Role and perceptions about communication: The case of new product development in the animal health industry

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B.S., Iowa State University, 2003

A THESIS

Submitted in partial fulfillment of the requirements

for the degree

MASTER OF AGRIBUSINESS

Department of Agricultural Economics

College of Agriculture

KANSAS STATE UNIVERSITY

Manhattan, Kansas

2018

Approved by:

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ABSTRACT

The development of vaccines and similar pharmaceutical products in the animal health industry are expensive and follow very specific pathways to comply with regulatory requirements for product licensure and registration. The vaccine development process is complex and involves numerous individuals, assets and departments within and outside the organization, and is a long process. The study stage of this long and complex process allows a company to confirm particular solutions to particular health incidents can be efficacious.

The study stage involves executives who decide on new products that may be developed, managers who oversee the development of the products and scientists who develop protocols to undertake animal studies to test various aspects of the new product. It also involves clinical study personnel and laboratory personnel who conduct the experiments and collect data for analyses about the new products being studied. The number of people and time sensitivity of the processes contribute to the complexity, making effective communication critical to getting new products developed on time and on budget. The objective of this research is to identify perceived gaps in communication among people in the different roles with the view to finding solutions to address these gaps.

Data were collected using an industry-focused online survey instrument. The instrument was designed to have both closed and open-ended questions. Survey participants were purposefully selected from across the global animal health industry, focusing on those directly involved in the study stage of new product development. The

results showed the majority of respondents were satisfied with their company's processes and systems for study development, initiation and execution, but people resources were viewed as the highest contributor to bottlenecks, which could demonstrate gaps in the communication links between groups. However, perceptions about challenges and gaps in communication seem to be influenced by who is providing information and who is receiving it. The different roles perceived the effect of timeliness, accuracy and clarity of communication on product development costs differently, with scientists presenting the highest cost of communication challenges and executives the lowest. On average, the perception was that these communication challenges increased the cost at the study stage of new product development by about 84% for biologicals and over 100% for pharmaceuticals.

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ACKNOWLEDGMENTS

I thank my wife for all of her love, support, and understanding over the last few years. I know it has not been easy. I would also like to thank the Masters of Agribusiness staff - Deborah Kohl, Mary Bowen, Gloria Burgert, and Program Director, Dr. Featherstone for creating and maintaining such an excellent Graduate Program. Finally, I would like to thank Dr. Vincent Amanor-Boadu for being such a great major professor and helping me take my understanding of economics and strategic thinking to a higher level.

CHAPTER I: INTRODUCTION

Animal vaccine sales in the U.S. have grown steadily over the past few decades. For example, between 2001 and 2010, animal vaccine sales increased from approximately $4.5 billion to about $5.5 billion (AHI 2016). Animal vaccine sales are estimated to reach $7.2 billion by 2020 (Hopkins 2016), and roughly one-third of the animal health industry's revenue is from vaccines with 80 billion doses of vaccine produced annually in the United States (AHI 2016). In 2015, the top ten animal health companies had combined revenues (vaccine and pharmaceutical products) of $20.87 billion with the top three companies (Zoetis, Merck Animal Health, Eli Lilly's Elanco) accounting for 54% of that (Weintraub 2016), an indication of the industry's concentration.

The vaccine development process is complex and involves many individuals, requiring numerous assets and capabilities both within and outside the organization. Vaccine licensure may take anywhere from five to seven years, and an additional one and a half to three years for regulatory approval (IFAH 2008). As a result of the foregoing, the process can be very expensive for animal health companies, costing anywhere from $4 million to $30 million for each developed vaccine that receives regulatory approval (Christmas 2016).

Vaccine production costs may be organized into two major categories: research and development costs; and manufacturing and distribution costs. The focus of this research is on the former. The number of people and departments involved in the development process implies there are real transaction costs that are often not accounted for in development costs. Communication and information flows influence these transaction costs in various

ways. A few of these transaction costs are: visibility of upcoming studies; inconsistent study throughput causing peaks and valleys in the study pipeline; personnel working on tasks in duplicate; incorrect sample collection/preparedness; inconsistent clinical observations; and inadequate number of personnel needed for the study conducted. Inadequate communication can result in rework of processes or steps in the development process. Rework may encompass activities such as a change in facilities, rooms, and study-specific animal room set-up. Specific challenges that contribute to these transaction costs are key stakeholders being left out of communication chains, lack of timely communication of study plans/timeline changes, and communications through email being misunderstood. Others are wrong stakeholders in discussions; too many stakeholders involved at the wrong time; unpredictable problems with equipment, facilities, or experimental products; and tasks not completed in a timely manner, such as a finalized protocol(s), or facilities not prepared for animal receipt.

1.1 Research Problem

The potential lack of visibility, coordination and communication results in either bottlenecks with people and facility resources or excess capacity with people and facility resources not fully utilized. This dilemma inhibits a smooth flow through the product development process. The potential consequences may include less animal studies conducted, increased errors in the animal phase causing rework, animal welfare concerns, lost time to market, and costs associated with underutilized facilities and personnel. In-life phase personnel are responsible for the setup of and the conduct of *in-vivo* phases of the animal studies, but the information to perform these activities are dependent upon reliable and timely information from managers and project leaders, scientists and/or laboratory personnel. The scientists are also dependent upon reliable and timely information from

managers and project leaders. While inadequate communication has been identified as a potential risk in vaccine development, to what extent do those involved in vaccine development see it as a problem? This is the motivating problem of this research.

1.2 Research Objectives

The overall objective of this research is to identify and rate the perceptions of individuals involved in the vaccine development process about the gaps in communication and in the coordination of information flow. The specific objectives are as follows:

1. Describe the vaccine product development process currently being used in the animal health industry, emphasizing the communication processes that ensures effectiveness of the process;
2. Determine how different groups in the vaccine development chain of the animal health industry view current communication processes and their perceptions about gaps in their communication processes; and
3. Present how industry participants see how identified communication gaps may be addressed and test if they differ across groups in the vaccine development chain; and
4. Use the results to develop recommendations for improving communication along the vaccine development chain.

1.3 Methods Overview and Thesis Outline

To achieve the foregoing objectives, we used a structured questionnaire to collect data on perceptions of industry players on the vaccine development process in the animal health industry. The results were analyzed using Stata 14™ to achieve the second through

fourth objectives. Objective 1 was achieved using the literature and the researcher's experience.

The next chapter presents the literature review guiding the study. It covers the state of the animal health industry and describes the vaccine development process and its related quality assurance and communication system. The third chapter presents a detailed overview of the data and the collection process, the analytical methods used, the theoretical foundations of the study, and the hypotheses that motivated the study. The results from the study are presented in Chapter 4 and the summary, conclusions and recommendations are presented in Chapter 5.

CHAPTER II: LITERATURE REVIEW

In this chapter, we present a summary of the relevant literature forming the foundation of this study. First, we provide an overview of the animal health industry's state in terms of its structure and performance. This is followed by a description of the vaccine development process and its challenges in the US industry. The section following that reviews the literature on communication effectiveness and its contribution to organizational competitiveness, linking it to vaccine and other animal health product development.

2.1 The State of the Animal Health Industry

The animal health industry is very concentrated. In 2014, the Concentration Ratio for the top four players (CR_4) in the industry accounted for 61% of sales, and the top ten players (CR_{10}) was 86% (PwC 2015). In 2015, the top ten companies in the animal health industry combined for a total of $20.87 billion in revenues. The top three companies alone accounted for $11.27 billion of this amount (Weintraub 2016). The industry has been refocusing on vaccines as opposed to antibiotics. A study in 2015 estimated the global animal vaccine market will be worth $7.2 billion by 2020, from $5.5 billion in 2010 (Hopkins 2016).

The major product groups in the animal health industry are pharmaceutical drugs and biologics. The latter is grouped into antibiotics and vaccines. Vaccines are a major component of the animal health industry, accounting for about a third of the industry's revenue. As the role of antibiotics in combating diseases decreases as a result of antibiotic resistance concerns, vaccines are becoming more important (Hopkins 2016). Vaccine use by animal owners is driven by cost for livestock producers and by other non-cost factors (e.g., emotions) by companion animal owners (HealthforAnimals, Oxford Analytica 2016).

Because of the importance of cost considerations in vaccine use in both livestock and companion animals, it is imperative for companies within the industry to focus on enhancing cost effectiveness in their production processes.

Competitive pressures in the industry have contributed to merger and acquisition (M&A) trends. Traditional M&A and lifecycle management for innovation could be diminishing for the top players in the animal health industry. As of 2015, the decrease in innovation has led to mature product portfolios with the average portfolio age being 15 years old for the top animal health players. The top ten animal health companies accounted for 86% of global sales, which limits M&A opportunities due to antitrust concerns. Weakened potential in the M&A arena puts pressure on profits, therefore increasing the importance of operational efficiency in the short-term.

Another value driver in the animal health industry is portfolio advantage and commercial excellence that includes having product portfolio breadth and/or depth, and maintaining focus on supply chain quality and efficiency. Large food producers (like Tyson Foods) play a major role in the products developed by the animal health industry, especially as producers move away from the use of antibiotics. Increasing revenue pressure may force animal health companies to revise their operating effectiveness to improve profitability (PwC 2015).

In this environment, the animal health industry may need to fill gaps in their portfolios and improve R&D productivity. They may need to focus on the different activities that affect all costs and efficiencies in their R&D processes. Understanding the issues related to enhancing efficiency in the R&D processes can be helpful in alleviating

pressure on profit margins. It could contribute to enhancing the competitiveness of firms that improve their ability in improving their operational efficiencies.

2.2 The Vaccine R&D Process in the Animal Health Industry

A vaccine is defined as “a preparation of killed microorganisms, living attenuated organisms, or fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease” (M. W. Dictionary 2017). An antibiotic is defined as “a substance produced by or semisynthetic substance from a microorganism and able in dilute solution to inhibit or kill another microorganism” (M. W. Dictionary 2017). In simpler terms, a vaccine stimulates the immune system to fight and/or prevent a viral or bacterial infection, whereas an antibiotic does not stimulate the immune system but is a semisynthetic substance that kills or inhibits the growth of another bacterial organism.

Livestock are fed approximately 80% of the antibiotics in the United States, and scientists’ state there is an association between the health of food animals and the human population with around 700,000 people dying annually from drug-resistant infections. The predominant use of antibiotics in livestock may contribute in those deaths because they permit super-bugs (microorganisms resistant to antibiotics) to flourish (Hopkins 2016). Due to the increase in antibiotic resistance, the animal health industry is working to become less dependent on antibiotics for animals with a focus on shifting to substitutes; one alternative being vaccines.

The development of vaccines (and similar pharmaceutical products) in the animal health industry is expensive and follows very specific pathways to comply with regulatory requirements for product licensure and registration. For the purposes of this research, development is defined as a process that begins with identification of vaccine need through

the research and development phases, to a solution, to product licensure by the Federal Government. The steps for vaccine development begins with identifying the specific microbe(s) for which a vaccine is needed, followed by initial passage (expansion culture of the microbe containing the antigen of interest), and then the purification/ characterization/cloning of the microbe. The second set of steps are the development of pre-master seed and master seed (cell line extensively tested for identity and purity, and eventually used for product manufacturing), which involves challenge models (studies used to ensure efficacy of the new vaccine) and proof of concept (PoC) models (demonstrates new vaccine proposal is feasible). After this come efficacy studies, field safety studies, pivotal studies, quality control (QC) testing (studies conducted in order to show the new vaccine is safe, efficacious in real world settings, and ready to be produced on a large scale by manufacturing), and dossier submission to the United States Department of Agriculture, Center for Veterinary Biologics (USDA-CVB). The final step is the product approval for licensure by the responsible government agencies.

Each of the steps described above encompasses several sub-steps. For example, during the development of the pre-master and master seed, scientists and laboratory personnel work the seed to maximize the passages and produce production batches for later use. This is completed by propagation and growth in the laboratory to optimize log expansion of the isolate. Sometimes the seed does not have the virulence necessary to produce desired results. When this happens, developers may use challenge models to enhance virulence. Challenge models can include the use of repeat passage and involves *in-vivo* studies in the target species to confirm virulence.

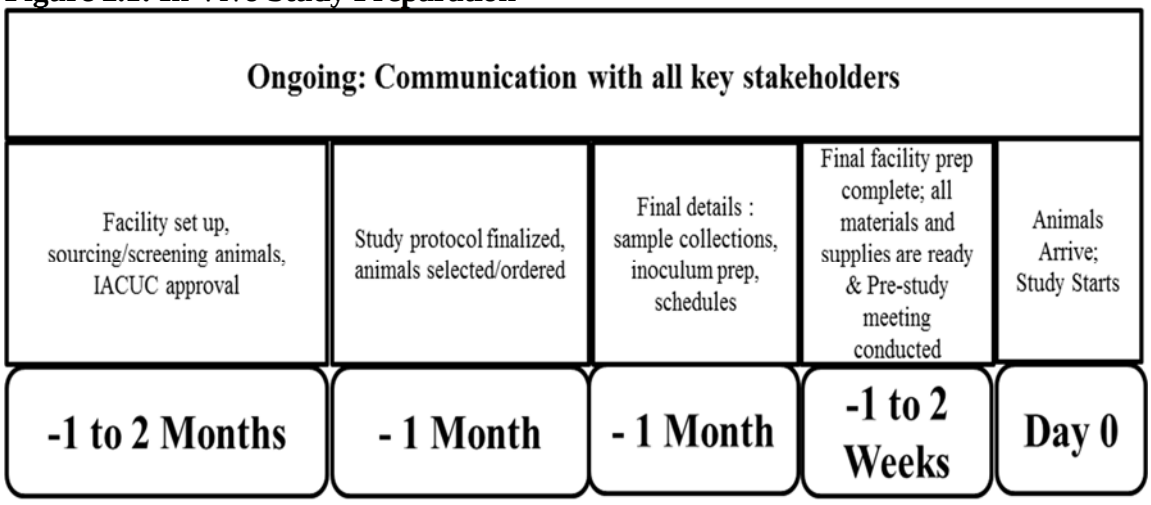
The process for an *in-vivo* challenge model study includes the following specific activities: ongoing communication between scientists, laboratory personnel, and (possibly) outside subject matter experts (SME's), with *in-vivo* study conduct personnel. This communication and planning for the study usually needs to begin at least two to three months prior to the planned study start date, or longer. Timelines, animal facilities, personnel, and animal availability must be coordinated with the study plan. This also includes writing the study protocol and Institutional Animal Care and Use (IACUC) protocols. The IACUC is a requirement under the USDA Animal Welfare Act (AWA). Each company in the vaccine development industry is required to have an IACUC committee. The IACUC committee's membership must include a chairman of the committee, a doctor of veterinary medicine with appropriate training or experience, and one individual who is not affiliated in any way with the research facility (Agriculture, Animal Welfare Act and Animal Welfare Regulations 2005). The IACUC committee is charged with inspecting facilities, preparing reports on animal welfare, and reviewing all proposed animal research activities (Agriculture, Animal Welfare Act and Animal Welfare Regulations 2005). This process safeguards the care, use, and welfare of all animals. Virtually all companies follow these regulations to ensure the 3 R's of animal research are followed: reduction, refinement, and replacement of animal use in research (Agriculture, 3Rs Alternatives: Technologies, and Approaches 2016).

One to two months prior to the planned animal study start date, facility set up and preparation, sourcing and screening the required animals from approved vendors begins, and IACUC protocol approval must be complete. During this timeframe, personnel responsible for the i*n-vivo* phase of the study are communicating regularly with the

scientists and the study scheduler to solidify the study start date and timelines. They are also coordinating with the appropriate personnel the resources needed in the facility, which will house the animals (type of feed, enrichment needs, size of enclosure, number of animals per enclosure, any special instructions, etc.). Approximately one month prior to the planned start date the study protocol is finalized and screened animals are selected and/or ordered. Communication between all personnel continues with final details worked out such as: sample collection quantities and types, material handling, on schedule inoculum preparation, and times of day for completing major study events.

Within one to two weeks of the planned study start date the final preparations for the facility are complete by ensuring all materials and supplies are ready, and the enclosure is setup according to study specifications. The facility with all materials and supplies may then be sanitized to allow the animals arrival into a clean, uncompromised environment. A pre-study meeting may take place with all personnel to confirm all parties know their role during the In-Life phase and all protocol requirements will be met. Finally, animals arrive and the study begins (Figure 2.1).

Figure 2.1: In Vivo Study Preparation



The conduct of challenge models, PoC/efficacy, and pivotal studies are all critical components needed for the eventual licensure of a vaccine. PoC/efficacy studies are conducted to ensure the candidate vaccines protect against the challenge isolate(s), thus determining the efficacy of the candidate vaccines. Upon completion of PoC/efficacy models, pivotal studies are completed with the candidate vaccine found to protect against the intended pathogen(s). The pivotal studies are conducted to demonstrate the safety, efficacy, and protection for the new vaccine label claims. This is the final study phase conducted in research & development (R&D) prior to preparing the dossier to be submitted to USDA-CVB. All three of these study categories are high cost and require a large amount of resources to be conducted efficiently and effectively. These include the need for animal, people, and facility resources.

Vaccine research and development (R&D) is driven by the innovation and its related processes used by the company. The R&D cycle times for vaccines can be as short as three years. This contrasts with pharmaceutical R&D cycles that can take a decade in some cases. Innovation in vaccine products in areas of unmet needs provide an opportunity for products with potential for sustaining long-term market profitability. Additional ways to improve R&D output include improvement of pipeline progression and success rates, and streamlining processes and procedures to reduce development costs (PwC 2015).

2.3 Current State of Veterinary Vaccine Development

Vaccines are becoming more important for front-line control with the increasing concerns of bacteria becoming resistant to antibiotics and for protecting humans from animal disease, also known as zoonosis (Chambers, Graham and La Ragione 2016). While cost data on vaccine development for people is challenging to obtain, it is even more

challenging to obtain for the animal health industry. However, the human pharma company, Aviron, reported a cost of $340 million for the development of their nasal flu vaccine (Francis 2010). On the human side, the investment/return ratio is important for governments and healthcare providers as they determine the desirability for a new vaccine (Leroux-Roels, et al. 2011). Recent trends in the animal health industry show that farm animal medicines have become more price sensitive, while companion animal medicines have increased in demand due to changing perceptions about companion animals. Similar to human pharma, due to investment/return ratios, it is also difficult for animal health companies to develop veterinary vaccines in which there is low incidence of disease (Heldens 2008). Although the scale and requirements of human vaccine development costs can be assumed as significantly different from veterinary vaccine development, one can conclude substantial investments are still required for developing veterinary vaccines.

Safety and efficacy studies that include vaccination/challenge work in the target animal species involves vaccinating the animal(s) with the new vaccine being developed and "challenging" the animal with the pathogen in which the new vaccine is meant to protect, are critical aspects needed for the licensing of veterinary vaccines. The USDA and Homeland Security acknowledge the need to have licensed vaccines available for important animal diseases not currently in the U.S. However, there are no companies that have licensed vaccines for these diseases due to the cost of development of a vaccine(s) not currently needed in the U.S. (Roth 2011). Keeping vaccine costs low for the market will encourage more vaccine use and less use of antibiotics and other antimicrobials. The industrial development of vaccines should be viewed in an economic environment, as the companies that produce these vaccines are in competition with each other (Heldens 2008).

2.4 Quality Assurance, Communication, and Development Chain Improvement

Due to limited literature available for supply chain process and procedure improvements of veterinary vaccine development; quality assurance, communication effectiveness and supply chain improvements are examined across various industries that have the possibility of implementation in veterinary vaccine development.

Developments in the food supply chain such as increased global trade and food quality require a more coordinated system to be more adaptable and agile in the face of competition. The more intricate and dynamic marketplace affects every level of the supply chain. The implementation of vertical integration favors transaction cost reductions. Risk reductions may also occur with vertical integration due to internal control and organization where large amounts of capital are required, such as people and facility resources, and where possibilities of shortages could occur and lead to waste of facility use. Vertical integration may also enable improved efficiency of processes and procedures to improve production. The disadvantages of vertical integration can include excess use of resources due to varying scale of operations at different stages of production that are needed for operational efficiency. There is also a great demand for capital with large investments needing to be offset by cost savings, or at least equal to opportunity costs of capital. Inflexibility of organizational structures is a disadvantage to vertical integration because of blunted incentives due to tightly connected and guaranteed linkages between the different stages within the integrated firm (Ziggers and Trienekens 1999).

Partnerships are important in improving productivity and success in supply chains. Innovation is needed to maintain permanence in terms of market share and throughput. Success in innovation is dependent upon distribution of power, agreement and alignment of

objectives, and sharing costs and benefits. The costs of making product demanded by consumers will likely be lower with tighter coordination of the systems, which involves improved communication practices. Partnerships are likely to expand across the food supply chain from inputs, to producers, to processors, and distributors. This implies increased dependence upon management in the form of effective communication involving negotiation connections with suppliers, distributors, etc. These should be considered crucial skills and may provide a competitive advantage. Thus, understanding the actors in the partnership and how they interact with one another is critical for improving supply chain efficiency and uncovering concerns of product development and differentiation. For vaccine development, this could be viewed as the partnerships between upper management, project leaders, scientists, and clinical study personnel with upper management ensuring communication across all groups of the product development chain. Conceptual and empirical work is needed (Ziggers and Trienekens 1999).

Vaccine development requires multi-disciplinary teams. These teams are specialized in different aspects of the vaccine development process (such as clinical study personnel performing the "hands-on" animal work of the In-life phase of a study and laboratory personnel conducting "bench work" for the study). It, "requires multiple expertise and coordinated teams of leaders working together for a common goal…" (Rappuoli and Medaglini 2014). For example, 10,000 scientists have been working together successfully at the CERN in Switzerland. This has been attributed to the fact that the culture at the CERN recognizes projects cannot be completed alone, and requires assistance from multiple other teams (Rappuoli and Medaglini 2014). This type of thinking is relevant in the vaccine development process as multi-disciplinary teams along with upper

management must be aligned and communicate well along the entire development chain in order for new products to be developed efficiently and effectively. Any gaps in communication are subject to transactions costs such as inconsistent throughput of study execution, or resources focused on lower priority vaccine development projects. Each communication gap has the potential to delay the time to market for a new product, costing a company millions of dollars.

The Theory of Constraints (TOC) is another type of process for improving supply chains, and has the potential to be applied to veterinary vaccine development. TOC can be applied to projects to decrease project duration, streamline project control, and allocate resources being shared by ongoing projects. Duration of a project should be considered an important constraint because, as stated above, lack of communication can lead to longer project duration and project delay could mean loss in market share for a new product. Extended project lengths can lead to increased overhead costs, and may lead to changes in scope. If projects are completed ahead of schedule, there is less time available for "needs" to be changed, thus eliminating scope changes. Up to 90%, by value, of all projects are conducted in a multi-project context, making resource allocation and effective communication of resource allocation a real problem. The TOC principles applied to manage multiple projects are the "five steps". The five steps of TOC include the following: identify the constraint(s) of the system, decide how to exploit the constraint(s), subordinate non-constraints to the decision(s) on the exploited constraint(s), elevate the constraint(s), i.e., take actions to widen the bottleneck, and return to step 1 to determine if a new constraint has been discovered, rendering the constraint under attention a non-constraint or less critical. This process also implies the criticality of communication throughout the

system in order to identify and improve upon constraints in the development chain. If processes and procedures are not effectively communicated along the chain, the five steps of TOC cannot be maximized, thus slowing down the forward progress of the development chain. The TOC process maximizes the number of projects moving through a system while still reducing project durations, and significantly reducing project costs (Steyn 2002). There is growing evidence in the literature of the benefits of implementing TOC, but as of 2003 acceptance was minimal with less than 5% of U.S. manufacturing facilities using TOC. The literature does cite that TOC techniques produce reasonable, not optimal results due to schedule assumptions that are unrealistic when applied to real world scenarios. There is also a problem of obtaining top management support due to the length of training required to master the process. TOC requires a change in organizational culture and needs top management support through the process (Watson, Blackstone and Gardiner 2007).

In the automotive industry, Hyundai put processes in place to synchronize its supply chain system. It developed a system to coordinate across its supply chain, primarily focusing on production planning and scheduling. They used a centralized approach to attain coordination along its supply chain. The system is not perfect, but has improved since implementation and continues to refine and improve policies. Managers at Hyundai found it difficult to synchronize tasks across groups within their own company. Hyundai used the concept of Supply Chain Management that focuses on function specialization, “each function is expected to perform value-adding activities required to achieve organizational goals. However, such specialization leads to differences in goals and in interpersonal relationships” (Hahn, Duplaga and Hartley 2000). These differences can cause issues with coordination of activities among groups, and effective communication across the supply

chain is necessary. Four major factors characterizing synchronized operations were identified: consistent shared data, a system wide viewpoint, swift communication to all pertinent people involved, and proactive response to changes.

Similar to the automobile industry, development of vaccines in the animal health industry requires accuracy, clarity, and timeliness of communication. These are, indeed, critical to ensuring efficiency in production. The supply chain needs to operate as a cohesive entity to respond quickly and effectively to the changing marketplace. Changing a production schedule can cause shortages and/or surplus capacity, as well as a ripple effect upstream in the supply chain. This is no different than changing a study protocol when facilities are already in the process of being prepared for an upcoming study, or the entire scope of a project is changed and not communicated to all key stakeholders. A centralized department was established at Hyundai and now has final say for production schedules: master schedule, monthly, weekly, and daily schedules. Issues that arose were difficulties managing information flows without a system in place for all groups to have access, and senior management making changes without going through the new centralized coordination department (Hahn, Duplaga and Hartley 2000). These are the same difficulties that can arise in the flow of communication of vaccine development if all groups, including management, do not have a system for efficient and effective distribution of information when working on a vaccine study or project.

Supply chain synchronization has become a key factor in developing improved supply chain competitive advantage. Use of web-enabled collaboration among supply chain partners, such as enterprise resource planning (ERP) systems can help to improve communication, partnerships, alliances, and cooperation in a dynamic supply chain (Jain,

Wadhwa and Deshmukh 2009). The Texas Department of Transportation (TxDOT), implemented an enterprise resource planning (ERP) system to allow for real-time information flow to be accessed, shared, and compared across divisions in order to increase efficiency and increase accountability. Some of the critical success factors identified for a successful ERP system launch included: top management support, ERP team competence, effective communication, effective project management, and training of end-users (Kim, Sadatsafavi and Soucek 2016). Effective communication for the TxDOT ERP system launch was a critical success factor. This again can be extrapolated to the animal health industry as project and study launches require effective communication to be successful and on time.

Many companies in manufacturing are working at continuous improvement in managing their supply chains, which is no different than the animal health industry and continuous improvement in product development. At the strategic level, supply chain management (SCM) use has increased. This includes the implementation of cross functional teams, which aide in organizational alignment with a process oriented structure, which is needed for a smooth flowing supply chain. “Control of process in a supply chain is crucial for improving performance…Well-defined and controlled processes are essential to better SCM” (Gunasekaran, Patel and McGaughey 2004). The reduction of lead times for processes in the supply chain leads to a decrease in supply chain response times. The reduction in supply chain lead times and response times is a source of competitive advantage. Based on a survey, there was a 76% positive response rate that return on investment had increased after implementing contemporary SCM practices. Showing

careful management of supply chains provide benefits to a company (Gunasekaran, Patel and McGaughey 2004).

CHAPTER III: DATA, THEORY AND METHODS

3.1 Introduction

In this chapter, an overview of the data collection process and the methods used to analyze them are presented. We also present the theory guiding the analyses and their roots in economics and management. Methods used to assist in determining a more effective process for coordinating information flow and activities within the animal health product development process will be discussed. The literature is lacking supply chain focus for new product development in animal health, but literature from various industries can be extrapolated to product development and study execution. Data were collected through an industry-focused survey from people within the animal health industry involved in various stages of the product development process.

3.2 Theory

Having an efficient and effective supply chain is critical in all industries, including the product development supply chain in the animal health industry. The focus of this research: timeliness, accuracy, and completeness of information affect work on the product development supply chain in the animal health industry. Communication and information, or lack thereof, affects the transaction costs of product development in such ways as inconsistent study throughput, tasks being performed in duplicate, number of personnel needed for study conduct, etc.

Karanges, et al. (2015) found that internal communication involves two primary roles: spanning provision of information and building a sense of community within the business. Research has recognized internal communication has a fundamental impact on employee engagement. Two of the benefits of employee engagement include improved

productivity, and improved financial returns – both of which are critical to the supply chain (Karanges, et al. 2015).

The literature also shows when supply chain management (SCM), the rearrangement of supply-side activities to take full advantage of customer value, is used; incorporating processes and promoting information sharing with supply chain partners, in this case internal parties involved with study development and execution, aim to minimize the interferences associated with the bullwhip effect. The bullwhip effect is caused by discrepancies between supply and demand in the supply chain, and typically leads to inefficiencies, added costs, increased waste and loss of throughput. By the use of SCM, and incorporating their procedures and promoting information exchange, supply chain partners can improve common plans and forecasts to harmonize production. Trust, commitment, and mutual need have substantial impact on supply integration (Vijayasarathy 2010). It has also been noted that information sharing, cooperative planning, cross-functional teams, and collaboration are essential elements in the process of internal integration of the supply chain. Internal integration can break down functional barricades and produces teamwork to meet requirements of customers rather than working within functional silos (Flynn, Huo and Zhao 2010). Jacobs, Yu and Chaves found that, "…Internal communication is found to impact employee satisfaction. Hence, for a firm to improve market performance through the coordination of material, information, and money amongst trading partners it must first establish effective internal communication processes and stimulate employee satisfaction" (Jacobs, Yu and Chaves 2016).

3.3 Survey

Data were collected through an industry-focused online survey (Appendix A) from people within the animal health industry involved in various stages of the product development process such as: oversight of entire product development processes, oversight of product development processes for some or all species categories, scientific development of study protocols and responsible for individual studies, completion of benchtop work for study laboratory processes, and personnel responsible for the setup of facilities, equipment, animals, etc. and preparation for the In-Life phase of studies, and/or "hands-on" animal work during In-Life phase of studies. Survey participants were from over five different animal health companies around the world. The survey questions focused on the product development phase, specifically vaccines, and even more specifically from protocol development through *in-vivo* study preparations.

3.4 Methods

Statistical analyses using Stata 14™ is the primary method used in the analysis of the data. We use counts and frequencies as well as measures of central tendency and dispersion to assess the differences in the perspectives of different employee groups.

The survey was distributed broadly to a target sample of professionals in the animal health industry. Of the 107 recipients of the study's survey, 77 (72%) responded completely to the survey questions. Nine people considered themselves unqualified to answer the questions. The response rate was 91%, which is deemed very good for an online survey. According to Fryrear (2015), internal surveys for companies yields only between 30% and 40% response rate.

The study identified five role categories in the animal health industry used in this research: executive; managers/project leaders; scientists; clinical study personnel; and laboratory personnel. Executives are responsible for oversight of the entire product development process within a company. Managers/project leaders are responsible for oversight of specific species categories or specific products. Scientists are responsible for study protocols and undertaking scientific studies. Clinical study personnel are responsible for the setup of facilities, equipment, animals, and in-vivo studies; generally executing the study protocols developed by the scientists. Finally, laboratory personnel are responsible for preparation of laboratory activities.

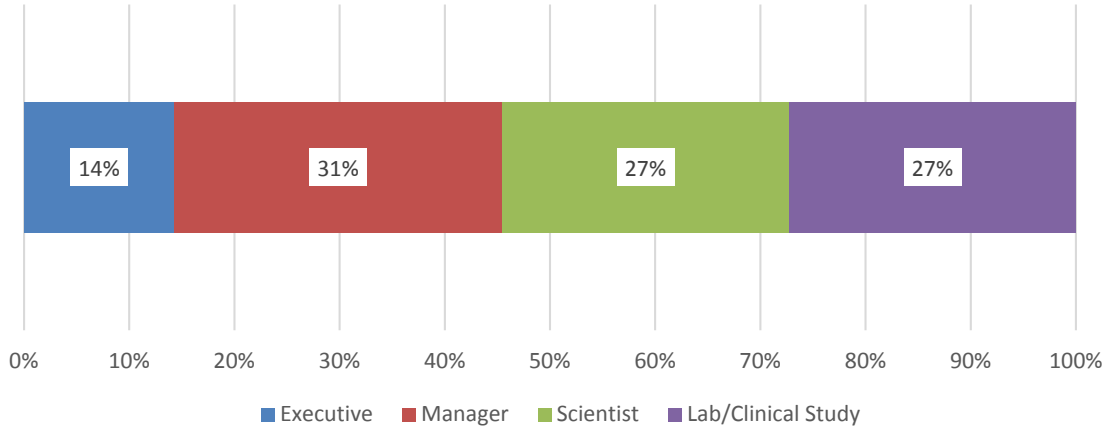
CHAPTER IV: ANALYSIS & DISCUSSION

We present the results of the survey in this chapter. The chapter is divided into four parts. The first presents the summary description of the respondents. The second subsection describes the vaccine development process, highlighting the importance of communication along the process to ensure effective achievement of results. The third subsection presents the survey results of how people at the different stages along the vaccine development process view communication effectiveness and test if perceptions differ across groups. The final subsection presents how different groups see how the communication gaps may be addressed and test if these solutions differ across the different groups.

4.1 Summary Statistics of Respondents

The distribution of respondents by their roles is presented in Figure 4.1. The figure shows that of the 77 respondents, 14.3% were executives, 31.2% were managers or project leaders, 27.3% were scientists and 28.3% were clinical study personnel or laboratory personnel.[1]

Figure 4.1: Distribution of Respondents by Role



[1] Laboratory personnel were merged with Clinical study personnel due to the limited number of the former.

Table 4.1 shows that about a third (32.5%) of respondents had a bachelor's degree, 22.1% had DVM or a PhD and 16.9% had a master's degree. The remainder had MBA or other degrees. More than half of clinical study personnel had a bachelor's degree while nearly 24% had a DVM. However, about 37.5% of managers or project leaders had a PhD compared to only 16.7% with a bachelor's degree and 20.8% with DVM. Nearly 55% of executives had a PhD, the group with the most PhD and the only group without anyone with less than a Masters or DVM.

Table 4.1: Distribution of Respondents by their Role and Education

Education Level	Clinical Study / Lab Personnel	Executive	Manager or Project Leader	Scientist	Total
Bachelors	52.38	0.00	16.67	47.62	32.47
DVM	23.81	27.27	20.83	19.05	22.08
MBA	0.00	0.00	4.17	0.00	1.30
Masters	14.29	9.09	20.83	19.05	16.88
Other	9.52	9.09	0.00	4.76	5.19
PhD	0.00	54.55	37.50	9.52	22.08
Total	100.00	100.00	100.00	100.00	100.00

The industry's activities may be grouped into biologics, pharmaceutical (or pharma) and both biologics and pharma. For the purposes of this thesis, biologics involves the development of vaccines against viruses and/or bacteria across various species, and pharma encompasses the development of drugs for use as antibiotics, parasiticides, and therapeutics. While only one-third of the animal health industry's revenue is from vaccines, they are becoming increasingly important as the industry moves away from the use of antibiotics due to increasing risks of antibiotic resistance (Hopkins 2016).

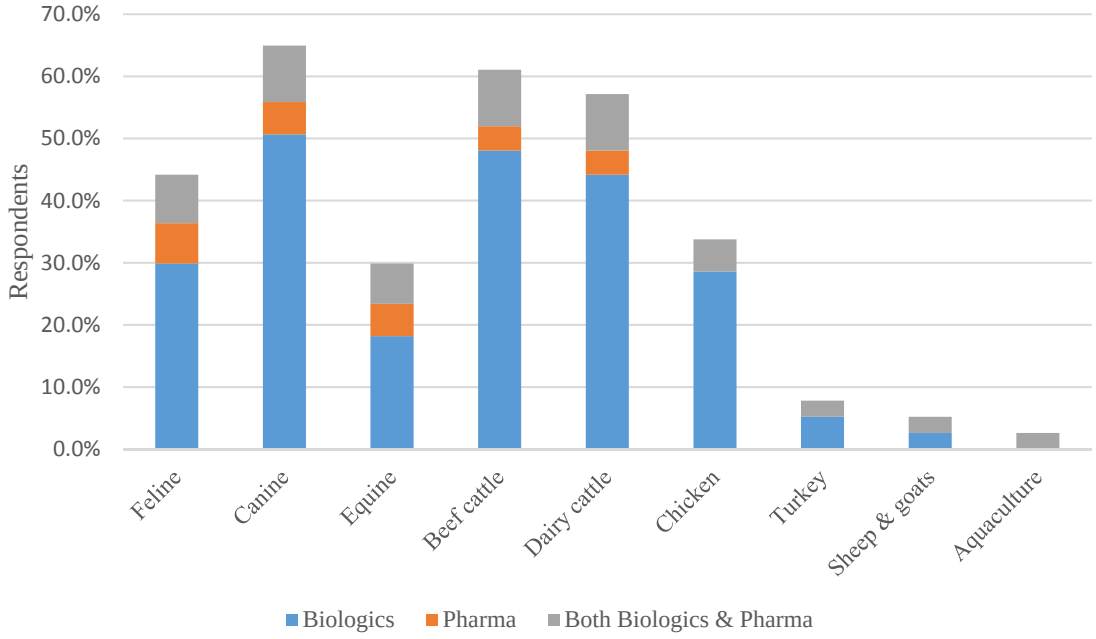
More than 92% of respondents were involved in biologics and/or pharmaceutical aspects of the animal health industry. Of those involved, 80.3% were involved in

biologics, 8.5% in pharma and the remaining 11.3% in both biologics and pharma. Regarding experience in the industry, about 16% of respondents had between one and five years' experience, while 22.1% had between five and 10 years' experience. The majority of respondents (62.3%) have more than 10 years' experience. This would imply that more than 84.4% of respondents have seen, experienced and dealt with a wide variety of issues and challenges in the industry, allowing us to be confident in their perspectives reflected in the research. This provides confidence in the responses they provided as rooted in their experience.

About 44.2%, 59.7% and 29.9% of respondents were involved with feline, canine and equine products, respectively. Respondents involved with beef cattle, dairy cattle, chicken, turkey, and sheep and goat products were respectively 61.0%, 57.1%, 33.8%, 7.8% and 6.5%.[2] Less than 3% of respondents indicated being involved in the production of aquaculture products. Swine was inadvertently not presented in the survey, thus there is no information on the proportion of respondents working on swine products. The distribution of effort, measured by the proportion of respondents working on particular species, reflects the importance of the species in the economy. These results are summarized by product focus in Figure 4.. The figure shows that across all the species, biologics dominated what respondents do.

[2] We accidentally excluded porcine in the species categories.

Figure 4.2: Proportion of Respondents by Species and Product Focus (N = 77)



Information along the decision chain is crucial in the product development process. Executives decide which products they need or want to develop and are willing to provide resources to support development based on the company's overall strategic direction, competitive environment and potential for sustained revenues. Once they make that decision, the information is transmitted to project leaders or managers, who work with scientists to develop the necessary study protocols to begin the transformation of the idea into a product. Scientists engage laboratory personnel, given the study protocols, to develop necessary assays and/or inoculum, and to process biological samples from the in-vivo portion of the study. Scientists also engage clinical study personnel to acquire the necessary resources, especially animals, and to undertake the hands-on aspect of the in-vivo studies that would be necessary for the product development activity.

The inter-dependencies among the people in these roles is evident. Studies cannot be initiated without the proper equipment, chemicals and reagents, adequate number of

animals for *in-vivo* experiments, clear protocols for undertaking measurements and recording data. All these are specified in study protocols, which cannot be completed without a clear appreciation of the product that is being developed. The choice of new products to pursue is the purview of executives who must let their managers or project leaders know given the products' target species. Obviously, the process is not as hierarchical as described. Executives and managers consult in the product selection process, and managers and scientists review alternatives even as executives and managers deliberate options to enhance the company's competitiveness. Clinical study personnel need information on the type of study and its requisite resources as well as start date and duration to organize such resources. People's perceptions about the timeliness, accuracy and completeness of information they receive from those required to transmit them are critical in how effectively they get their part of the process completed on time and accurately.

4.2 Timing of Communication

New product development begins when executives decide the product they want to invest in to achieve their companies' financial and other objectives. We asked decision-makers and scientists to indicate the extent to which they agreed with the statement that executives keep managers or project leaders informed about potential product development ideas. This is important because sharing information at the ideation stage of product development could help project managers and project leaders to engage scientists in the preparation of study protocols ahead of time and improve efficiencies in the preparation for clinical studies.

About 95.2% of managers/project leaders and 100% of executives agreed that executives keep managers and project leaders informed about potential product development ideas. However, only 60% of scientists agreed, with 20% of them disagreeing with the statement and 20% neither agreeing nor disagreeing. Since the communication is between managers and executives, the perspective of managers is weighed higher than that of scientists. The difference between executives and managers on the former keeping the latter informed about potential product development ideas is not statistically significant. However, the difference between scientists' perception about executives keeping managers informed and those of either managers or executives is statistically significant at the 1% level [$|t| = 3.27$; $P>|t| = 0.002$].

Executives, managers and scientists were asked the extent to which they agreed that sources of animals required for studies started only when product development is approved. When sourcing starts is important, because it requires a significantly longer lead-time to accomplish since it involves external suppliers. Sourcing and screening of animals is crucial to ensure the type of animal needed for a study is available when a study is targeted to start. Sourcing too soon can cause bad relations with animal vendors, and sourcing too late can delay the start of a study, which can have a cascade effect on the entire project development plan.

The results show that 68.4% of executives and 57.1% of managers agreed that sourcing of animals started only when product development is approved. However, only 40% of scientists agreed that this was the case. And while 31.6% of executives and 42.9% of managers disagreed with the statement, 50% of scientists disagreed. The differences between the perceptions were not statistically significant, suggesting that

executives, managers and scientists, statistically speaking, shared similar perceptions about when study animals were procured.

The start date for product development studies is important because it sets the process in place for when all downstream activities get accomplished – when study animals are ordered, screened and delivered to laboratories, when equipment are set up, and when clinical and laboratory personnel schedules are determined, among other. We asked executives, managers and scientists for their perceptions about the statement that "Study start date is set and finalized too late, causing downstream stress (protocol development, animal sourcing, preparing facilities). While 65% and 57.1% of executives and managers disagreed with the statement, 40% of scientists agreed. As with the previous statement, the differences between the perceptions presented by the different roles were not statistically significant, suggesting that executives, managers and scientists, statistically speaking, shared similar perceptions about how late study dates were finalized.

Screening animals for studies can take time. Ensuring that there are enough qualifying animals to conduct the study can be expensive if enough lead-time is not provided for clinical study personnel to procure the animals and have them screened according to the study's protocol. Sometimes, managers and executives are unaware of the procurement and screening challenges and may establish timelines that may be too tight to get the preparations done without unnecessary pecuniary and non-pecuniary costs.

We asked executives, managers and scientists for their perceptions about the statement that "Screening of animals begins as soon as tentative study start date is

established." The results show that while 100% of scientists agreed with the statement, only about three-quarters of managers and executives agreed. About 25% of executives and 14.3% of managers disagreed while 9.5% of managers neither agreed nor disagreed. The difference between the perception of scientists and executives was statistically significant at the 5% level [|t| = 2.52; P>|t| = 0.015], as was the difference between the perceptions of managers and executives [|t| = 2.36; P>|t| = 0.022]. However, there was no statistically significant difference between the perceptions of scientists and managers. This will suggest that scientists and managers, being closer to the process, probably see the process through similar lenses than executives, who are more removed from the process of animal screening.

Recall that clinical study personnel are responsible for setting up the facility and procuring animals for studies. It is helpful for them to communicate the required needs of the animal facility early so that procurements can be scheduled. As in the previous statement, the start date has a significant influence on these procurement and other preparations for the study. In this light, we asked executives, managers and scientists for their perception on when clinical study personnel communicate animal facility needs for studies. We asked them to indicate their extent of agreement with the statement: "Clinical Study Personnel quickly communicate animal facility needs for studies as soon as tentative study start date is established." While 100% of executives and 90% of scientists agreed with the statement, only 85.7% of managers did, with the remainder indicating they neither agree nor disagree with the statement. The difference between the perceptions of managers and executives was statistically significant at the 10% level [|t| =

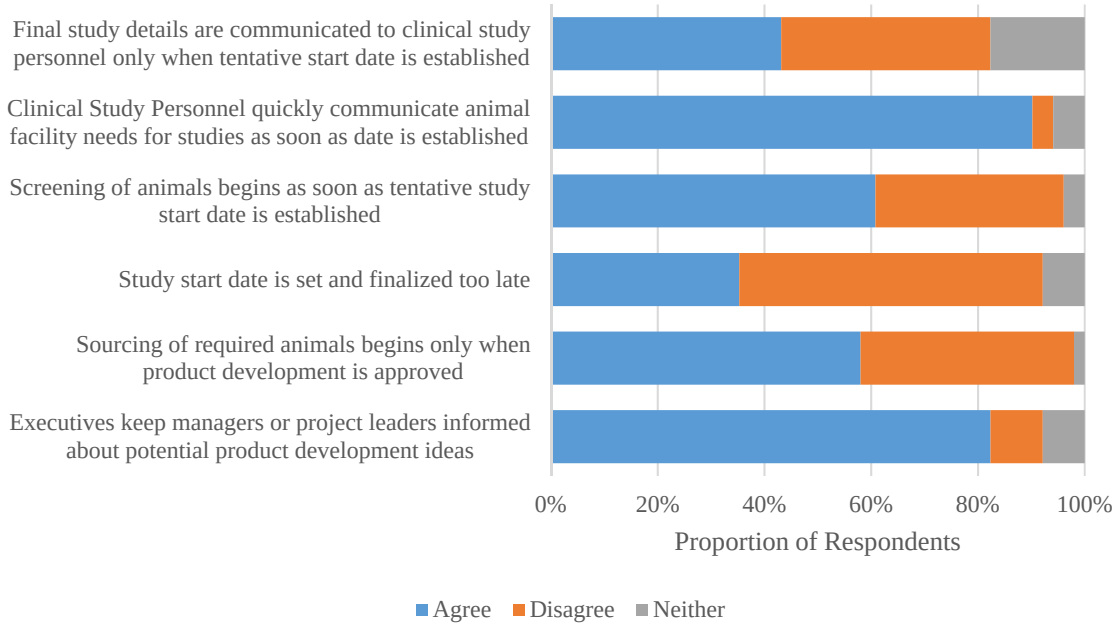
1.83, P>|t| = 0.074]. However, the differences between the perceptions of managers and scientists and executives and scientists were not statistically significant.

Finally, we asked executives, managers and scientists for their perception on when final study details are communicated to clinical study personnel. Keeping clinical study personnel informed of study start dates is critical as people in this role typically handle the logistics of preparing facilities, animal sourcing/ordering, study supplies, and conducting in-vivo studies. If personnel in these roles are not informed early enough of study details, they can be exposed to unnecessary stress because of their dependence on external stakeholders to get their work accomplished. Any gap in this area has the potential to delay a study or even cause a study to be repeated, thus further delaying the development of a new product and increasing product development cost and/or time to market. The respondents were asked to indicate the extent of their agreement with the statement that "Final study details are communicated to clinical study personnel only when tentative start date is established." The results show that 50% of executives and scientists compared with 33.3% of managers disagreed with the statement. On the other hand, 45% and 42.9% of scientists and managers compared with 20% of executives agreed with the statement. There was no statistically significant difference between the perceptions of the different roles.

In summary, we find executives and managers agree more when the communication is between them than when it is further removed from them. Because they work more closely with clinical study personnel, scientists and managers tended to agree more on issues relating to clinical study personnel's activities. Figure 4.3 presents the overall distribution of the extent of agreeability. For example, 90% of executives,

managers and scientists agreed that clinical study personnel quickly communicate animal facility needs for studies as soon as a tentative start date for the study is established.

Figure 4.3: Executives, Managers and Scientists' Perceptions about Timing of Product Development Activities (N = 51)



Another statement with high agreement was executives keeping managers/project leaders informed about potential product development ideas. Here, 82.4% of executives, managers and scientists agreed compared with 9.8% disagreeing. On animal screening beginning as soon as a tentative start date for the study is established, we observed that 80.4% of all respondents agreed while 15.4% disagreed, with the remainder neither agreeing nor disagreeing.

4.3 Preparation of Protocols

In the previous section, we wanted to know the extent of agreement by executives, managers and scientists about executives keeping managers informed about product development ideas at all times. In this section, we focus on managers'

communications with scientists and the timeliness of protocol preparations. We asked executives, managers and scientists to indicate their agreement with the statement: Managers/Project Leaders keep scientists informed about potential product development ideas at all times." While 40% and 23.8% of scientists and managers disagreed with this statement, only 10% of executives disagreed. However, while 71.4% of managers and 70% of executives agreed with the statement, only 60% of scientists agreed. There was no statistically significant difference between the perceptions expressed about this statement.

The study protocol is the blueprint for conducting any study supporting the development of a new product. The studies are designed to ensure and assure the efficaciousness and safety of the products at different dosages and any side effects that may be associated with the products. They are important in getting regulatory approvals and provide the foundations for the final product specifications. We asked executives, managers and scientists to indicate their agreement with the statement: "Study protocol draft writing begins only when all necessary information for the proposed study is available."

The results indicate that 75% of scientists, 61.9% of managers and 60% of executives disagreed that writing draft study protocols begun only after all necessary information is available. Only 25% of scientists, 38.1% of managers and 30% of executives agreed. About 10% of executives neither agreed nor disagreed. There was no statistically significant difference between the perceptions expressed about this statement.

In the application of laws and guidelines for conducting research involving animals in the United States, the Institutional Animal Care and Use Committees

(IACUCs) are critical. Every research facility needs to have an IACUC in accordance with the Animal Welfare Act and the Policy on Humane Care and Use of Laboratory Animals. No clinical study involving animals may proceed without submitting study protocols to the local IACUC and obtaining its approval. Therefore, completing study protocols and initiating IACUC applications are crucial to effective preparations for the study.

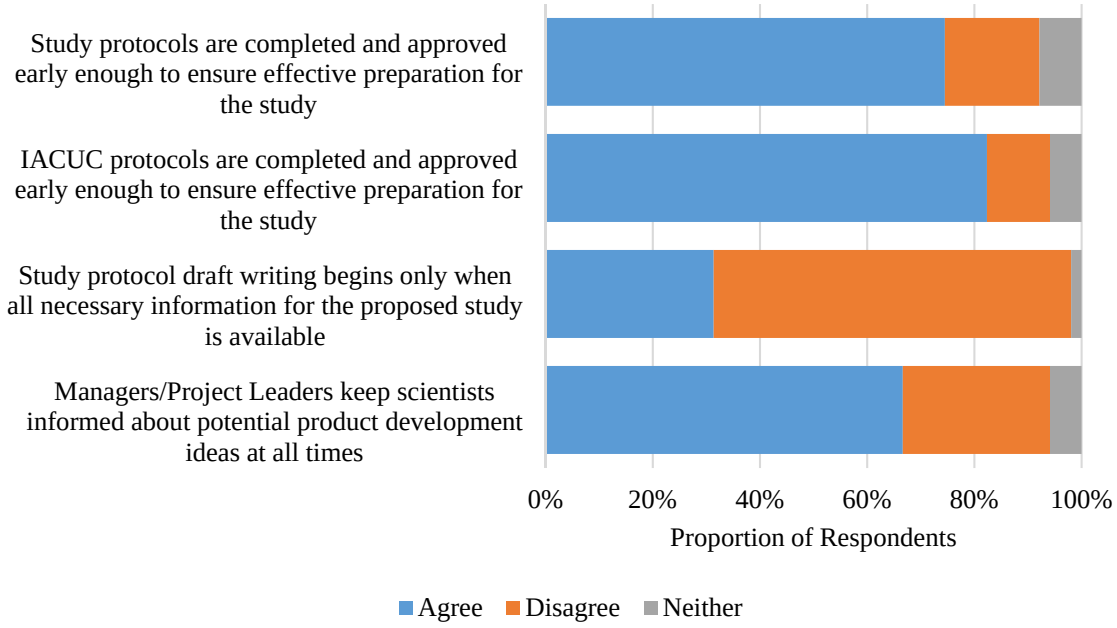
We asked executives, managers and scientists to indicate their agreement with the statement: “IACUC protocols are completed and approved early enough to ensure effective preparation for the study.” The results show that 100% of executives, 71.4% of managers and 85% of scientists agreed with the statement and 23.8% of managers and 5% of scientists disagreed. The difference between the perceptions of scientists and executives about this statement was statistically significant at the 10% level [$|t| = 1.71$; $P>|t| = 0.094$]. However, the difference between the perceptions of managers and executives was statistically significant at the 1% level [$|t| = 2.75$; $P>|t| = 0.008$]. There was no statistically significant difference between the perceptions of scientists and managers about how early IACUC protocols were completed. This is not surprising given that executives are often not as close to the IACUC processes as managers and scientists are.

Because all studies, if they are going to be done according to regulations and guidelines, must proceed from their protocols, completing and securing approvals for study protocols is crucial to ensuring effective preparations for the study. We asked executives, managers and scientists to indicate their agreement with the statement: “Study protocols are completed and approved early enough to ensure effective preparation for

the study." The results show that while 80% of scientists and executives agreed with the statement, only 66.7% of managers did, while 10% and 20% of scientists and executives disagreed with the statement, 23.8% of managers disagreed. There was, however, no statistically significant difference between the perceptions presented by the respondents in the different roles.

Respondents' overall agreement with specific issues contributing to timeliness of preparation for product development are summarized in Figure 4.4. It shows that 82% of respondents, regardless of role, agreed that IACUC (Institutional Animal Care and Use Committee) protocols are completed and approved early enough to ensure effective preparation for the study. On the other hand, only 31% agreed that the writing of the draft study protocol occurs only when all necessary information for the proposed study is available. This implies that at least 67% disagreed that this is the case, suggesting that people begin drafting study protocols even when all necessary information for the study is not available. That is, decision-makers are proactive and prepare ahead of time, knowing that resource dedication resulting from the completion of the decision to proceed will require lead-time preparation.

Figure 4.4: Executives, Managers and Scientists' Perceptions about Preparation Protocols for Product Development Activities (N = 51)



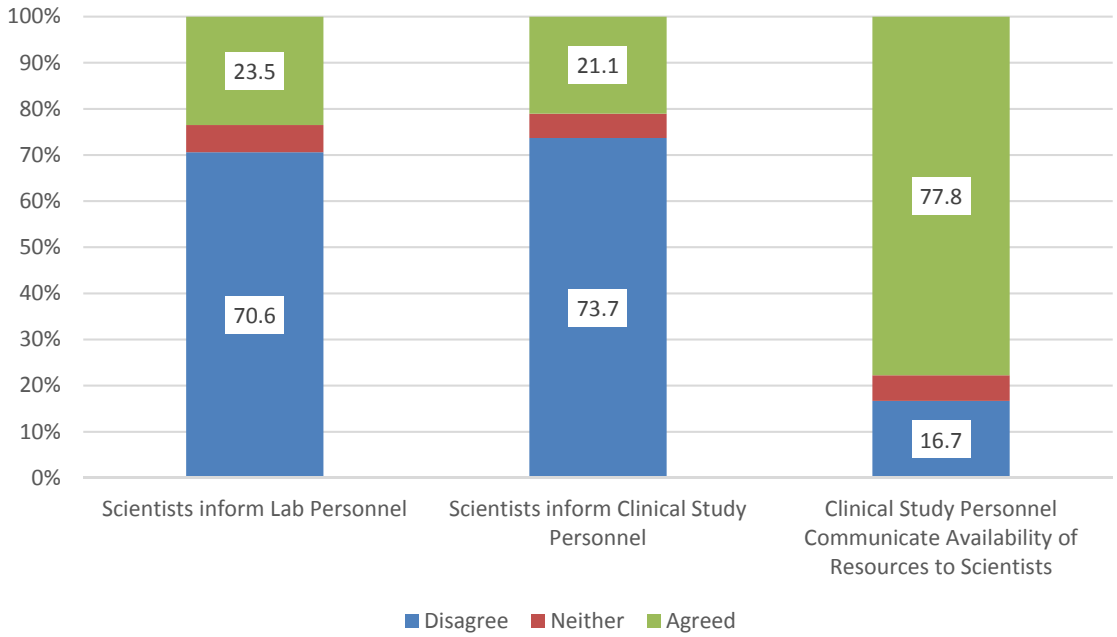
4.4 Communication between Scientists and Laboratory and Clinical Study Personnel

There are many reasons why a scientist will wait until there is certainty about a product being developed before communicating it to clinical study personnel. For example, without waiting for confirmation that the study is going forward, a scientist might inadvertently set the clinical study personnel on a preparation adventure that can prove to be costly for the company. However, informing them earlier can also indicate a higher level of trust and a confidence that they can begin preparations without actually incurring costs that could be sunk in case the project does not move forward.

We asked scientists, laboratory/clinical study personnel to indicate the extent of their agreement with a number of statements about the timing of their communications about new product development. We wanted to know if scientists informed laboratory and clinical study personnel about potential product development only when they were completely sure that management has made the decision to move the product forward and

if clinical study personnel communicate the availability of animal facility, animals and other study resources to scientists frequently. The results are presented in Figure 4. and shows that more than 70% of scientists disagreed that they inform laboratory personnel and clinical study personnel about potential product development projects only if they are completely sure about the project moving forward. This suggests that they communicate information about projects before decisions are finalized, a move that is necessary to minimize potential delays in starting studies once approvals have been received. Nearly 80% of them agreed with the statement that clinical study personnel communicate animal facility availability, clinical study personnel availability, and animal availability for proposed studies to scientists frequently. This would suggest scientists are constantly aware of the resource availability situation, not only when studies are due.

Figure 4.5: Distribution of Agreement Profile Regarding Scientists' Communication Statements with Laboratory/Clinical Study Personnel and Clinical Study Personnel Communication about Resource Availability



4.5 Perspectives about Lead Time

Decisions take time and communication of decisions and effectuation of action also take time. For example, once a product development decision is made, it is communicated to managers and scientists who then complete and finalize their IACUC protocols and submit them for approvals. There is always a time lag between when IACUC applications being submitted and when approvals for studies are received. Therefore, building significant slack into the timing of activities leading to animal studies is important for controlling costs and delivering results on time.

We assessed scientists and lab/clinical study personnel perspectives about the lead-time associated with the activities preceding the initiation of studies. On the statement, "IACUC protocols are completed and approved well ahead of tentative study start date, say two months," 68.4% of lab/clinical study personnel disagreed, compared to 71.4% of managers and 50% of scientists. Only 23.8%, 31.6% and 44.4% agreed with the statement. There were no statistically significant differences among the responses from people in the different roles.

Approximately 46.4% of lab/clinical study personnel agreed to the statement, "Writing of the study protocol begins as soon as information about a study is available." On the other hand, almost 90% of scientists and 76.2% of managers agreed. It is important to recognize that completing protocols lies within the control of scientists. However, because of its impact on others in the process, they are often aware of when these protocols are completed and approvals received. About 36.8% of lab/clinical study personnel, 10.5% of scientists and 23.8% of managers disagreed with the statement, i.e., they did not agree that IACUC protocols are completed at least two months ahead of tentative start dates.

While there was no statistically significant difference between the perspectives of lab/clinical study personnel and those of managers on this issue, the difference in perspectives between lab/clinical study personnel and scientists was statistically significant at the 5% [|t|=2.64; P>|t| = 0.011]. There was no statistically significant difference between managers and scientists' perspective either.

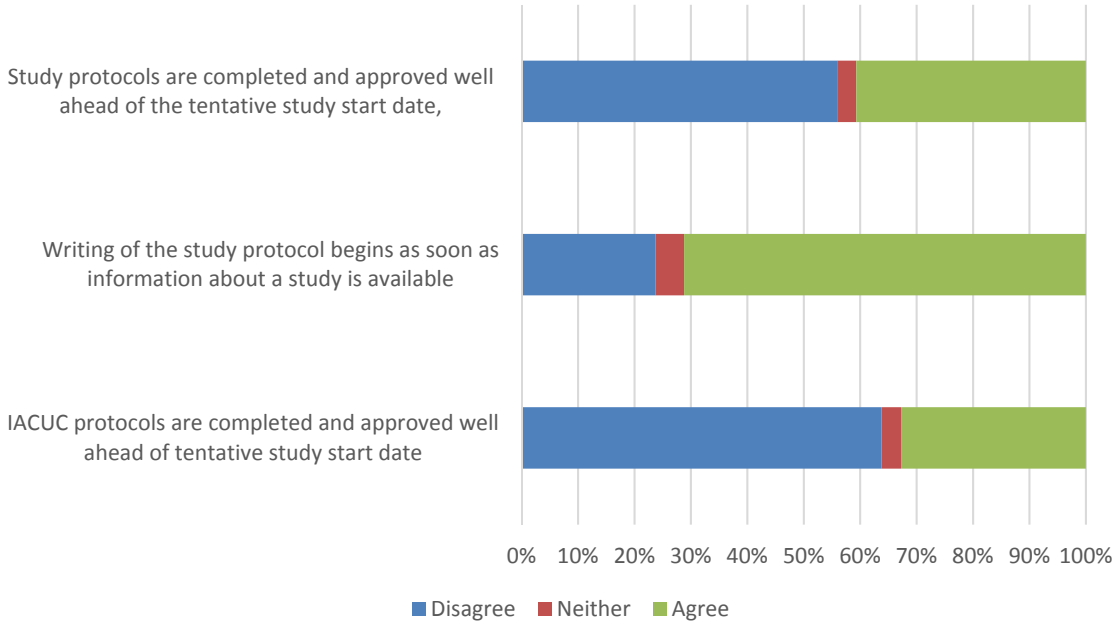
Scientists, managers and lab/clinical study personnel perspectives on whether study protocols are completed and approved at least a month ahead of study start dates reveal that while only 31.6% of lab/clinical study personnel and 28.6% of managers agreed that this was indeed the case, about 63.2% of scientists agreed. This implies that while disagreement with the statement for lab/clinical study personnel and managers was in the low to high 60%, it was only 36.8% among scientists. The difference in the perspective expressed by lab/clinical study personnel and that expressed by scientists was statistically significant at the 5% level [|t|=2.00; P>|t|=0.050]. The difference between managers' perspective and scientists' perspective was also statistically significant at the 10% level [|t|=1.97; P>|t|=0.053]. However, the difference between lab/clinical study personnel and managers' perspectives was not statistically significant.

Recall that managers, executives and scientists had been asked to provide their opinion on when facility preparation begins for a study. We present the same statement to the same group except we excluded executives and included lab/clinical study personnel. The results show that while only 31.6% of lab/clinical study personnel agreed to the statement, "Facility preparation begins only when all of the information for the proposed study is available," 43.8% and 57.1% of scientists and managers respectively agreed. On the contrary, 63.2% of lab/clinical study personnel and 56.3% of scientists disagreed with

the statement compared to 38.1% of managers. This may be because lab/clinical study personnel are closer to facilities' preparations and are, therefore, more aware of things than managers and scientists are. Despite the seeming disparity among the different roles' perspectives, the differences in their perceptions were not statistically significant.

The overall perspective of respondents, regardless of their roles, is summarized in Figure 4.. It shows that 63.8% of all respondents disagreed with the statement that IACUC protocols are completed and approved well ahead of study start date while 71.2% agreed that writing of the study protocol begins as soon as information about a study is available. In other words, they do not wait until all information about the study is in. Finally, while 51.8% of respondents disagreed with the statement that "Facility preparation begins only when all of the information for the proposed study is available," another 44.6% agreed, and those agreeing were mostly lab/clinical study personnel.

Figure 4.6: Distribution of Agreement About Lead-Time for Specific Activities Required for Project Studies



4.6 Exploring Solutions to Timeliness of Communication

Respondents were asked the following questions: “Given your role in your organization what is the most important thing you can do to improve the timeliness of information about product development between you and your staff”? Executives and managers suggested that the “most important thing to improve” to increase the timeliness of communication was overwhelmingly better, increased communication. The same was true for scientists and lab/clinical study personnel. Respondents suggested sharing information as soon as it is available and being “relentless in sharing information with all who can do something with it, and not just those who need to know.” Other suggestions are encouraging greater participation and ensuring follow through by project leaders with their functional representatives. One clinical study personnel observed that improving timeliness of communication requires proactive requests for information. “Don’t wait to hear”, the respondent stated. However, another lab/clinical study respondent indicated the need for scientists and managers to make communicating of activities a priority so that “people can know what they need to know on time.” Another put it simply: “Organize more update meetings.” A manager noted that ensuring that all staff are aware of the timeliness will help improve the timeliness of communication since those with the information will be conscious of the importance for those without it but need it to get it so they can deliver what they are supposed to on time.

It is, however, not surprising that communication is identified as the “problem” to fix to improve timeliness of information about product development. Raina (2010) observed that managers need to communicate continuously and in a timely manner to ensure communication effectiveness. This is supported by respondents’ indication that

managers must maintain regular contact with their subordinates. These improvements in communication, one respondent seems to sum it up, will demand an improved alignment and trust in the communication channels in the product development chains of animal health companies. Brown and Eisenhardt (1995) had also indicated the importance of cross-functional communication in achieving product development objectives.

4.7 Improving Accuracy of Information

Information timeliness must be matched with information accuracy. Respondents were asked to identify the one thing they could do to improve the accuracy of information they shared with others in their teams. A number of responses by executives suggested that empowering people at all levels to make decisions would contribute to improving information accuracy. Seeming to bolster the foregoing, another respondent indicated that there should be support for clear and transparent priorities of the organization and the company must ensure that the required resources are available. “Support employees to take risks” was one lab/clinical study personnel’s suggestion. There were a number of suggestions from executives related to meeting more frequently to provide updates. One manager suggested creating an environment where everyone will be comfortable to talk about their deficiencies so that the process can be enhanced. “Keep everyone informed, not just research leads,” was another suggestion for enhancing accuracy of information. After all, if more than a few people have the information, then they can crosscheck each other’s mental models about its transformation into action or debate its meaning since meaning can be contextual. Managers believed executives must communicate objectives and their related strategies more clearly.

Lab/clinical study personnel suggested improving accuracy through developing a shared vision and helping all team members build a desire to have accurate information. Others aligned with the foregoing thought is increasing the “open lines of communication between all stakeholders” in the product development chain. “Communicate changes quickly” was another suggestion by a manager to indicate the need to replace information that is no longer accurate with new ones that are accurate. A manager noted that timely reporting of results would help improve communication accuracy because people will be communicating from data and not guessing. A couple of scientists suggested encouraging “more open communication” because when more people know, then there is a lower risk of error since someone will catch the errors and help ameliorate them. It is imperative that in the search for accuracy through increased sharing of information, product development leaders must work hard to encourage dissent since any signal that different opinions are not tolerated would create “groupthink” (Bnabou, 2013).

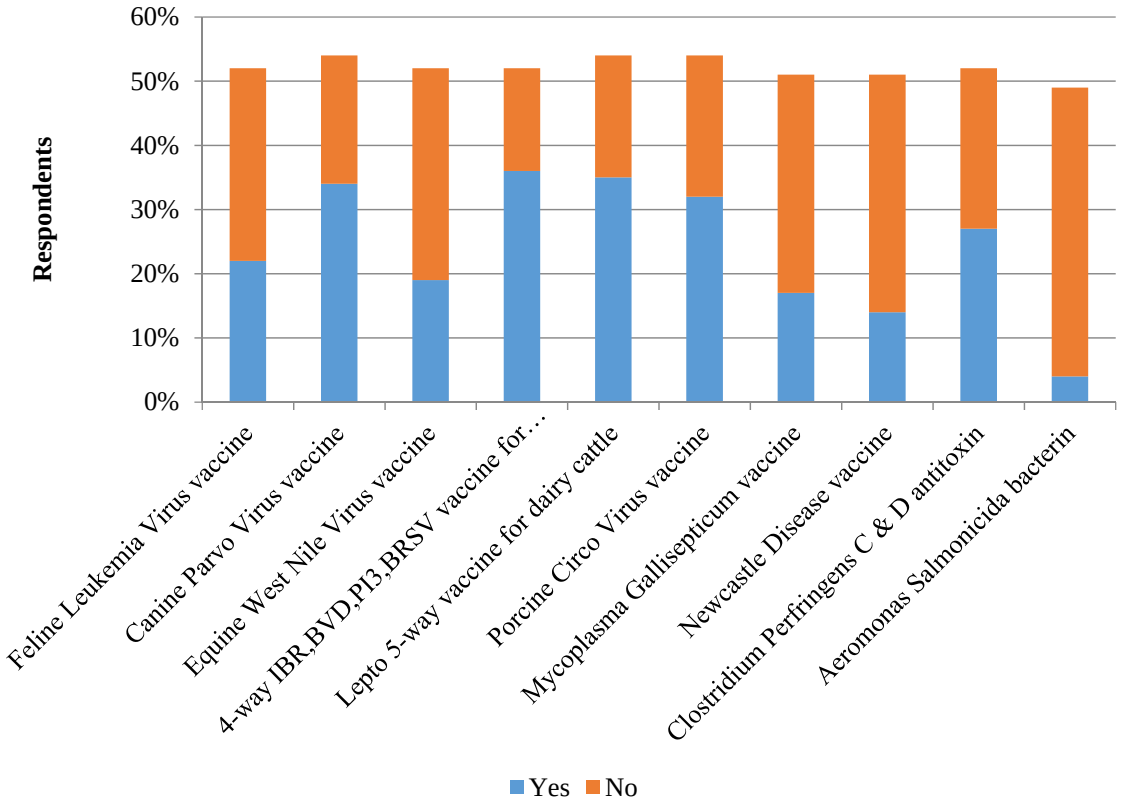
4.8 Time

The time it takes to identify a new compound or antigen and develop into a new drug or vaccine for product licensure or registration is time consuming and expensive. Licensure for a new vaccine may take anywhere from five to seven years, and an additional one and a half to three years for regulatory approval (IFAH 2008). Time is critical in the product development process and any improvements in the process can save a company development costs, reduce potential money loss from a slower time to market, and bring a new innovative product to market that improves the lives of animals even faster.

With a focus on veterinary vaccine development, all respondents were asked,"…Which of the following vaccine development challenges (or similar situations) do you have enough knowledge to think about implementing (or have implemented) in your company if it became necessary". The choices included feline leukemia virus vaccine, canine parvo virus vaccine, equine west nile virus vaccine, 4-way IBR, BVD, PI3, BRSV vaccine for beef cattle, Lepto 5-way vaccine for dairy cattle, porcine circo virus vaccine, mycoplasma gallisepticum vaccine, newcastle disease vaccine, clostridium perfringens C & D antitoxin, and aeromonas salmonicida bacterin for aquaculture.

A total of 70% (N=54) of the respondents had enough knowledge to be included in at least one of the vaccine development challenges listed above. This would imply that the majority of respondents have dealt with a wide variety of vaccine development challenges, again allowing us to be confident in their perspectives reflected in the research. A swine vaccine development challenge was included in this part of the survey with 59% of the respondents having enough knowledge to think about porcine circo virus vaccine. Knowledge of the various vaccine development challenges ranged greatly, with 69% of respondents having enough knowledge to address 4-way IBR, BVD, PI3, BRSV vaccine for beef cattle to only 8% having enough knowledge to address aeromonas salmonicida bacterin for aquaculture. These results are summarized by vaccine development challenge in Figure 4.7

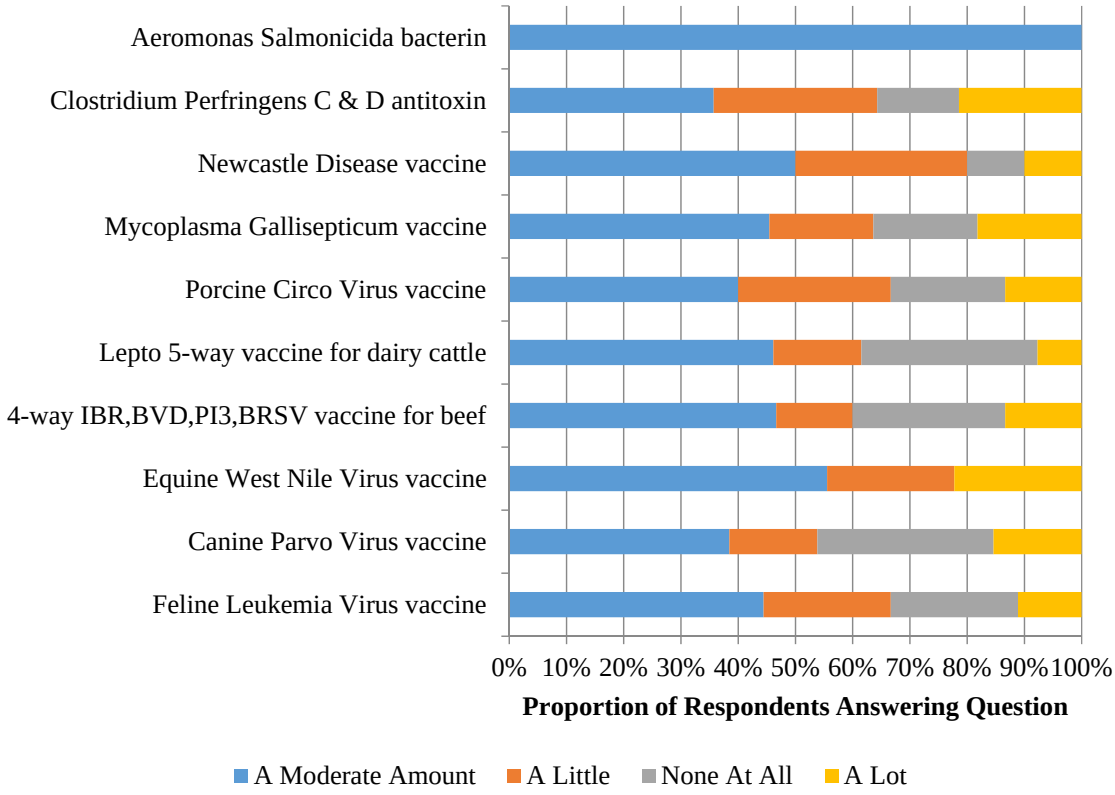
Figure 4.7: Proportion of Respondents with Enough Knowledge to Think About Various Vaccine Development Challenges (N=49 to 54)



The executive and manager groups were asked, “Given the prevailing conditions under which you work, to what extent will the time it takes you and your team to identify and develop a vaccine solution to the identified challenges differ under your current operating conditions compared to ideal operating conditions”? The options for the respondents to choose from were, ”A Great Deal”, “A Lot”, “A Moderate Amount”, “A Little”, and “None At All”. The most prevalent selection was “A Moderate Amount” with 45% of all respondents across all proposed challenges selecting this option. The next most prevalent selection was “A Little” at 21%, followed by “None At All” at 20% and “A Lot” at 15%. Zero respondents selected, “A Great Deal”. With almost half of all

respondents across all proposed challenges selecting “A Moderate Amount”, and more than double the next most prevalent selection of “A Little”, this demonstrates that executives and managers believe and recognize the product development process has gaps and there is room in the process to shorten the timeframe needed for vaccine development. Figure 4.8 below breaks down the respondents’ selection by proposed vaccine challenges.

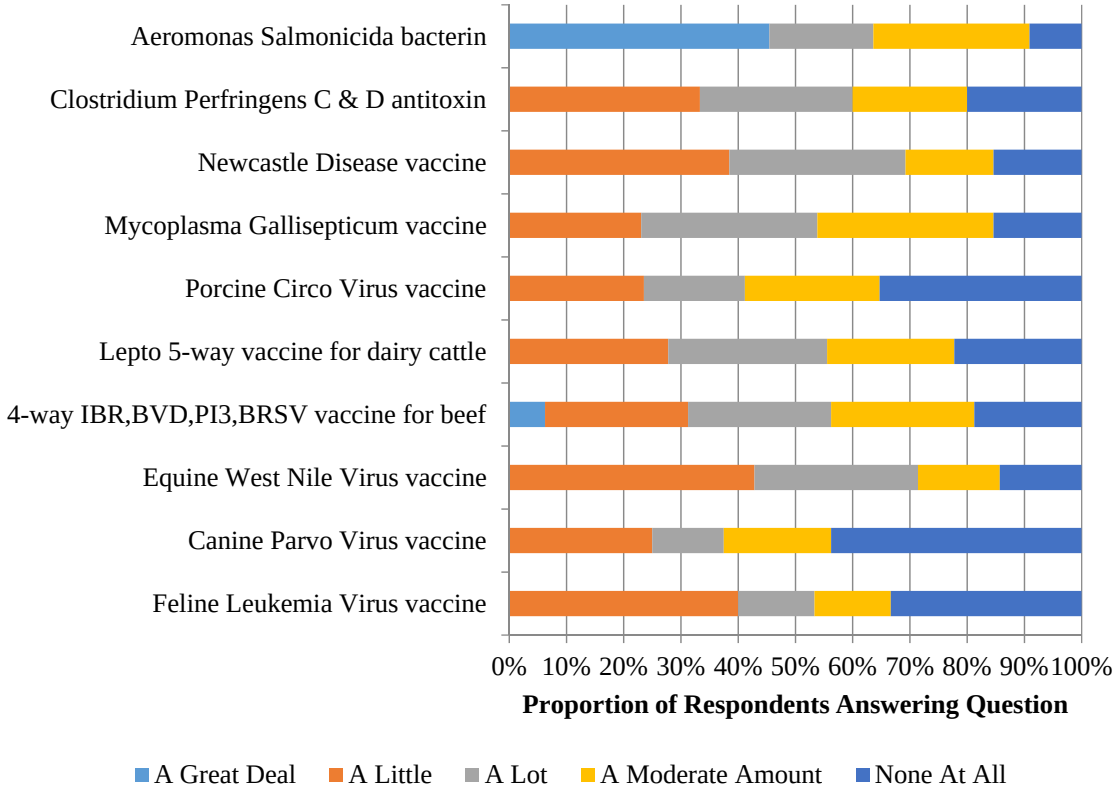
Figure 4.8: How Current Time Taken to Develop Various Vaccine Solutions Differs from Ideal Time to Develop Vaccine Solutions by Executives and Manager



Protocol writing and approval, along with material preparation (test vaccine, challenge material, etc.) is another part of the development process that takes time, and has to be of high quality to ensure the supply chain continues to move forward towards product licensure. The scientist and laboratory personnel were asked a similar question

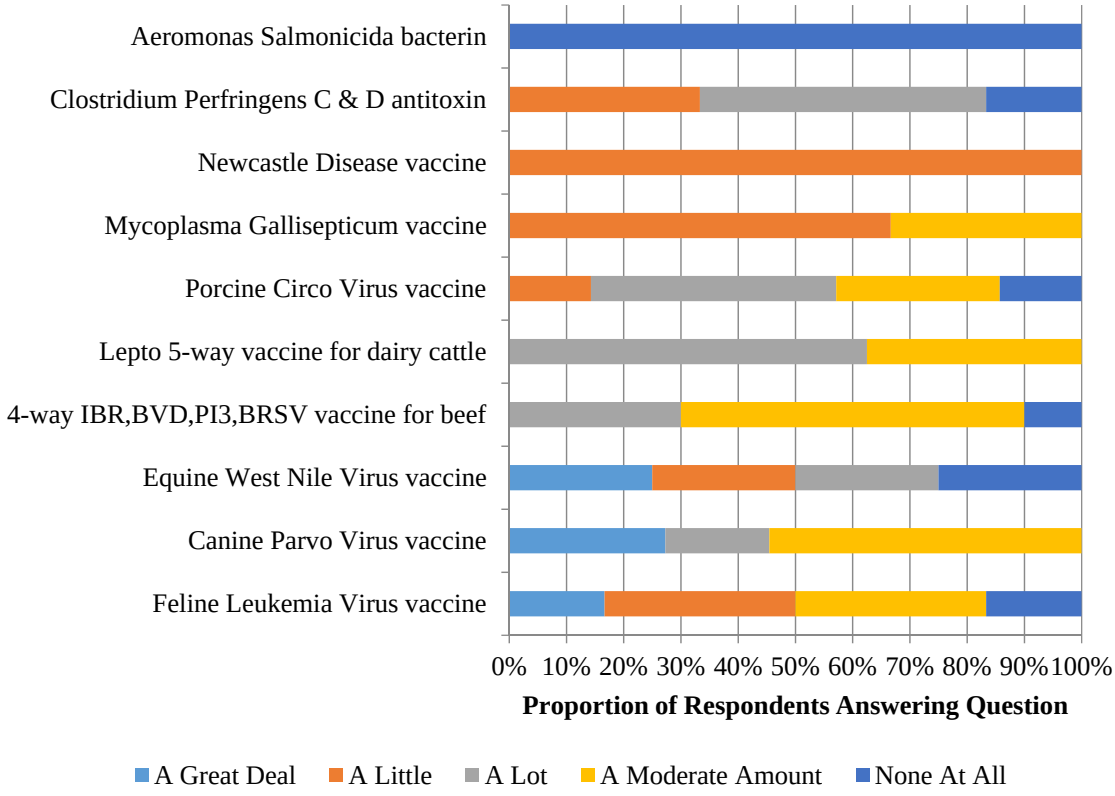
the executives and managers were asked, but this question pertained to current versus ideal time it takes to prepare all materials and protocols in order to initiate a study. The options for the respondents to choose from were, “A Great Deal”, “A Lot”, “A Moderate Amount”, “A Little”, and “None At All”. The most prevalent selection was “A Little” with 28% of all respondents across all proposed challenges selecting this option. The next most prevalent selection was “None At All” at 24%, followed by “A Lot” at 23%, “Moderate Amount” at 21%, and, “A Great Deal” at 4%. The results show some alignment between executives and managers, and scientists and laboratory personnel of the opinion there is room to shorten the timeframe needed for vaccine development. However, scientists and laboratory personnel do appear to be more spread out with less alignment on perceptions of typical time vs ideal time. Figure 4.9 below breaks down the respondents’ selection by proposed vaccine challenges.

Figure 4.9: How Current Time Taken to Develop Various Vaccine Solutions Differs from Ideal Time to Develop Vaccine Solutions by Scientists and Laboratory Personnel



The clinical study personnel group was asked how preparation of study materials, facilities, sourcing of animals, etc. differs under current operating conditions compared to ideal operating conditions. The most responses by the clinical study personnel across the various vaccine development challenges was “A Moderate Amount” at 35%, “A Lot” at 30%, “A Little” at 16%, followed by “None At All” and “A Great Deal” with 11% and 9% respectively (Figure 4.10). 74% of the clinical study personnel responded that the typical vs ideal times differ by a moderate amount or greater. It appears as though all respondent groups recognize there is opportunity to improve the time it takes to develop a vaccine, but the clinical study personnel perceive the gap to be much greater than any other groups.

Figure 4.10: How Current Time Taken to Develop Various Vaccine Solutions Differs from Ideal Time to Develop Vaccine Solutions by Clinical Study Personnel

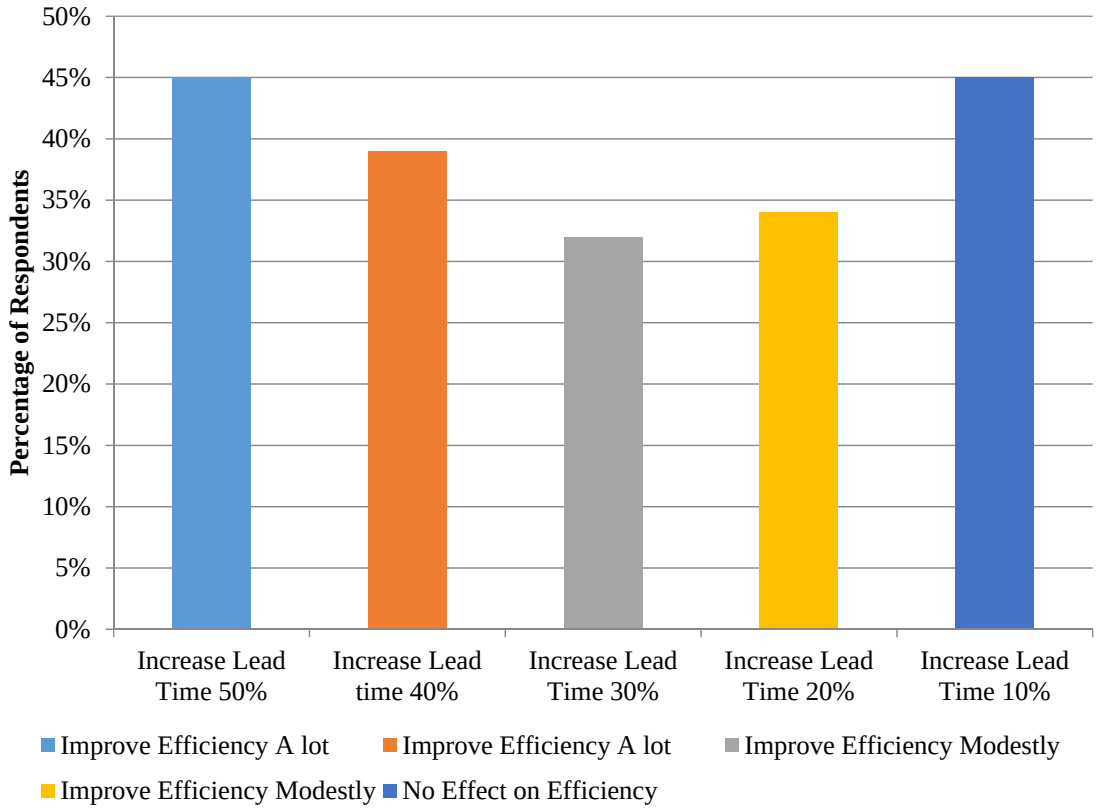


Each respondent group was then asked via free text the most important reason between the typical and ideal time. The executive and manager groups felt in general, the difference was due to lack of transparency and slow decision-making. Scientists and laboratory personnel groups felt IACUC challenges as well as facility availability in general were the reasons for the difference. Receiving protocols (IACUC and study protocols) were in general the primary reasons why the clinical study personnel group felt there was a difference between typical and ideal time to develop various vaccine solutions. This creates an opportunity to enhance the development of the required processes to get approvals and undertake the necessary studies according the specified standards and protocols.

4.9 Economic Effects Communication Challenges

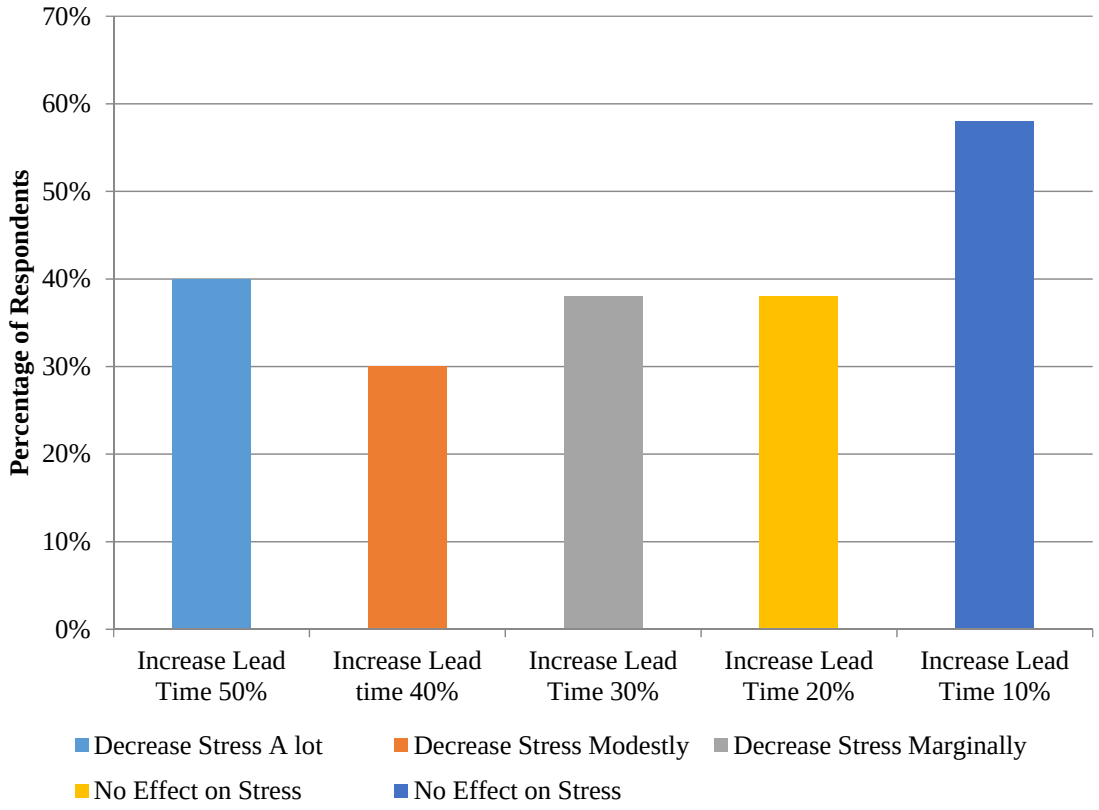
With respect to receiving and preparing items in an appropriate amount of time, all respondents, except the executive group, were asked to rank lead time. Specifically, how adequate it the amount of lead time they currently get prior to putting the necessary actions in place in order to support the development of a new product. They were also asked how increased lead-time could increase their efficiency and alter their stress level. People performance is a key economic driver of any company. The research looked to see how lead-time affects stress levels and how efficiency can be improved. Of the 56 people that ranked their current amount of lead-time, 45% said their current lead-time was moderately adequate, while 23% felt it was neither adequate nor inadequate. Another 23% felt their current lead-time was moderately inadequate while only 7% felt it was very adequate. Most respondents felt that increasing lead-time by 40% to 50% would improve their efficiency a lot; while a smaller percentage of the groups felt increasing lead-time 20% to 30% would improve their efficiency modestly. About 45% of respondents did not believe a 10% increase in lead-time would have any effect on efficiency (Figure 4.11). These results indicate lack of effective lead-time is also a gap in the development process.

Figure 4.11: Effect of Lead Time on Efficiency



The same approach was taken towards stress and lead-time. Most respondents felt that increasing lead-time by 50% would decrease stress a lot; while 40% of the groups felt increasing lead-time 40% would decrease their stress modestly. 38% of respondents thought a 30% increase in lead-time would decrease stress marginally, and the majority felt an increase in lead-time of 10%-20% would have no effect on stress (Figure 4.12).

Figure 4.12: Effect of Lead Time on Stress



When these groups were asked, "What is the most important thing you think your direct superiors can do to increase your current efficiency"? The main responses included: provide/allow adequate time, people, and facility resources, improved communication (transparent, accurate, timely), and faster decision-making. Again, we see a trend in which communication is one of the key areas people in the product development supply chain feel needs to be improved.

All groups were asked to indicate the extent of their satisfaction with their company's processes and systems for effectiveness, adequacy, and compliance for study development, initiation, and execution. Of the 64 people who responded to these questions, approximately 75%, 73%, and 74% were satisfied with their company's processes and systems for effectiveness, adequacy and compliance for study development. 20%, 17%,

and 13% were dissatisfied. When the same groups were asked how much more a 10% improvement in compliance rate in their company's processes and systems for study development, initiation, and execution would improve the effectiveness in study conduct, about 44% felt the impact would only be slightly higher, while about 38% felt it would be about the same. These results would indicate the majority of people feel satisfied with their company's processes and systems for effectiveness, adequacy, and compliance for study development, initiation, and execution, thus eliminating a possible gap in the development chain. Questions that could have been asked and may need to be asked in the future would include how many respondents feel they have ownership in their company's processes and procedures, and does this make a difference? Also, what percentage increase in compliance to processes would make a much higher impact on study development, initiation, and execution effectiveness?

In order to try to help pinpoint potential delays along the process development chain, a question was focused on where perceived bottlenecks occur. The question asked was, "To what extend do the following contribute to the bottlenecks hindering effectiveness of current processes and systems for study execution in your company"? Respondents were able to select the following choices: animal availability, facility resources, people resources, information availability, or other. Animal availability, facility resources and people were identified by 90% or more respondents as bottlenecks to the effectiveness of a study. Information, despite its prominence above, was selected by less than 90% of respondents.

People resources were viewed as the highest contributor to bottlenecks followed by facility resources, and animal availability. This could demonstrate a link between lack of

communication between the different groups and issues with lead-time. If items are not communicated clearly and soon enough, there is the risk of not having facilities available and missing the opportunity to arrange for the animals needed for a particular study. This could be due to lack of people resource as well. It was also noted that change in study scope does occur, with 52% of respondents selecting “unclear communication about project/study requirements” being what best describes the reason for change in study scope.

Lack of communication appears to be a trend in the survey results, as all groups were asked how often they think lack of accuracy, clarity, or timeliness of communication affects their work in different ways. 95% believe lack of accuracy, clarity or timeliness of communication causes bottlenecks with people and facility resources, while 92% believe this affects both their quality of work for study preparation and execution, and their ability to complete tasks right the first time. Finally, 79% believe lack of accuracy, clarity or timeliness of communication affects their work by causing excess capacity of people and facility resources.

The four work items listed above are all critical to effective and efficient product development, but as shown, an overwhelming majority of respondents on all four work items listed is affected by lack of accuracy, clarity, or timeliness of communication. This most certainly has an impact on a company’s bottom line.

Finally, all respondents were asked the following question, “Suppose the cost of developing, initiating and executing a study to support a typical biologics product is $100. How much does this cost increase because of the communication challenges across the internal supply chain you have indicated above?” The challenges create costs resulting from untimely sharing of information, inaccuracies in shared information, lack of clarity in

communication, etc., which contribute to delays, procurement errors, experimental design flaws, etc. The purpose of this question is to gauge the perceived cost of communication challenges. That is, if the perceived costs are considered a percentage increase in study costs resulting from these communication challenges, then stakeholders can multiply that by their actual costs to get an idea of the cost of their communication challenges. That realization should be a motivation for doing something urgently about the problem.

The average perceived cost over all respondents was $84.09/$100.00, i.e., approximately 84.1%. That is to say, respondents – regardless of their role, saw an average increase in study implementation cost by more than 84% because of communication challenges in biologics studies. Scientists saw an even higher cost resulting from communication challenges – more than 117% - while executives saw a relatively lower cost of about 32%. This may be because scientists are closer to these studies and tend to see how the gaps in communication from their superiors could help them do things a little more efficiently. What is interesting is that the cost of communication challenges is positive and statistically different from zero for all roles. The results are summarized in Table 4.2.

Table 4.2: Summary Statistics of the Perceived Cost of Communication Challenges for Biologics Study

Role	Average	Std. Dev.	Median	Minimum	Maximum
Lab/Clinical	$57.12	$50.34	$50.00	$1.00	$200.00
Scientists	$117.33	$143.54	$50.00	$5.00	$500.00
Managers	$97.06	$237.80	$25.00	$0.00	$1,000.00
Executives	$32.00	$39.47	$20.00	$5.00	$100.00
Total	$84.09	$155.73	$35.00	$0.00	$1,000.00

The difference of $85.33 between the mean cost of communication challenges for biologics study as perceived by scientists and executives was statistically significant at the

5% level [|t| = 2.08; p>|t| = 0.042]. However, the differences between all other perceptions were not statistically significant.

For a pharma study, the average perceived cost was even higher - $104.69/$100.00. As with the case for biologics' studies, executives perceived the lowest cost. Table 4.3 presents the summary statistics for the different roles' perceived costs associated with communication challenges. It is worth noting that for both biologics and pharma, executives saw the least cost effect associated with communication challenges. Why would managers and scientists' perceptions of this cost be between three and seven-fold higher? This is a question that we did not anticipate and, hence, do not have a good answer to. We present it for further investigation. In addition, it is important to note that each group may have a different understanding and/or interpretation of the product development process, therefore the answers to perceived cost challenges may not be on a consistent valuation across groups.

Table 4.3: Summary Statistics of the Perceived Cost of Communication Challenges for Pharmaceutical Study

Role	Average	Std. Dev.	Median	Minimum	Maximum
Lab/Clinical	$53.33	$51.47	$40.00	$0.00	$200.00
Scientists	$121.33	$136.71	$50.00	$5.00	$500.00
Managers	$145.00	$368.36	$30.00	$0.00	$1,500.00
Executives	$22.50	$3.54	$22.50	$20.00	$25.00
Total	$104.69	$230.70	$40.00	$0.00	$1,500.00

The perceptions of lab/clinical personnel about the cost of communication challenges in pharmaceutical study was statistically significant from that of scientists at the 10% level [Difference = $68.00; |t| = 1.80; p>|t| = 0.078] and between lab/clinical personnel and executives was statistically significant at the 5% level [Difference = $30.83; |t| = 2.28; p>|t| = 0.027]. The perception of scientists about the cost of communication challenges was

statistically significant from that of executives at the 1% level [Difference = $98.83; |t| = 2.78; p>|t| = 0.007]. None of the other differences was statistically significant. As seen under the biologics study, the difference between executives and the scientists, especially, may be because while scientists talk to managers and lab/clinical personnel on a more frequent basis, they do not necessarily talk to executives on the same level of frequency. This produces a more coherent view of the problem among them than with executives.

CHAPTER V: CONCLUSION

When the need for producing a new animal health product is determined, the supply chain can be improved with better timeliness, accuracy, and completeness of information communicated between internal groups; understanding their problems in the system and increasing production can possibly result in the development of new products faster and at a lower cost. The objective of this research was to identify gaps in the process for coordinating information flow and activities within animal health product development to minimize production costs and accelerate speed to market. With the specific objectives of:

1. Describe the vaccine product development process currently being used in the animal health industry, emphasizing the communication processes that ensure effectiveness of the process;
2. Determine how different groups in the vaccine development chain of the animal health industry view current communication processes and their perceptions about gaps in their communication processes; and
3. Present how industry participants see how identified communication gaps may be addressed and test if they differ across groups in the vaccine development chain; and
4. Use the results to develop recommendations for improving communication along the vaccine development chain.

There is no literature in the public domain that asks or addresses these questions about product development in the animal health industry and by researching these objectives; answers can be found to identify gaps and potential solutions. Animal Health companies

will benefit by getting products to market faster and the public benefits by getting new, innovative products to address their specific pet and livestock needs.

As the industry changes focus to vaccines as opposed to antibiotics, and vaccines require ongoing innovation to meet market needs, improvement in the product development supply chain becomes even more critical for companies to be first to market. Although there is no literature specifically on improving the supply chain for product development in the animal health industry, there are examples that can be extrapolated to veterinary vaccine development, such as emphasis on internal (and external) partnerships, utilizing Theory of Constraints, or a centralized approach to attain coordination along the supply chain, and the importance of accurate, timely, and clear flow of communication for the processes to work. All of these possibilities have positives and negatives, and with the lack of available literature this research is all the more important.

In order to answer the research objectives, a survey (Appendix A) comprised of approximately thirty-nine questions, was sent to 107 animal health professionals in 14 animal health companies around the world in order to gain a better understanding of the viewpoints of communication and process flow from people in the industry in different roles along the product development supply chain. This included the time product development takes under current operating conditions versus ideal operating conditions and why there is a difference, amount of lead time needed to properly prepare for a study, amount of stress involved based on too little lead time, how efficiencies can be improved, primary bottlenecks, what causes these bottlenecks, and how lack of accurate, clear, and timely communication affects the product development process. Of the 107 people, about 72% responded and the survey completion rate was 91%. Five role categories in the

animal health industry were used in this study: executive; managers or project leaders; scientists; clinical study personnel; and laboratory personnel with general responsibilities defined for the purposes of the survey. More than 92% of respondents were involved in biologics and or pharmaceutical aspects of the animal health industry and the majority of respondents (62.3%) had more than 10 years' experience.

The results of this research suggest a disconnect between various groups along the product development supply chain. For example, the difference between scientists' perception about executives keeping managers/project leaders informed about product development ideas when compared to executives and managers/project leaders' perceptions is statistically significant at the 1% level, with only 60% of scientists perceiving this to be true versus 95.2% and 100% of managers/project leaders and executives. Although the communication is between executives and managers/project leaders, there does appear to be a potential gap if the next level of the development chain, scientists, perceive communication about product development ideas to not be communicated to managers/project leaders. There was also statistical significance at the 5% level between scientists and managers/project leaders with executives on the questions of screening animals once a tentative start date is established. Scientists and managers/project leaders are closer to the process than executives, which could explain this result. A question to ask would be should executives have a better idea of a process such as this, because animals and the ability to procure them for product development is a very crucial step in the process. There also appears to be a disconnect of perceptions for clinical study personnel and their communication of facility needs for studies. There was a statistical significance at the 10% level between executives and managers/project

leaders on the perception of clinical study personnel communicating facility needs as soon as tentative study dates are established, with 100% of executives agreeing and only 85.7% of managers/project leaders agreeing. There was no statistical significance between managers and scientists or executives and scientists, but why the gap with managers and executives, especially since executives are most removed from the process. When looking at if protocols are completed early enough to ensure effective preparation for a study, the perceptions between executives and scientists, and executives and managers/project leaders were statistically significant at the 10% and 1% levels respectively. Again, this can be explained because executives are not as close to these processes as the managers/project leaders and scientists. Nonetheless, the criticality of having protocols prepared so groups further down the development chain have time to fully prepare for a study may be a process in which decision makers, i.e., executives will want to have a better understanding in order to help facilitate improvement in the entire process.

When looking at perspectives that include lab/clinical study personnel along with managers/project leaders and scientists, gaps in perception occur as well. When looking at completion of IACUC protocols, the perceptions between scientists and lab/clinical study personnel show statistical significance at the 5% level. 63.2% of lab/clinical study personnel perceive that IACUC protocols are completed at least two months ahead of study start dates, whereas 89.5% of scientists perceive this to be true. The gap identified with this question should raise concerns as these groups typically work together closely. Perceptions on this subject should be better aligned and the question of effective communication, and/or expectations should be addressed. Similar results are seen when

asking about perceptions about study protocol completion. 63.2% of scientists perceive study protocols are completed and approved at least one month ahead of study start date, but only 31.6% and 28.6% of lab/clinical study personnel and managers/projects leaders agreed with this statement. Again, we see statistical significance between scientists and lab/clinical study personnel at the 5% level. In addition, we see statistical significance between scientists and managers/project leaders at the 10% level. Concerns should be raised with this lack of alignment between perceptions as well. Could the scientists' perceptions be causing stress down the development chain to lab/clinical study personnel as the scientists believe they are completing study protocols in a more timely fashion than reality, or do lab/clinical study personnel believe they are still not getting enough time to prepare once they receive a final protocol? These questions need to be asked. Keep in mind, manager/project leaders were in closer alignment with lab/clinical study personnel. This may be something their role needs to address with the scientists' group.

All respondents agreed that there needs to be better, increased communication and there is room for improvement in the current time needed to develop a vaccine when compared to the perceived ideal time needed. The research also indicates there is a lack of adequate lead time in the product development process and a 40% to 50% increase in lead time would reduce stress modestly to a lot, respectively. The research showed the majority of respondents were satisfied with their company's processes and systems for study development, initiation, and execution thus eliminating a potential gap in the process. People resources were viewed as the highest contributor to bottlenecks, which could demonstrate a link with lack of communication between groups. When a change in study scope occurs, 52% of respondents believed unclear communication about

project/study requirements was the reason for the change in scope. Almost 90% of respondents felt that four core work items of: quality of work for study preparation & execution, ability to complete tasks right the first time, excess capacity of people and facility resources, and bottlenecks with people and facility resources are affected by lack of accuracy, clarity, or timeliness of communication.

The perceived extra cost of product development for biologics due to timeliness, accuracy, and clarity challenges was an approximate increase of 84%. The perceived extra cost of communication challenges for product development of pharmaceuticals was even higher at approximately 104.7%. As mentioned earlier, the perceived cost associated with communication challenges was the least with executives for both biologics and pharmaceuticals, but it is important to note that each group may have a different understanding and/or interpretation of the product development process, therefore the answers to perceived cost challenges may not be on a consistent valuation across groups.

There currently is no literature addressing the product development supply chain in the animal health industry, specifically the animal phase of vaccine development. This research demonstrates companies should re-evaluate their own expectations for communication between and amongst critical groups in product development, as lack of communication is costing companies money by slower development times and lost time to market.

The primary focus of this research was on vaccine development, specifically, the animal phase. Pharmaceutical respondents were also included in this research, but this category was not broken out. Future research should include this component in order to analyze differences between vaccines and pharmaceutical animal health product

development, and the factors affecting the differences. Linear regression analysis may also be used to look for statistical significance between different respondent categories – areas of agreement and disagreement, current versus ideal operating conditions, and bottlenecks in the process. Finally, utilization of a more quantitative approach (how does each group define a moderate amount, etc.) to simulate current and alternative processes to identify the most cost effective and value enhancing communication and activity process for the development of animal health products would be of great value to the research and the industry.

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APPENDIX A: ONLINE SURVEY QUESTIONS "EFFICENCY IN PRODUCT DEVELOPMENT"

Q1 Adam Tjernagel has already written to you indicating his need for your help in collecting the information being solicited by this survey to complete his thesis for his Master of Agribusiness degree at Kansas State University. His thesis is exploring Barriers to Efficiency in Product Development in the Animal Health Industry. Your response to this survey will provide him with the needed insights to identify solutions to this problem. The research is being supervised by Dr. Vincent Amanor-Boadu, Agribusiness Economics and Management Professor at Kansas State University. If you have any questions about this survey, please contact Dr. Vincent by email (vincent@ksu.edu) or by phone (785-532-3520). The survey should take no more than 15 minutes of your time. While your participation is very much desired, you are under no obligation to participate in this survey. There will be no penalty or reward for your decision. Finally, your anonymity is guaranteed. The results will be presented in ways that do not allow any of your responses to be traced back to you.Are you willing to participate in the survey?

- ❍ Yes (1)
- ❍ No (3)

Q2 Which of the following best describes how long you have you been working in the Animal Health Industry?

- ❍ Less than a year (1)
- ❍ 1 to 5 years (2)
- ❍ 5 to 10 years (3)
- ❍ More than 10 years (4)

Q3 Please indicate which of the following best describes your current role. We use the following definitions for the roles: Executive: oversight of entire product development process for your company Manager/Project Leader: oversight of product development process for some or all species categories Scientist: scientific development of study protocols and responsible for individual studies Laboratory Personnel: perform benchtop work for study conduct processes, typically reporting to Scientists or Managers/Project Leaders Clinical Study Personnel: set up facilities, equipment, animals, etc. and prepare for In-Life phase of a study, and/or "hands-on" animal work during In-Life phase of a study

- ❍ Executive (5)
- ❍ Manager or Project leader (4)
- ❍ Scientist (3)
- ❍ Laboratory Personnel (2)
- ❍ Clinical Study Personnel (1)

Q4 Please indicate which of the following best describes your highest level of educational attainment

- ❍ PhD (1)
- ❍ DVM (2)
- ❍ MBA (3)
- ❍ Masters (4)
- ❍ Bachelors (5)
- ❍ Other (6)

Q5 Does your current position allow you to work on biologics and/or pharma products in your company?

- ❍ Yes (1)
- ❍ No (3)

Q6 Please indicate which of the following products you focus on in your current position.

- ❍ Biologics (1)
- ❍ Pharma (2)
- ❍ Biologics and Pharma (3)

Q7 Which of the following species do you work on given your selected product focus?

	Biologics (1)	Pharma (2)	Biologics and Pharma (3)
Feline (1)	❍	❍	❍
Canine (2)	❍	❍	❍
Equine (3)	❍	❍	❍
Beef Cattle (4)	❍	❍	❍
Dairy Cattle (5)	❍	❍	❍
Chicken (6)	❍	❍	❍
Turkey (7)	❍	❍	❍
Sheep & Goat (8)	❍	❍	❍
Aquaculture (9)	❍	❍	❍

Q8 To what extent do you agree with the following statements?

	Strongly agree (11)	Agree (12)	Somewhat agree (13)	Neither agree nor disagree (14)	Somewhat disagree (15)	Disagree (16)	Strongly disagree (17)
Executives keep managers or project leaders informed about potential product development ideas. (1)	❍	❍	❍	❍	❍	❍	❍
Sourcing of required animals begins only when product development is approved. (2)	❍	❍	❍	❍	❍	❍	❍
Study start date is set and finalized too late, causing downstream stress (protocol development, animal sourcing, preparing facilities, etc.). (7)	❍	❍	❍	❍	❍	❍	❍
Screening of animals begins as soon as tentative study start date is established. (4)	❍	❍	❍	❍	❍	❍	❍

Clinical Study Personnel quickly communicate animal facility needs for studies as soon as tentative study start date is established. (5)	❍	❍	❍	❍	❍	❍	❍
Final study details are communicated to clinical study personnel only when tentative start date is established. (3)	❍	❍	❍	❍	❍	❍	❍

Q9 Please indicate the extent to which you agree with the following statements.

	Strongly agree (4)	Agree (5)	Somewhat agree (6)	Neither agree nor disagree (7)	Somewhat disagree (8)	Disagree (9)	Strongly disagree (10)
Managers/Project Leaders keep scientists informed about potential product development ideas at all times. (1)	❍	❍	❍	❍	❍	❍	❍
Study protocol draft writing begins only when all necessary information for the proposed study is available. (2)	❍	❍	❍	❍	❍	❍	❍
IACUC (Institutional Animal Care and Use Committee) protocols are completed and approved early enough to ensure effective preparation for the study. (3)	❍	❍	❍	❍	❍	❍	❍
Study protocols are completed and approved early enough to ensure effective preparation for the study. (4)	❍	❍	❍	❍	❍	❍	❍

Q10 To what extent do you agree with the following statements?

	Strongly agree (4)	Agree (5)	Somewhat agree (6)	Neither agree nor disagree (7)	Somewhat disagree (8)	Disagree (9)	Strongly disagree (10)	N/A (11)
Scientists inform laboratory personnel about potential product development only if they are completely sure about it moving forward. (1)	❍	❍	❍	❍	❍	❍	❍	❍
Scientists will give clinical study personnel information about a potential project only if they are completely sure about it moving forward. (3)	❍	❍	❍	❍	❍	❍	❍	❍

Clinical Study Personnel communicate animal facility availability, clinical study personnel availability, and animal availability for proposed studies to scientists frequently. (2)	❍	❍	❍	❍	❍	❍	❍	❍

Q11 Please indicate the extent to which you agree with the following statements.

	Strongly agree (1)	Agree (2)	Somewhat agree (3)	Neither agree nor disagree (4)	Somewhat disagree (5)	Disagree (6)	Strongly disagree (7)	N/A (8)
IACUC protocols are completed and approved well ahead of tentative study start date, say two months. (4)	❍	❍	❍	❍	❍	❍	❍	❍
Writing of the study protocol begins as soon as information about a study is available. (1)	❍	❍	❍	❍	❍	❍	❍	❍
Study protocols are completed and approved well ahead of the tentative study start date, say about one month. (3)	❍	❍	❍	❍	❍	❍	❍	❍

Facility preparation begins only when all of the information for the proposed study is available. (2)	❍	❍	❍	❍	❍	❍	❍	❍

Q12 Given your role in your organization, what is the most important thing you can do to improve the timeliness of information about product development between you and your staff?

	Most Important Thing to Improve Timeliness of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q13 Given your role in your organization, what is the most important thing you can do to improve the timeliness of information about product development between you and your superiors?

	Most Important Thing to Improve Timeliness of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q14 Given your role in your organization, what is the most important thing you think your superiors can do to improve the timeliness of information about product development?

	Most Important Thing to Improve Timeliness of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q15 Given your role in your organization, what is the most important thing you can do to improve the accuracy of information about product development between you and your staff?

	Most Important Thing to Improve Accuracy of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q16 Given your role in your organization, what is the most important thing you can do to improve the accuracy of information about product development between you and your superiors?

	Most Important Thing to Improve Accuracy of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q17 Given your role in your organization, what is the most important thing you think your superiors can do to improve the accuracy of information about product development?

	Most Important Thing to Improve Accuracy of Information (1)
Executive (x5)	
Manager or Project leader (x4)	
Scientist (x3)	
Laboratory Personnel (x2)	
Clinical Study Personnel (x1)	

Q18 On average, how many years does it take to develop a vaccine from initial idea/concept to product licensure?

Number of years to develop a vaccine from concept to licensure (1)

Q19 On average, how many years does it take to develop a drug from initial idea/concept to product registration?

Number of years to develop a drug from concept to registration (1)

Q20 In this section, we will conduct some thought experiments based on your specified role above. Which of the following vaccine development challenges (or similar situations) do you

have enough knowledge to think about implementing (or have implemented) in your company if it became necessary?

	Yes (24)	No (25)
Feline Leukemia Virus vaccine (5)	❍	❍
Canine Parvo Virus vaccine (4)	❍	❍
Equine West Nile Virus vaccine (7)	❍	❍
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (8)	❍	❍
Lepto 5-way vaccine for dairy cattle (9)	❍	❍
Porcine Circo Virus vaccine (10)	❍	❍
Mycoplasma Gallisepticum vaccine (11)	❍	❍
Newcastle Disease vaccine (12)	❍	❍
Clostridium Perfringens C & D Antitoxin (13)	❍	❍
Aeromonas Salmonicida Bacterin for aquaculture (14)	❍	❍

Q21 Given the prevailing conditions under which you work, to what extent will the time it takes you and your team to identify and develop a vaccine solution to the identified

challenges differ under your current operating conditions compared to ideal operating conditions?

	A great deal (13)	A lot (14)	A moderate amount (15)	A little (16)	None at all (17)
Feline Leukemia Virus vaccine (x5)	❍	❍	❍	❍	❍
Canine Parvo Virus vaccine (x4)	❍	❍	❍	❍	❍
Equine West Nile Virus vaccine (x7)	❍	❍	❍	❍	❍
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (x8)	❍	❍	❍	❍	❍
Lepto 5-way vaccine for dairy cattle (x9)	❍	❍	❍	❍	❍
Porcine Circo Virus vaccine (x10)	❍	❍	❍	❍	❍
Mycoplasma Gallisepticum vaccine (x11)	❍	❍	❍	❍	❍
Newcastle Disease vaccine (x12)	❍	❍	❍	❍	❍
Clostridium Perfringens C & D Antitoxin (x13)	❍	❍	❍	❍	❍
Aeromonas Salmonicida Bacterin for aquaculture (x14)	❍	❍	❍	❍	❍

Q22 What do you think is the most important reason for the difference between your typical and ideal time in defining a solution to the vaccine development challenges ?

	Most Important Reason (1)
Feline Leukemia Virus vaccine (xx5)	
Canine Parvo Virus vaccine (xx4)	
Equine West Nile Virus vaccine (xx7)	
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (xx8)	
Lepto 5-way vaccine for dairy cattle (xx9)	
Porcine Circo Virus vaccine (xx10)	
Mycoplasma Gallisepticum vaccine (xx11)	
Newcastle Disease vaccine (xx12)	
Clostridium Perfringens C & D Antitoxin (xx13)	
Aeromonas Salmonicida Bacterin for aquaculture (xx14)	

Q23 To what extent will the time it takes you and your team to prepare all materials, protocols, etc. in order to initiate a study so as to begin the process of defining a solution to

the vaccine development challenges differ under your current operating conditions compared to ideal operating conditions?

	A great deal (11)	A lot (12)	A moderate amount (13)	A little (14)	None at all (15)
Feline Leukemia Virus vaccine (x5)	❍	❍	❍	❍	❍
Canine Parvo Virus vaccine (x4)	❍	❍	❍	❍	❍
Equine West Nile Virus vaccine (x7)	❍	❍	❍	❍	❍
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (x8)	❍	❍	❍	❍	❍
Lepto 5-way vaccine for dairy cattle (x9)	❍	❍	❍	❍	❍
Porcine Circo Virus vaccine (x10)	❍	❍	❍	❍	❍
Mycoplasma Gallisepticum vaccine (x11)	❍	❍	❍	❍	❍
Newcastle Disease vaccine (x12)	❍	❍	❍	❍	❍
Clostridium Perfringens C & D Antitoxin (x13)	❍	❍	❍	❍	❍
Aeromonas Salmonicida Bacterin for aquaculture (x14)	❍	❍	❍	❍	❍

Q24 What do you think is the most important reason for the difference between the typical and ideal time it takes you and your team to prepare all materials, protocols, etc. in order to initiate a study so as to begin defining a solution to the vaccine development challenges?

	Most Important Reason (1)
Feline Leukemia Virus vaccine (xx5)	
Canine Parvo Virus vaccine (xx4)	
Equine West Nile Virus vaccine (xx7)	
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (xx8)	
Lepto 5-way vaccine for dairy cattle (xx9)	
Porcine Circo Virus vaccine (xx10)	
Mycoplasma Gallisepticum vaccine (xx11)	
Newcastle Disease vaccine (xx12)	
Clostridium Perfringens C & D Antitoxin (xx13)	
Aeromonas Salmonicida Bacterin for aquaculture (xx14)	

Q25 To what extent will the time it takes you and your team to prepare all materials, facilities, source animals, etc. in order to initiate a study so as to begin the process of defining a

solution to the vaccine development challenges differ under your current operating conditions compared to ideal operating conditions?

	A great deal (13)	A lot (14)	A moderate amount (15)	A little (16)	None at all (17)
Feline Leukemia Virus vaccine (x5)	❍	❍	❍	❍	❍
Canine Parvo Virus vaccine (x4)	❍	❍	❍	❍	❍
Equine West Nile Virus vaccine (x7)	❍	❍	❍	❍	❍
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (x8)	❍	❍	❍	❍	❍
Lepto 5-way vaccine for dairy cattle (x9)	❍	❍	❍	❍	❍
Porcine Circo Virus vaccine (x10)	❍	❍	❍	❍	❍
Mycoplasma Gallisepticum vaccine (x11)	❍	❍	❍	❍	❍
Newcastle Disease vaccine (x12)	❍	❍	❍	❍	❍
Clostridium Perfringens C & D Antitoxin (x13)	❍	❍	❍	❍	❍
Aeromonas Salmonicida Bacterin for aquaculture (x14)	❍	❍	❍	❍	❍

Q26 What do you think is the most important reason for the difference between the typical and ideal time it takes you and your team to prepare all materials, facilities, source animals, etc. in order to initiate a study so as to begin defining a solution to the vaccine development challenges?

	Most Important Reason (1)
Feline Leukemia Virus vaccine (xx5)	
Canine Parvo Virus vaccine (xx4)	
Equine West Nile Virus vaccine (xx7)	
4-way IBR, BVD, PI3, BRSV vaccine for beef cattle (xx8)	
Lepto 5-way vaccine for dairy cattle (xx9)	
Porcine Circo Virus vaccine (xx10)	
Mycoplasma Gallisepticum vaccine (xx11)	
Newcastle Disease vaccine (xx12)	
Clostridium Perfringens C & D Antitoxin (xx13)	
Aeromonas Salmonicida Bacterin for aquaculture (xx14)	

Q27 How would you rank the amount of lead time you currently get prior to putting the necessary preparatory activities in place to undertake a study to support the development of a product?

- 1 = Very inadequate (1)
- 2 = Moderately inadequate (2)
- 3 = Neither adequate nor inadequate (3)
- 4 = Moderately adequate (4)
- 5 = Very adequate (5)

Q28 Please indicate how changes in the lead time you get could improve your efficiency in preparing for studies to support product development.

	Improve Efficiency Marginally (1)	Improve Efficiency Modestly (2)	Improve Efficiency a lot (3)	No Effect on Efficiency (4)	Decrease Efficiency Marginally (5)	Decrease Efficiency Modestly (6)	Decrease Efficiency a lot (7)
Increase current lead time by 50% (1)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 40% (2)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 30% (3)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 20% (4)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 10% (5)	❍	❍	❍	❍	❍	❍	❍

Q29 Please indicate how changes in the lead time could alter your current stress level when preparing for studies to support product development.

	Increase Stress Marginally (1)	Increase Stress Modestly (2)	Increase Stress a lot (3)	No Effect on Stress (4)	Decrease Stress Marginally (5)	Decrease Stress Modestly (6)	Decrease Stress a lot (7)
Increase current lead time by 50% (1)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 40% (2)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 30% (3)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 20% (4)	❍	❍	❍	❍	❍	❍	❍
Increase current lead time by 10% (5)	❍	❍	❍	❍	❍	❍	❍

Q30 What is the most important thing you think your direct superiors can do to increase your current efficiency?

Q31 Please indicate the extent of your satisfaction with your company's current processes and systems for study development, initiation, and execution.

	Extremely satisfied (11)	Moderately satisfied (12)	Slightly satisfied (13)	Neither satisfied nor dissatisfied (14)	Slightly dissatisfied (15)	Moderately dissatisfied (16)	Extremely dissatisfied (17)
Effectiveness of current processes and systems (26)	❍	❍	❍	❍	❍	❍	❍
Adequacy of current processes and systems (27)	❍	❍	❍	❍	❍	❍	❍
Compliance with of current processes and systems (28)	❍	❍	❍	❍	❍	❍	❍

Q32 How much more do you think a 10% improvement in the compliance rate with your company's current processes or systems for study development, initiation, and execution would improve the effectiveness with which studies are conducted?

- ❍ Much higher (39)
- ❍ Moderately higher (40)
- ❍ Slightly higher (41)
- ❍ About the same (42)
- ❍ Slightly lower (43)
- ❍ Moderately lower (44)
- ❍ Much lower (45)

Q33 To what extent do the following contribute to the bottlenecks hindering effectiveness of current processes and systems for study execution in your company?

	A great deal (26)	A lot (27)	A moderate amount (28)	A little (29)	None at all (30)
Animal availability (1)	❍	❍	❍	❍	❍
Facility resources (2)	❍	❍	❍	❍	❍
People resources (3)	❍	❍	❍	❍	❍
Information availability (4)	❍	❍	❍	❍	❍
Other: (5)	❍	❍	❍	❍	❍

Q34 What in your view is the most important contributor to you classifying the selections above as important bottlenecks?

Animal availability (1)

Facility resources (2)

People resources (3)

Information availability (4)

Other: (5)

Q35 Please indicate how frequently study start dates are delayed due to the following:

	Always (16)	Most of the time (17)	About half the time (18)	Sometimes (19)	Never (20)
Facilities not ready (1)	❍	❍	❍	❍	❍
Required facilities already in use by other studies (11)	❍	❍	❍	❍	❍
Unavailability of the right people to undertake the study (2)	❍	❍	❍	❍	❍
Study protocol not completed on time (12)	❍	❍	❍	❍	❍
IACUC protocol not completed on time (16)	❍	❍	❍	❍	❍
Change in study scope (13)	❍	❍	❍	❍	❍
Change in overall project scope (14)	❍	❍	❍	❍	❍
Change in portfolio priorities (15)	❍	❍	❍	❍	❍

Q36 What best describes the reason for each delay listed below?

	Inaccurate communication about project/study requirements (1)	Unclear communication about project/study requirements (2)	Poor timeliness of communication about project/study requirements (3)
Facilities not ready (x1)	❑	❑	❑
Required facilities already in use by other studies (x11)	❑	❑	❑
Unavailability of the right people to undertake the study (x2)	❑	❑	❑
Study protocol not completed on time (x12)	❑	❑	❑
IACUC protocol not completed on time (x16)	❑	❑	❑
Change in study scope (x13)	❑	❑	❑
Change in overall project scope (x14)	❑	❑	❑
Change in portfolio priorities (x15)	❑	❑	❑

Q37 Please indicate how often you think lack of accuracy, clarity, or timeliness of communication affects the following:

	A great deal (11)	A lot (12)	A moderate amount (13)	A little (14)	None at all (15)
Quality of work for study preparation and execution (1)	❍	❍	❍	❍	❍
Ability to complete tasks right the first time (2)	❍	❍	❍	❍	❍
Excess capacity of people and facility resources (3)	❍	❍	❍	❍	❍
Bottlenecks with people and facility resources (4)	❍	❍	❍	❍	❍

Q38 Suppose the cost of developing, initiating and executing a study to support a typical biologics product is $100. How much does this cost increase because of the communication challenges across the internal supply chain you have indicated above?

Extra Cost due to timeliness, accuracy and clarity of communication challenges (1)

Q39 Suppose the cost of developing, initiating and executing a study to support a typical pharma product is $100. How much does this cost increase because of the communication challenges across the internal supply chain you have indicated above?

Extra Cost due to timeliness, accuracy and clarity of communication challenges (1)