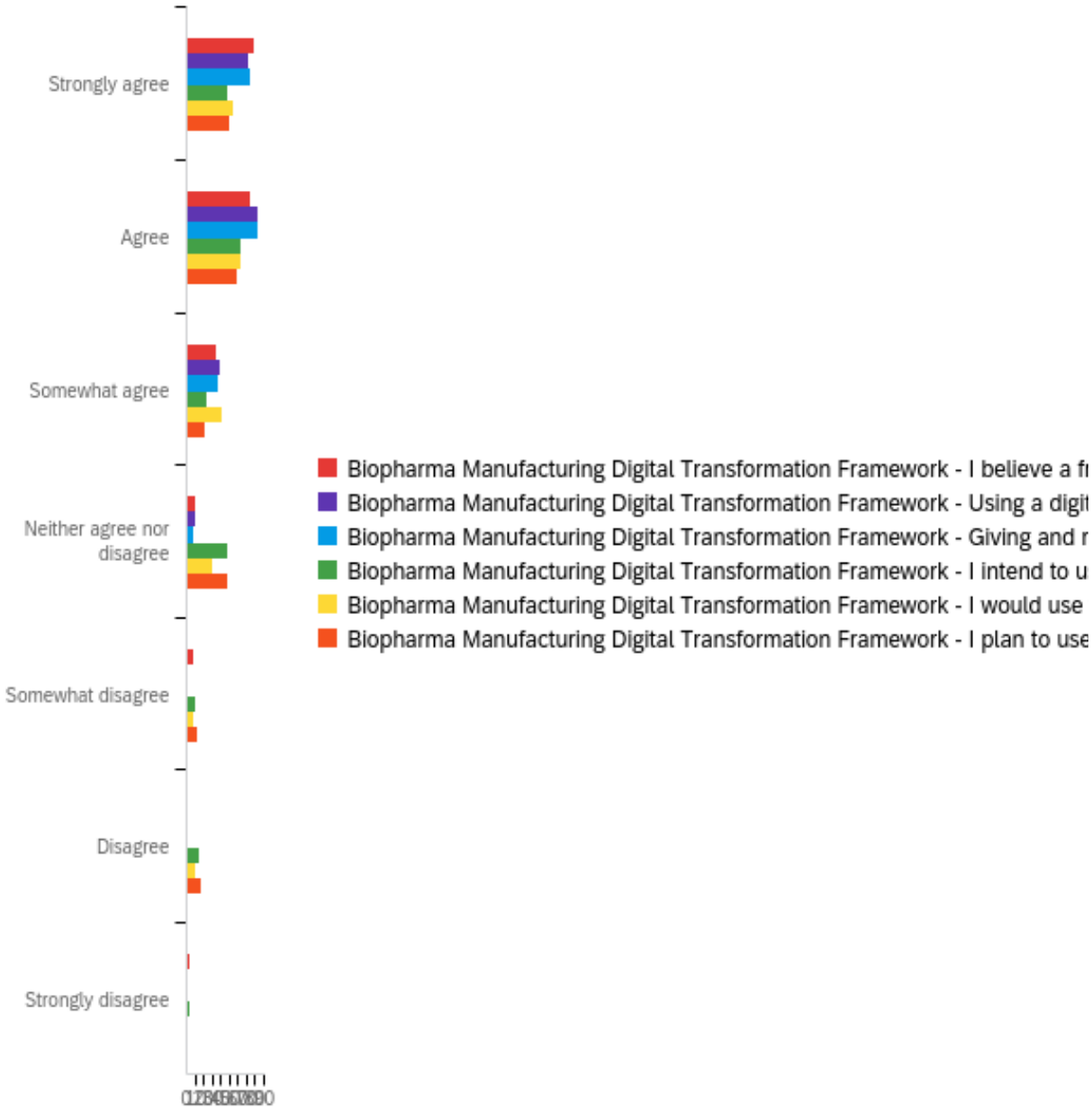


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Learning to use this framework would be easy for me.	1.00	7.00	2.63	1.47	2.16	210
2	I would find it easy to transform this framework to do what I wanted it to represent.	1.00	7.00	2.63	1.33	1.76	210
3	Using this framework would be clear and understandable.	1.00	7.00	2.57	1.39	1.93	210
4	I find this framework to be flexible to use.	1.00	7.00	2.54	1.30	1.69	210
5	It would be easy for me to become skillful at using this framework.	1.00	7.00	2.52	1.32	1.74	210
6	I would find this framework easy to use.	1.00	7.00	2.66	1.42	2.00	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	Learning to use this framework would be easy for me.	25.24%	53	31.90%	67	17.14%	36	11.90%	25	8.57%	18	4.76%	10	0.48%	1	210
2	I would find it easy to transform this framework to do what I wanted it to represent.	19.05%	40	36.19%	76	22.38%	47	10.95%	23	8.10%	17	2.86%	6	0.48%	1	210
3	Using this framework would be clear and understandable.	23.33%	49	33.81%	71	20.95%	44	12.38%	26	4.76%	10	3.33%	7	1.43%	3	210
4	I find this framework to be flexible to use.	21.90%	46	36.67%	77	18.57%	39	14.76%	31	5.71%	12	1.43%	3	0.95%	2	210
5	It would be easy for me to become skillful at using this framework.	22.86%	48	35.24%	74	20.48%	43	14.76%	31	2.38%	5	3.33%	7	0.95%	2	210

6	I would find this framework easy to use.	21.90 %	46	33.33 %	70	18.57%	39	14.29 %	30	8.10%	17	2.38%	5	1.43%	3	210

Q15 – Please select the option that accurately represents your response based on how you view using a digital transformation framework within your current role.

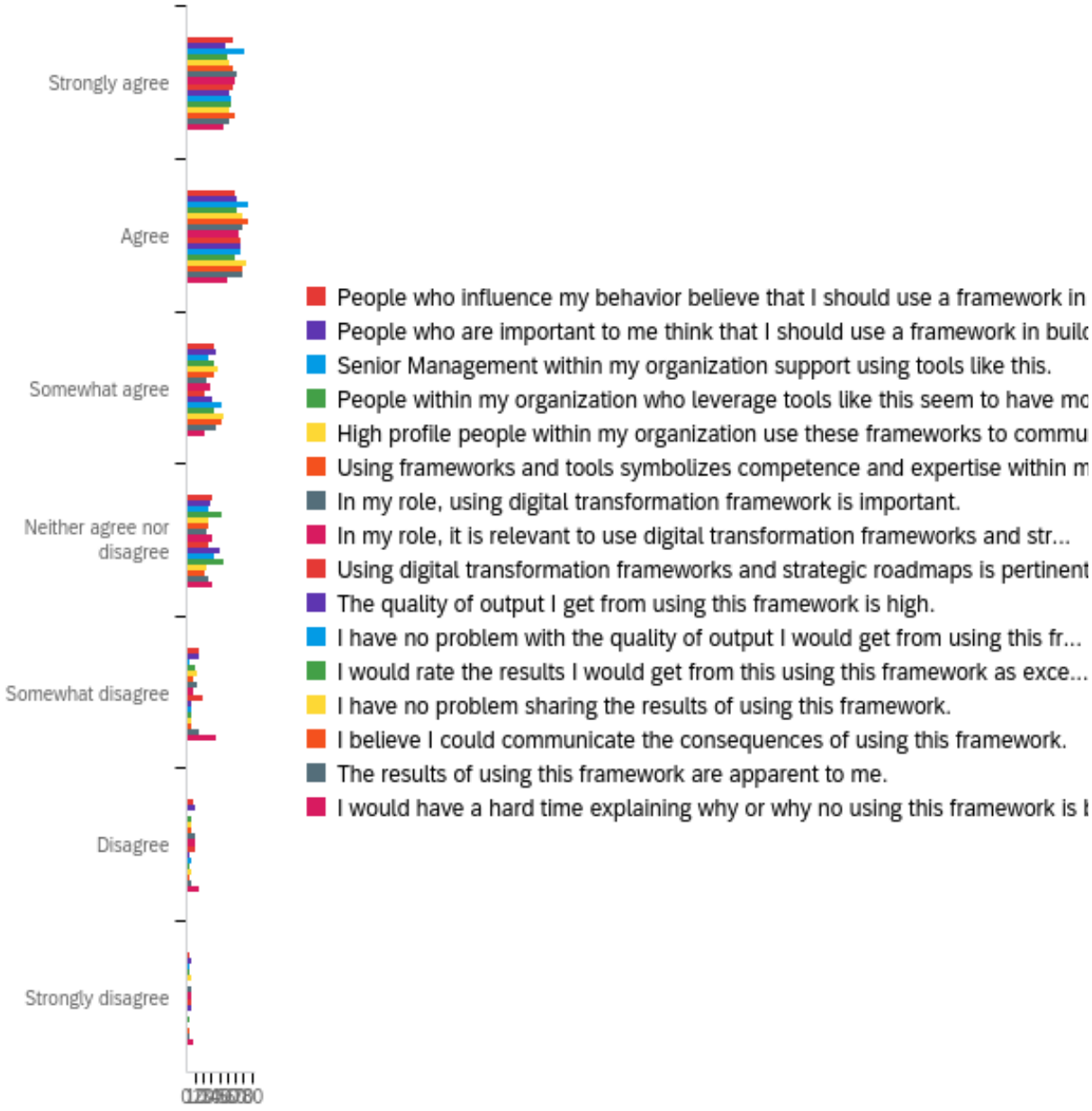


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	Biopharma Manufacturing Digital Transformation Framework – I believe a framework is required for any organization that plans to take on any digital transformation effort.	1.00	7.00	2.07	1.21	1.46	210
2	Biopharma Manufacturing Digital Transformation Framework – Using a digital transformation framework to express the big picture and generalize ideas is a positive idea.	1.00	7.00	2.02	1.06	1.11	210
3	Biopharma Manufacturing Digital Transformation Framework – Giving and receiving feedback through the use of a digital transformation framework is a good idea.	1.00	7.00	1.95	0.96	0.93	210
4	Biopharma Manufacturing Digital Transformation Framework – I intend to use this digital transformation framework.	1.00	7.00	2.83	1.58	2.49	210
5	Biopharma Manufacturing Digital Transformation Framework – I would use this digital transformation framework.	1.00	7.00	2.55	1.41	1.98	210
6	Biopharma Manufacturing Digital Transformation Framework – I plan to use this digital transformation framework.	1.00	7.00	2.86	1.59	2.51	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	Biopharma Manufacturing Digital Transformation Framework – I believe a framework is required for any organization that plans to take on any digital transformation effort.	37.62%	79	36.19%	76	16.19%	34	4.76%	10	3.33%	7	0.48%	1	1.43%	3	210
2	Biopharma Manufacturing Digital Transformation Framework – Using a digital transformation framework to express the big picture and generalize ideas is a positive idea.	34.76%	73	40.00%	84	18.57%	39	4.76%	10	0.00%	0	0.95%	2	0.95%	2	210

3	Biopharma Manufacturing Digital Transformation Framework – Giving and receiving feedback through the use of a digital transformation framework is a good idea.	36.19%	76	40.48%	85	18.10%	38	3.81%	8	0.48%	1	0.48%	1	0.48%	1	210
4	Biopharma Manufacturing Digital Transformation Framework – I intend to use this digital transformation framework.	22.86%	48	30.00%	63	11.43%	24	22.86%	48	4.29%	9	6.67%	14	1.90%	4	210
5	Biopharma Manufacturing Digital Transformation Framework – I would use this digital transformation framework.	26.67%	56	30.00%	63	20.00%	42	14.76%	31	3.33%	7	4.29%	9	0.95%	2	210
6	Biopharma Manufacturing Digital Transformation Framework – I plan to use this digital transformation framework.	23.81%	50	28.10%	59	10.48%	22	23.33%	49	5.71%	12	7.62%	16	0.95%	2	210

Q6 – In this final section, please select the option that accurately represents your response based on your current role within your organization.



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	People who influence my behavior believe that I should use a framework in communicating my organization's digital transformation strategy.	1.00	7.00	2.64	1.50	2.25	210
2	People who are important to me think that I should use a framework in building my organization's digital transformation strategy.	1.00	7.00	2.79	1.57	2.47	210
3	Senior management within my organization support using tools like this.	1.00	7.00	2.22	1.29	1.67	210
4	People within my organization who leverage tools like this seem to have more prestige and success than those who do not.	1.00	7.00	2.65	1.41	1.99	210
5	High profile people within my organization use these frameworks to communication their ideas.	1.00	7.00	2.60	1.49	2.22	210
6	Using frameworks and tools symbolizes competence and expertise within my organization.	1.00	7.00	2.40	1.33	1.76	210
7	In my role, using digital transformation framework is important.	1.00	7.00	2.57	1.60	2.56	210
8	In my role, it is relevant to use digital transformation frameworks and strategic roadmaps.	1.00	7.00	2.59	1.56	2.43	210
9	Using digital transformation frameworks and strategic roadmaps is pertinent to my job-related tasks.	1.00	7.00	2.71	1.67	2.79	210
10	The quality of output I get from using this framework is high.	1.00	7.00	2.57	1.42	2.01	210
11	I have no problem with the quality of output I would get from using this framework.	1.00	7.00	2.45	1.27	1.61	210
12	I would rate the results I would get from this using this framework as excellent.	1.00	7.00	2.59	1.42	2.01	210
13	I have no problem sharing the results of using this framework.	1.00	7.00	2.38	1.23	1.50	210
14	I believe I could communicate the consequences of using this framework.	1.00	7.00	2.41	1.35	1.82	210
15	The results of using this framework are apparent to me.	1.00	7.00	2.58	1.42	2.01	210
16	I would have a hard time explaining why or why no using this framework is beneficial.	1.00	7.00	3.21	1.79	3.22	210

#	Question	Strongly agree		Agree		Somewhat agree		Neither agree nor disagree		Somewhat disagree		Disagree		Strongly disagree		Total
1	People who influence my behavior believe that I should use a framework in communicating my organization's digital transformation strategy.	27.14%	57	28.57%	60	16.67%	35	15.24%	32	7.14%	15	3.81%	8	1.43%	3	210
2	People who are important to me think that I should use a framework in building my organization's digital transformation strategy.	22.86%	48	30.00%	63	17.62%	37	14.29%	30	7.62%	16	5.24%	11	2.38%	5	210
3	Senior management within my organization support using tools like this.	33.81%	71	36.19%	76	12.38%	26	13.33%	28	1.90%	4	0.48%	1	1.90%	4	210

4	People within my organization who leverage tools like this seem to have more prestige and success than those who do not.	24.29%	51	30.00%	63	16.19%	34	20.95%	44	4.76%	10	2.38%	5	1.43%	3	210
5	High profile people within my organization use these frameworks to communication their ideas.	25.24%	53	32.86%	69	18.10%	38	12.38%	26	6.19%	13	2.38%	5	2.86%	6	210
6	Using frameworks and tools symbolizes competence and expertise within my organization.	27.62%	58	36.67%	77	15.71%	33	12.38%	26	3.81%	8	3.33%	7	0.48%	1	210
7	In my role, using digital transformation framework is important.	29.52%	62	33.33%	70	11.90%	25	11.90%	25	5.71%	12	4.76%	10	2.86%	6	210
8	In my role, it is relevant to use digital transformation frameworks and strategic roadmaps.	29.05%	61	30.48%	64	13.81%	29	15.24%	32	4.29%	9	4.76%	10	2.38%	5	210
9	Using digital transformation frameworks and strategic roadmaps is pertinent to my job-related tasks.	27.62%	58	31.90%	67	10.48%	22	12.86%	27	9.05%	19	4.76%	10	3.33%	7	210
10	The quality of output I get from using this framework is high.	25.71%	54	32.38%	68	14.76%	31	20.00%	42	3.33%	7	1.43%	3	2.38%	5	210
11	I have no problem with the quality of output I would get from using this framework.	26.19%	55	31.90%	67	20.95%	44	15.71%	33	2.38%	5	2.38%	5	0.48%	1	210
12	I would rate the results I would get from this using this framework as excellent.	26.67%	56	29.05%	61	15.71%	33	21.43%	45	3.33%	7	1.90%	4	1.90%	4	210
13	I have no problem sharing the results of using this framework.	25.71%	54	35.71%	75	21.90%	46	11.43%	24	2.38%	5	2.38%	5	0.48%	1	210
14	I believe I could communicate the consequences of using this framework.	28.10%	59	33.33%	70	20.95%	44	10.48%	22	3.33%	7	1.90%	4	1.90%	4	210
15	The results of using this framework are apparent to me.	24.76%	52	33.33%	70	17.62%	37	13.33%	28	7.14%	15	2.38%	5	1.43%	3	210
16	I would have a hard time explaining why or why no using this framework is beneficial.	21.43%	45	23.81%	50	10.95%	23	15.24%	32	17.14%	36	7.14%	15	4.29%	9	210

Bibliography

Aagaard, A. (2021). *Digital Maturity Assessment Tool*. School of Business and Social Sciences, Aarhis University. https://btech.au.dk/en/research/research-sections-and-centres/dbd/digital-maturity-assessment-tool/

Abu-Dalbouh, H. M. (2013). A questionnaire approach based on the technology acceptance model for mobile tracking on patient progress applications. *J. Comput. Sci.*, *9*(6), 763–770.

Aguilar, F. J. (1967). *Scanning the business environment*. New York: Macmillan.

Ajzen, I. (1991). The theory of planned behavior. Organizational Behavior and Human Decision Processes, 50(2), 179–211.

Alagarsamy, S., Kandasamy, R., Selvamani, D., & Latha, S. (2019). Applications of Internet of Things in Pharmaceutical Industry. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3441059

Andrieu, M. (2018, September 10). *Digital Transformation Frameworks: Why You Need One | Appian*. Appian Blog. https://www.appian.com/blog/digital-transformation-frameworks-why-you-need-one-and-how-to-get-going/

Andriole, S. (2021). *3 Main Reasons Why Big Technology Projects Fail – & Why Many Companies Should Just Never Do Them*. Forbes. https://www.forbes.com/sites/steveandriole/2021/03/25/3-main-reasons-why-big-technology-projects-fail---why-many-companies-should-just-never-do-them/

Anisimov, D. E., & Reshetnikov, I. S. (2011). Management aspects in MES implementation projects. *Automation & Remote Control*, *72*(6).

Anttonen, E., Harmik, B., Dubs, M., Helliwell, I., & Selva, J. (2017, February 17). *Digital plant maturity model (DPMM) v1: The development of a digital plant maturity model to aid transformation in biopharmaceutical manufacturing*. BioPhorum. https://www.biophorum.com/download/the-development-of-a-digital-plant-maturity-model-to-aid-transformation-in-biopharmaceutical-manufacturing/

Arden, N. S., Fisher, A. C., Tyner, K., Yu, L. X., Lee, S. L., & Kopcha, M. (2021). Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. *International Journal of Pharmaceutics*, *602*, 120554. https://doi.org/10.1016/j.ijpharm.2021.120554

Bartodziej, C. J. (2017). The concept industry 4.0. In *The concept industry 4.0* (pp. 27–50). Springer.

Bingham, A. (2017). *101 Design Methods – Actionable Books*. https://www.actionablebooks.com/en-ca/summaries/101-design-methods/

Bishop, D. (2020). Building a winning business case for standards adoption. *IEEE Engineering Management Review*, *48*(1), 14–17.

Boyce, P. (2021, February 6). *Complementary Goods Definition (8 Examples and Graph)—BoyceWire*. BoyceWire. https://boycewire.com/complementary-goods-definition/

Brown, C. V. (2003). The IT organization of the future. *Competing in the Information Age: Align in the Sand (Ed, Luftman, JN). Oxford University Press, New York, NY*, 191–207.

Bumann, J., & Peter, M. (2019). *Action Fields of Digital Transformation—A Review and Comparative Analysis of Digital Transformation Maturity Models and Frameworks* (pp. 13–40).

CB Insights Research. (2018, September 13). *Where Big Tech is Placing Bets on Healthcare Investments | CB Insights*. CB Insights Research. https://www.cbinsights.com/research/top-tech-companies-healthcare-investments-acquisitions/

Centers for Disease Control and Prevention. (2022). *Centers for Disease Control and Prevention*. https://www.cdc.gov/

Chakraborty, M., & Al Rashdi, S. (2018). Venkatesh et al.'s Unified Theory of Acceptance and Use of Technology (UTAUT)(2003). In *Technology adoption and social issues: Concepts, methodologies, tools, and applications* (pp. 1657–1674). IGI Global.

Chen, B., Wan, J., Shu, L., Li, P., Mukherjee, M., & Yin, B. (2018). Smart Factory of Industry 4.0: Key Technologies, Application Case, and Challenges. *IEEE Access*, *6*, 6505–6519. https://doi.org/10.1109/ACCESS.2017.2783682

Colli, M., Berger, U., Bockholt, M., Madsen, O., Møller, C., & Wæhrens, B. V. (2019). A maturity assessment approach for conceiving context-specific roadmaps in the Industry 4.0 era. *Annual Reviews in Control*, *48*, 165–177.

Coundouris, A. (2020, December 2). *Top 5 digital transformation frameworks in 2020*. Run Frictionless. https://runfrictionless.com/blog/top-5-digital-transformation-frameworks-2020/

Craven, J. (2021, February 26). *COVID-19 vaccine tracker*. https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker

Dalenogare, L. S., Benitez, G. B., Ayala, N. F., & Frank, A. G. (2018). The expected contribution of Industry 4.0 technologies for industrial performance. *International Journal of Production Economics*, *204*, 383–394.

DAlleva, N. (2019, July 12). *12 Best Outsourcing Quotes of All Time*. SAS Call Center. https://www.sascallcenter.com/12-of-the-best-quotes-about-outsourcing/

Davis, F., Bagozzi Richard, P., & Warshaw Paul, R. (1989). User acceptance of computer technology: A comparison of two theoretical models. *Management Science*, *35*(8), 982–1003.

De Carolis, A., Macchi, M., Negri, E., & Terzi, S. (2017). *A maturity model for assessing the digital readiness of manufacturing companies*. 13–20.

Deshmukh, A. (2021, September 17). *Visualizing the World's Biggest Pharmaceutical Companies*. Visual Capitalist. https://www.visualcapitalist.com/worlds-biggest-pharmaceutical-companies/

Desjardins, J. (2019, January 30). *Visualizing the Future of the Pharma Market*. Visual Capitalist. https://www.visualcapitalist.com/future-pharma-market/

Dilmegani, C. (2021, April 18). *Digital Transformation: What it is, case studies & best practices*. https://research.aimultiple.com/digital-transformation/

Ding, B. (2018). Pharma industry 4.0: Literature review and research opportunities in sustainable pharmaceutical supply chains. *Process Safety and Environmental Protection*, *119*, 115–130.

Diwan, M., & Changi, S. M. (2019). Forum Plenary: Opportunities and Challenges with Journey from Industry 4.0 to Pharma 4.0 (Invited Talks). *2019 AIChE Annual Meeting*.

Doil, F., Schreiber, W., Alt, T., & Patron, C. (2003). Augmented reality for manufacturing planning. *Proceedings of the Workshop on Virtual Environments 2003*, 71–76. https://doi.org/10.1145/769953.769962

Drucker, P. F. (1994a). The theory of the business. *Alfred P. Sloan: Critical Evaluations in Business and Management*, *2*, 258–282.

Drucker, P. F. (1994b, September 1). The Theory of the Business. *Harvard Business Review*. https://hbr.org/1994/09/the-theory-of-the-business

Dutton, G. (2019, August 1). Smart Manufacturing Widens Pharma's Horizons. *GEN - Genetic Engineering and Biotechnology News*. https://www.genengnews.com/on-your-radar/smart-manufacturing-widens-pharmas-horizons/

Emmerson Process Management. (2021). *DeltaV Life Sciences | Emerson US*. https://www.emerson.com/en-us/automation/brands/deltav/deltav-systems-life-science-solutions

Ernst & Young. (2017, May 10). *How to manage disruptions to gain competitive advantage*. https://www.ey.com/en_us/life-sciences/how-to-manage-disruptions-to-gain-competitive-advantage

ETCIO. (2016, July 25). *Convergence of IT & OT: A new business imperative to fortify information security - ET CIO*. ETCIO.Com. http://cio.economictimes.indiatimes.com/news/digital-security/convergence-of-it-ot-a-new-business-imperative-to-fortify-information-security/53374920

Filipov, V., & Vasilev, P. (2016). MANUFACTURING OPERATIONS MANAGEMENT – THE SMART BACKBONE OF INDUSTRY 4.0. *Industry 4.0*, *1*(1), 19–24.

Fletcher, E. R. (2022, February 16). *BioNTech To Ship Modular MRNA Vaccine Facilities In Containers To African Countries To Jump-start Production—Health Policy Watch*. Health Policy Watch Independent Global Health Reporting. https://healthpolicy-watch.news/biontech-to-set-up-modular-mrna-vaccine-production-facilities-in-africa/

Ford, J. (2020, August 24). *Biopharma leaders prioritize R&D, technological transformation, and global market presence*. Deloitte Insights. https://www2.deloitte.com/us/en/insights/industry/life-sciences/pharmaceutical-industry-trends.html

Foroohar, R. (2019). *Don't be Evil: How Big Tech Betrayed Its Founding Principles—And All of Us*. Broadway Business.

Frank, A. G., Dalenogare, L. S., & Ayala, N. F. (2019). Industry 4.0 technologies: Implementation patterns in manufacturing companies. *International Journal of Production Economics, 210*, 15–26.

Geschke, M. (2017, March 17). *The 5 Stages of Digital Transformation Maturity in Mid-Sized Businesses*. https://www.xuviate.com/5-stages-of-digital-transformation-maturity-in-mid-sized-businesses/

Gilgeous, V., & Gilgeous, M. (1999). A framework for manufacturing excellence. *Integrated Manufacturing Systems, 10*(1), 33–44. https://doi.org/10.1108/09576069910247582

Gill, M., & VanBoskirk, S. (2016). The digital maturity model 4.0. *Benchmarks: Digital Transformation Playbook*.

Gimpel, H., Hosseini, S., Huber, R., Probst, L., Röglinger, M., & Faisst, U. (2018). Structuring digital transformation: A framework of action fields and its application at ZEISS. *Journal of Information Technology Theory and Application (JITTA)*, *19*(1), 3.

GlobalData Healthcare. (2022, May 3). Top 20 biopharmaceutical companies hold their spot despite market cap drop in Q1 2022. *Pharmaceutical Technology*. https://www.pharmaceutical-technology.com/comment/top-20-biopharmaceutical-companies/

Godoe, P., & Johansen, T. (2012). Understanding adoption of new technologies: Technology readiness and technology acceptance as an integrated concept. *Journal of European Psychology Students*, *3*(1), Article 1. https://doi.org/10.5334/jeps.aq

Gregor, S. (2006). The nature of theory in information systems. *MIS Quarterly*, 611–642.

Gregor, S., & Hevner, A. R. (2013). Positioning and presenting design science research for maximum impact. *MIS Quarterly*, 337–355.

Gurbaxani, V., & Dunkle, D. (2019). Gearing up for successful digital transformation. *MIS Quarterly Executive*, *18*(3).

Hair, J. F., Risher, J. J., Sarstedt, M., & Ringle, C. M. (2019). When to use and how to report the results of PLS-SEM. *European Business Review*, *31*(1), 2–24.

Hair Jr, J. F., Hult, G. T. M., Ringle, C. M., & Sarstedt, M. (2021). *A primer on partial least squares structural equation modeling (PLS-SEM)*. Sage publications.

He, D., Lobov, A., & Martinez Lastra, J. L. (2021). ISA-95 Tool for Enterprise Modeling. *Proceeding of ICONS*.

Hevner, A. R., March, S. T., Park, J., & Ram, S. (2004). Design science in information systems research. *MIS Quarterly*, 75–105.

Hitomi, K. (1996). Manufacturing excellence for 21st century production. *Technovation*, *16*(1), 33–41. https://doi.org/10.1016/0166-4972(95)00018-6

Hornik, R., Ajzen, I., & Albarracín, D. (2007). An extension of the theory of reasoned action and its successors to multiple behavior interventions. *Predicting Change in a Health Behavior: Applying a Reasoned Action Approach. Mahwah: Lawrence Erlbaum Associates*, 53–67.

Hozdić, E. (2015). *SMART FACTORY FOR INDUSTRY 4.0: A REVIEW*. 8.

Hughes, A. (2017, March). *The Seven Lives of Manufacturing Operations Management (MOM)*. https://blog.lnsresearch.com/the-seven-lives-of-manufacturing-operations-management

Hugos, M. H. (2009). *Business agility: Sustainable prosperity in a relentlessly competitive world*. John Wiley and Sons.

Hugos, M. H. (2018). *Essentials of supply chain management*. John Wiley & Sons.

Irwin, A., & Nkengasong, J. (2021). What it will take to vaccinate the world against COVID-19. *Nature*, *592*(7853), 176–178.

ISA. (2021). *ISA95, Enterprise-Control System Integration- ISA*. https://www.isa.org/standards-and-publications/isa-standards/isa-standards-committees/isa95

ISPE. (2018). *Pharma 4.0™: Hype or Reality?* ISPE | International Society for Pharmaceutical Engineering. https://ispe.org/pharmaceutical-engineering/july-august-2018/pharma-40tm-hype-or-reality

ISPE. (2021). *Pharma 4.0™*. ISPE | International Society for Pharmaceutical Engineering. https://ispe.org/initiatives/pharma-4.0

Jones, K. (2020, December 18). *The Race to Save Lives: Comparing Vaccine Development Timelines*. Visual Capitalist. https://www.visualcapitalist.com/the-race-to-save-lives-comparing-vaccine-development-timelines/

Joshi, A., Kale, S., Chandel, S., & Pal, D. K. (2015). Likert scale: Explored and explained. *British Journal of Applied Science & Technology*, *7*(4), 396.

Josimovski, S., Mijoska, M., & Jovevski, D. (2017). Digital Maturity Assessment in the Banking Industry in the Republic of Macedonia. *International Journal–Knowledge*.

Kapetaneas, N., & Kitsios, F. (2022). Digital Transformation Approach to Public Hospitals Environment: Technology Acceptance Model for Business Intelligence Applications. In M. Themistocleous & M. Papadaki (Eds.), *Information Systems* (pp. 453–462). Springer International Publishing. https://doi.org/10.1007/978-3-030-95947-0_32

Kavadias, S., Ladas, K., & Loch, C. (2016). The transformative business model. *Harvard Business Review*, *94*(10), 91–98.

Kesselheim, A. S., Avorn, J., & Sarpatwari, A. (2016). The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *JAMA*, *316*(8), 858. https://doi.org/10.1001/jama.2016.11237

Kimberling, E. (2020, September 18). How to Write the Perfect Business Case for your Digital Transformation. *Third Stage Consulting Group*. https://www.thirdstage-consulting.com/how-to-write-the-perfect-business-case/

Kock, N. (2015). Common method bias in PLS-SEM: A full collinearity assessment approach. *International Journal of E-Collaboration (Ijec)*, *11*(4), 1–10.

Koop, A. (2021, August 17). *When Will Your Country Recover from the Pandemic?* Visual Capitalist. https://www.visualcapitalist.com/when-will-your-country-recover-from-the-pandemic/

Korachi, Z., & Bounabat, B. (2020). General Approach for Formulating a Digital Transformation Strategy. *Journal of Computer Science*, *16*, 493–507. https://doi.org/10.3844/jcssp.2020.493.507

Kozak-Holland, M., & Procter, C. (2019). *Managing transformation projects: Tracing lessons from the industrial to the digital revolution*. Springer.

Kozak-Holland, M., & Procter, C. (2020). The Challenge of Digital Transformation. In *Managing Transformation Projects* (pp. 1–11). Springer.

Kumar, S. H., Talasila, D., Gowrav, M. P., & Gangadharappa, H. V. (2020). Adaptations of Pharma 4.0 from Industry 4.0. *Drug Invention Today*, *14*(3).

Kumar, V. (2012). *101 design methods: A structured approach for driving innovation in your organization*. John Wiley & Sons.

Lasi, H., Fettke, P., Kemper, H.-G., Feld, T., & Hoffmann, M. (2014). Industry 4.0. *Business & Information Systems Engineering*, *6*(4), 239–242.

LePan, N. (2020, March 14). *Visualizing the History of Pandemics*. Visual Capitalist. https://www.visualcapitalist.com/history-of-pandemics-deadliest/

Lucke, D., Constantinescu, C., & Westkämper, E. (2008). Smart Factory—A Step towards the Next Generation of Manufacturing. In M. Mitsuishi, K. Ueda, & F. Kimura (Eds.), *Manufacturing Systems and Technologies for the New Frontier* (pp. 115–118). Springer. https://doi.org/10.1007/978-1-84800-267-8_23

Mabkhot, M. M., Al-Ahmari, A. M., Salah, B., & Alkhalefah, H. (2018). Requirements of the Smart Factory System: A Survey and Perspective. *Machines*, *6*(2), Article 2. https://doi.org/10.3390/machines6020023

Macdonald, G. J. (2020). Biomanufacturing Makes Sense of the Industry 4.0 Concept. *Genetic Engineering & Biotechnology News*, *40*(S3), S7–S10. https://doi.org/10.1089/gen.40.S3.03

Männistö, T. (2020). *Methods of SE Research—Design Science*.

Mao, Q., Xu, M., He, Q., Li, C., Meng, S., Wang, Y., Cui, B., Liang, Z., & Wang, J. (2021). COVID-19 vaccines: Progress and understanding on quality control and evaluation. *Signal Transduction and Targeted Therapy*, *6*(1), 1–7.

Markarian, J. (2018). Pharma 4.0. *Pharmaceutical Technology*, *42*(4), 24–24.

Matt, C., Hess, T., & Benlian, A. (2015). Digital Transformation Strategies. *Business & Information Systems Engineering*, *57*(5), 339–343. https://doi.org/10.1007/s12599-015-0401-5

Maufacturing Chemist. (2019, April 9). *Why you need PAT to move from batch to continuous processing*. https://manufacturingchemist.com/news/article_page/Why_you_need_PAT_to_move_from_batch_to_continuous_processing/153593

Maureen, S. (2016, August 24). Extended technology acceptance model (TAM2) [Personality & TKMS series]. *RealKM*. https://realkm.com/2016/08/24/extended-technology-acceptance-model-tam2-personality-tkms-series/

McAfee, G. W., Didier Bonnet, and Andrew. (2014, January 7). *The Nine Elements of Digital Transformation*. MIT Sloan Management Review. https://sloanreview.mit.edu/article/the-nine-elements-of-digital-transformation/

McClellan, M. (1997). *Applying Manufacturing Execution Systems*. CRC Press.

McClellan, M. (2002). *Collaborative manufacturing: Using real-time information to support the supply chain*. CRC Press.

Menear, H. (2020). The history of digital transformation. *Technology*, *17*.

Morakanyane, R., O'Reilly, P., McAvoy, J., & Grace, A. (2020). *Determining digital transformation success factors*. Proceedings of the 53rd Hawaii International Conference on System Sciences.

Narain, N. R. (2016, August 18). *An Industry Overdue for Disruption*. Drug Discovery and Development. https://www.drugdiscoverytrends.com/an-industry-overdue-for-disruption/

Nee, A. Y. C., Ong, S. K., Chryssolouris, G., & Mourtzis, D. (2012). Augmented reality applications in design and manufacturing. *CIRP Annals*, *61*(2), 657–679. https://doi.org/10.1016/j.cirp.2012.05.010

Nelson, R. R. (2005). *Project Retrospectives: Evaluating Project Success, Failure, and Everything in Between*. 13.

Nelson, R. R. (2007). IT project management: Infamous failures, classic mistakes, and best practices. *MIS Quarterly Executive*, *6*(2).

Nemudryi, A., Valetdinova, K., Medvedev, S., & Zakian, S. (2014). TALEN and CRISPR/Cas genome editing systems: Tools of discovery. *Acta Naturae (Англоязычная Версия)*, *6*(3 (22)), 19–40.

Nwaiwu, F. (2018). Review and Comparison of Conceptual Frameworks on Digital Business Transformation. *Journal of Competitiveness*, *10*(3), 86–100. https://doi.org/10.7441/joc.2018.03.06

Osterholm, M. T. (2007). Unprepared for a pandemic. *Foreign Aff.*, *86*, 47.

Peffers, K., Tuunanen, T., Rothenberger, M. A., & Chatterjee, S. (2007). A design science research methodology for information systems research. *Journal of Management Information Systems*, *24*(3), 45–77.

Persistence Market Research. (2015). *Life Science Market: Global Industry Analysis and Forecast 2016 - 2024*. Persistence Market Research. http://www.persistencemarketresearch.com/market-research/life-science-market.asp

Peters, D., Calvo, R. A., & Ryan, R. M. (2018). Designing for Motivation, Engagement and Wellbeing in Digital Experience. *Frontiers in Psychology*, *9*. https://doi.org/10.3389/fpsyg.2018.00797

Prajwal, A. T., Muddukrishna, B. S., & Vasantharaju, S. G. (2020). Pharma 4.0–impact of the internet of things on health care. *International Journal of Applied Pharmaceutics*, *12*(5), 64–69.

Pratt, M. K. (2021, March 3). *Why IT projects still fail*. CIO. https://www.cio.com/article/3211485/why-it-projects-still-fail.html

Proclinical. (2021). *Life sciences*. Proclinical. http://www.proclinical.com/life-sciences

Rashid, A., & Tjahjono, B. (2016). Achieving manufacturing excellence through the integration of enterprise systems and simulation. *Production Planning & Control*, *27*(10), 837–852. https://doi.org/10.1080/09537287.2016.1143132

Ringle, C. M., Wende, S., & Becker, J.-M. (2015). *SmartPLS 3*. SmartPLS GmbH. http://www.smartpls.com

Rogers, B. (2016). *Why 84% Of Companies Fail At Digital Transformation*. Forbes. https://www.forbes.com/sites/brucerogers/2016/01/07/why-84-of-companies-fail-at-digital-transformation/

Rogers, D. L. (2016). *The Digital Transformation Playbook: Rethink Your Business for the Digital Age*. Columbia University Press.

Rossmann, A. (2018). *Digital maturity: Conceptualization and measurement model*.

Sainger, G. (2018). *Leadership in Digital Age: A Study on the Role of Leader in this Era of Digital Transformation*. *6*(1), 7.

Sarstedt, M., Ringle, C. M., Cheah, J.-H., Ting, H., Moisescu, O. I., & Radomir, L. (2020). Structural model robustness checks in PLS-SEM. *Tourism Economics*, *26*(4), 531–554.

Sauro, J. (2019, May 8). *10 Things to Know about the Technology Acceptance Model – MeasuringU*. https://measuringu.com/tam/

Schallmo, D. R., & Williams, C. A. (2018). History of digital transformation. In *Digital Transformation Now!* (pp. 3–8). Springer.

Schlingman, J. (2021, June 7). Four International Pandemics That Occurred Prior to COVID-19. *Dark Daily*. https://www.darkdaily.com/2021/06/07/four-international-pandemics-that-occurred-prior-to-covid-19/

Scholten, B. (2007). Integrating ISA-88 and ISA-95. *ISA EXPO*, 13.

Schuh, G., Anderl, R., Gausemeier, J., ten Hompel, M., & Wahlster, W. (2017). Industrie 4.0 maturity index. *Managing the Digital Transformation of Companies. Munich: Herbert Utz*.

Sharma, D. K., Bhargava, S., & Singhal, K. (2020). Internet of Things applications in the pharmaceutical industry. In *An Industrial IoT Approach for Pharmaceutical Industry Growth* (pp. 153–190). Elsevier.

Sharma, M., & Kodali, R. (2008). Development of a framework for manufacturing excellence. *Measuring Business Excellence*, *12*(4), 50–66. https://doi.org/10.1108/13683040810919962

Tian, W., Wang, M., & Wang, Q. (2022). *The Core Competentness of Apple Inc*. 718–725.

Tichy, E. M., Hoffman, J. M., Suda, K. J., Rim, M. H., Tadrous, M., Cuellar, S., Clark, J. S., Wiest, M. D., Matusiak, L. M., & Schumock, G. T. (2021). National trends in prescription drug expenditures and projections for 2021. *American Journal of Health-System Pharmacy: AJHP*, *78*(14), 1294–1308. https://doi.org/10.1093/ajhp/zxab160

Tiersky, H. (2017, March 13). *5 top challenges to digital transformation in the enterprise*. CIO. https://www.cio.com/article/3179607/5-top-challenges-to-digital-transformation-in-the-enterprise.html

Torabi, N. (2020, June 5). *A strategic framework for successful Digital Transformations*. Medium. https://medium.com/swlh/a-framework-for-successful-digital-transformation-b5432e325fb5

Trevor. (2017, October 24). Pharma 4.0 how Industry 4.0 impacts on the pharmaceutical industry! *PharmOut*. https://www.pharmout.net/pharma-4-0/

Tucci, L. (2021, March 10). *Ultimate Guide to Digital Transformation for Enterprise Leaders*. SearchCIO. https://searchcio.techtarget.com/feature/Ultimate-guide-to-digital-transformation-for-enterprise-leaders

Turner, M., Kitchenham, B., Brereton, P., Charters, S., & Budgen, D. (2010). Does the technology acceptance model predict actual use? A systematic literature review. *Information and Software Technology*, *52*(5), 463–479.

University of St. Gallen, Kiselev, C., Winter, R., University of St. Gallen, Rohner, P., & University of St. Gallen. (2020). Project Success Requires Context-Aware Governance. *MIS Quarterly Executive*, 199–211. https://doi.org/10.17705/2msqe.00033

Unver, H. O. (2013). An ISA-95-based manufacturing intelligence system in support of lean initiatives. *The International Journal of Advanced Manufacturing Technology*, *65*(5), 853–866. https://doi.org/10.1007/s00170-012-4223-z

U.S. Bureau of Labor Statistics. (2021, July 8). *6.2 million unable to work because employer closed or lost business due to the pandemic, June 2021: The Economics Daily: U.S. Bureau of Labor Statistics*. https://www.bls.gov/opub/ted/2021/6-2-million-unable-to-work-because-employer-closed-or-lost-business-due-to-the-pandemic-june-2021.htm

Vagelos, P. R. (1991). Are Prescription Drug Prices High? *Science, New Series*, *252*(5009), 1080–1084.

Venkatesh, V., & Davis, F. D. (2000). A theoretical extension of the technology acceptance model: Four longitudinal field studies. *Management Science*, *46*(2), 186–204.

Venkatesh, V., Morris, M. G., Davis, G. B., & Davis, F. D. (2003). User acceptance of information technology: Toward a unified view. *MIS Quarterly*, 425–478.

Verdict Media Limited. (2020, December 8). *Pharma—Poll # 39 – In-person physician interactions with Pharma Reps*. https://survey.alchemer.eu/s3/90337837/Pharma-Poll-39-In-person-physician-interactions-with-Pharma-Reps

Virkkala, P., Saarela, M., Hänninen, K., & Simunaniemi, A.-M. (2020). Business Maturity Models for Small and Medium-Sized Enterprises: A Systematic Literature Review. *Management*, *20*, 22.

VirtualArmour. (2019, November 15). *Operational Technology vs. Information Technology: Differences, Similarities, & How the Intermix With Industrial Control Systems | VirtualArmour*. https://www.virtualarmour.com/operational-technology-vs-information-technology-differences-similarities-how-the-intermix-with-industrial-control-systems/

Wagire, A. A., Joshi, R., Rathore, A. P. S., & Jain, R. (2020). Development of maturity model for assessing the implementation of Industry 4.0: Learning from theory and practice. *Production Planning & Control*, *0*(0), 1–20. https://doi.org/10.1080/09537287.2020.1744763

Westerman, G., Bonnet, D., & McAfee, A. (2014). The nine elements of digital transformation. *MIT Sloan Management Review*, *55*(3), 1–6.

Williams, C., Schallmo, D., Lang, K., & Boardman, L. (2019). Digital maturity models for small and medium-sized enterprises: A systematic literature review. *ISPIM Conference Proceedings*, 1–15.

Wingo, N. P., Ivankova, N. V., & Moss, J. A. (2017). Faculty Perceptions about Teaching Online: Exploring the Literature Using the Technology Acceptance Model as an Organizing Framework. *Online Learning*, *21*(1). https://doi.org/10.24059/olj.v21i1.761

Yang, Tom, Shah, Sonal, & Chang, Christine. (2020, March 23). *The future of the pharmaceutical industry | Deloitte Insights*. Deloitte. https://www2.deloitte.com/us/en/insights/industry/health-care/future-of-pharmaceutical-industry.html

Yucel, S. (2018). Modeling Digital Transformation Strategy. *2018 International Conference on Computational Science and Computational Intelligence (CSCI)*, 221–226. https://doi.org/10.1109/CSCI46756.2018.00049

Yue, L., Wang, Z., Fang, Y., & Han, Z. (2020). *Implementation of Smart Manufacturing Maturity Assessment Framework: A Socio-Technical Perspective*. *179*, 02023.