AN EXPLORATION OF THE GLOBAL CLINICAL TRIAL ANCILLARY SUPPLY CHAIN AND THE DRIVERS OF SUCCESS DURING THE PRE, IN, AND POST PHASES

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ABSTRACT

Until recently, academic and practitioner research on clinical trial supply chains focused on identifying innovative models and solutions in providing comparator and study drugs to global clinical sites. Due to the expansion of outsourcing efforts by pharmaceutical organizations, newly enacted global laws and regulations, and the continued push to increase the speed at which new drugs gain market approval, a new and extremely complex global "ancillary" supply chain has emerged. This manuscript focuses on the clinical trial ancillary supply chain: a supply chain that develops the end-to-end process resulting in the distribution and quality management of medical products and devices, consumable supplies, and patient giveaways to global clinical trial sites. Based on a series of quantitative analyses, this research assesses the influence of the customer, country, and product on the overall success of the supply chain. Three factors emerged from these analyses as having a direct influence on the clinical trial ancillary supply chain; product characteristics, magnitude (components of size), and stability (components of changes in scope). Part II of this research sought to understand the success of the supply chain by evaluating the moderating effects of knowledge management, organizational culture, therapeutic area, and type of shipment. Assessments of 444 customer and server surveys yielded components of a sense of shared culture, shared communication and transparency, and feeling educated and supported. Quantitative data analysis supported that these components had a moderating influence on success during the pre-trial phase of the supply chain. These research findings provide insight into the internal and external drivers of success within the complex and emergent clinical trial supply chain – a supply chain that helps pharmaceutical organizations bring innovative

therapies to market and most important, those patients in need of such therapies to improve or even save their lives.

Keywords: supply chain success, knowledge management, organizational culture, clinical trial supply chains, ancillary supplies

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CHAPTER 1: INTRODUCTION

Clinical Trials and Their Supply Chains

The pharmaceutical industry is fraught with extensive and unprecedented challenges in drug discovery. Expiring patents on blockbuster drugs, changing sources of profits, globalization of the clinical trial, and governmental and international regulations are restricting the flow and overall performance of clinical trials as life science organizations search for tomorrow's innovative and proven therapies. Global pharmaceutical revenue is expected to rise at an average of 5.1% per year over the next five years; however, big pharma faces significant challenges arising from financial and governmental pressures in healthcare, R&D risks, and clinical trial escalating expenditures as noted:

Table 1

Cost Estimates of Clinical Trials

Study	Cost Estimates
DiMasi et al. (2003)	$802 Million (1994)
Sertkaya et al. (2016)	$161 Million to $2 Billion (2012)
DiMasi and Grabowski (2007)	$1.2 Billion (2007)
O'Hagan & Farkas (2009)	$2.2 Billion (2009)

In addition to the escalating costs of successful clinical trials, which are those that lead to a marketable drug, pharmaceutical organizations face the costs of failure. Estimated failure costs range from $800M to $1.4B per incident with a mere one out of ten drugs making it to market. The success of these highly complex clinical trials that continue to expand in diverse regions of the world is heavily dependent on the clinical trial drug and ancillary supply chains throughout the course of the study (Kumar, 2008).

A significant portion of this increased spend (approximately 40% of total) is a direct result of costs associated with the clinical trial ancillary supply chain (Mignani et al., 2016; Abdelkafi et al., 2009). The clinical trial ancillary supply chain (CTASC) is a highly regulated and specialized model based on the individual needs of each clinical protocol and each clinical site across the world (Kumar, 2008). The CTASC is a global, highly variable, independently regulated, and decentralized system that delivers non-drug materials to sites for clinical investigator and patient use. Pharmaceutical organizations generally outsource their fulfillment of ancillary supplies to preferred partners, CTASC companies. These organizations utilize an integrated, end-to-end process that includes protocol and dosing schedule analyses to determine supply requirements, import and export regulatory analysis and control, sourcing and procurement, inventory and depot management, shipments on demand or in advance of patient arrivals, and reclamation/disposition management of materials remaining at site/trial closeout.

Many factors come into play that influence the overall outcome of the clinical trial ancillary supply chain at the pre, in and post phases. A few of these factors are as follows:

1. CTASC ships medical devices and lab equipment to global clinical trials and trial clinicians gather, record, and submit patient data to authorities (trial monitors and regulatory agencies). It is necessary to provide standardized medical devices and lab equipment across all global sites to ensure consistency and reliability of the retrieved data.

2. Medical devices and lab equipment requiring factory calibration and up-to-date certificates are maintained at sites and presented to authorities as proof of

compliance. The CTASC manages and is accountable for this process across the globe. Out-of-date or improper calibrations will result in rejection by governing drug approval agencies of any data captured from these devices.

3. In-country import regulations for medical supplies are always changing, often and without notice. If shipments are in transit during a change in regulations, the products will be returned to the provider firm and sites will go without necessary equipment or medical devices.

It becomes apparent that standardized products, quality assurance and regulatory compliance, product expiry/calibration requirements, and on-hand evidentiary documentation issues have the potential to challenge the provider and in worst-cases, cause trial-derailment with huge financial and legal ramifications to the drug discovery organization. As a result, it becomes imperative that all clinical trial materials and evidence of their handling are properly prepared with strict adherence to regulatory requirements prior to distribution (Lis et al., 2009). The clinical trial ancillary supply chain entails much specificity compared to the standard supply chain, as disruptions and stoppages may arise when viable solutions fail to provide the desired outcomes. Aspects of expiration dating, bulk product availability, and specific country labeling requirements are elements for careful analysis when developing and initiating the clinical trial supply chain (Abdelkafi et al., 2009; Lis et al., 2009). The internationalization of business, diversity and complexity of new drugs, and the diminishing protection provided by patents are some of the factors driving these changes (Papageorgiou et al., 2001).

Drug vs. Ancillary Supplies

Global clinical trial supply chains that manage drug and ancillary supplies are quite diverse and the differences between these supply chains are substantial. The drug supply chain organization manages the flow of study and comparator drug products to global clinical sites and procures, warehouses, manages inventory and expiry dating, schedules, and ships upon demand and in time for distribution to patients enrolled in clinical trials.

It is important to provide an overview of characteristics of planning processes utilized by pharmaceutical (pharma) companies for drug supply and CTASC organizations to best facilitate the readers' understanding. The chart below depicts some of the similarities and differences between a drug supply chain and the CTASC:

Table 2

Drug vs. Ancillary Supply Chains

Characteristics of the Supply Chain	Drug Supply Chain	CTASC
Products are critical to the end-point of the trial. Observations and data collected originating from these products are reported to authorities throughout the course of the trial and the during drug approval stage	Yes	Yes/No - Data collected from some equipment (centrifuges) and supplies (pregnancy test) are critical to end-point results and are reported to authorities
Proactive, organized approaches to determine demand, supply chain optimization, production planning, capacity, utilization plans, infrastructure support and investment to mitigate risk	Yes - 12-24 months prior to trial launch	No - 1-6 weeks prior to site initiation visit (SIV) and First Patient/First Visit (FPFV)
Pharma leadership teams intimately involved in the planning and process stages	Yes - Led by Medical and Clinical Operations Teams	No - Led by Operational teams such as Global Trial Management (GTM)

Table 2 (continued)		
In-country approvals by the Ministries of Health (MOH) for clinical products. This includes in-country drug registrations, gathering of certificates/documents and import clearances well in advance of shipment release	Yes - MOH approves comparator and study drugs. These drugs appear on all import documents	No - Ancillary supplies are not included on MOH approvals. Import of Record documents prepared by the CTASC at time of request. There is the imminent risk for delays and refusals during shipment
Supply Chain lead times clearly delineated to Global Trial Manager, (GTM) Clinical Research Associate (CRA), and global clinical sites so that receipt and inspection at clinical sites is brisk	Yes - Sites receive advance delivery schedules and are prepared to receive and inspect all deliveries	No - GTM requests supplies at site 2-8 days prior to when supplies are required. CTASC coordinates and manages all aspects of the delivery
Product manufacturers identified and negotiated procurements contracts signed.	Yes	No - Late stage factory negotiations and procurement initiatives take place
Supply forecasts and shipping schedules shared with factories and supply chain	Yes	No - High risk of product shortages
All supplies approved for use in all countries where clinical trial occurs	Yes - Products are listed on Ministry of Health, (MOH) approval documents in all countries	No - Many products are not pre-approved for use in all countries. High risk of procurement and shipping delays
In-country regulations remain consistent throughout the course of the trial	Yes - Once MOH approval is granted, shipments flow without interruptions	No - Product regulations change without notice thus posing risk to supply chain and delivery time lines.
Product is consistent in all countries throughout the chain	Yes - Drug supply is standard across the chain and without variations or substitutions	No - Product type varies based on country licensure and availability. The CTASC must procure similar / compatible products in-country. Huge risk that substituted products deliver inconsistent results

The CTASC organization faces a multitude of challenges that influence performance outcomes such as shortened lead times, little or no visibility of the project during the pre-planning/pre-protocol launch phase, uncertainty in product licensure, and in-country regulatory changes, etc. Simply stated, the "perfect storm" is brewing as the threat of the CTASC's ability to meet demands of the clinical trial grows with each passing day. So, the question remains, how might CTASC experts mitigate risks and overcome the threat of field service disruptions and failures?

Many researchers suggest that supply chain preparedness and success are achieved by developing strategic operational and inventory models. One common strategy is the utilization of process simulations that include regulatory and import/export preparedness, current and historical field data analysis, and looking ahead to anticipate adverse events. The ability of supply chain experts to develop adaptive designs and appropriate processes and procedures may fundamentally contribute to the success of clinical trial supply chain execution. Adaptive designs, as they relate to clinical trials, deliver flexibility and efficiency and allow clinicians to make necessary changes in protocol procedures such as sample size, amounts of medicinal dosing, etc. (Lis et al, 2009; Fleischhacker & Zhao, 2011; Fleischhacker et al., 2011; Gaydos et al, 2009; Chow and Chang, 2008). The principles of adaptive design can be applied to the CTASC to achieve supply chain readiness.

Modern business visionary Peter Drucker made famous the phrase, "innovate or die" (Drucker 1999). While there have been countless examples of paradigm shifts in the market across all industries that demonstrate Drucker's philosophy (e.g. Woolworths, Polaroid, Alta Vista, Kodak, Blockbuster, Borders), if we heed Drucker's edict in the

context of a participant in this emerging and ever-evolving ancillary supply chain, our next question becomes one of how do we innovate? How do we achieve this considering that supply-based clinical chains operate in an industry seemingly based on innovation?

Research Focus

A vast quantity of research on clinical trial drug supply exists in the literature that focus on a plethora of topics, including supply chain optimization, continuous improvement, best practices, transactional cost analysis, capacity planning, risk mitigation, etc. (Shah, 2004; Gatica et al., 2003; Sousa et al., 2011; Chen et al., 2012; Fleischhacker & Zhao, 2011; Fleischhacker et al., 2015).

Unfortunately, limited research exists on the topic of the CTASC. As this emergent supply chain is projected to grow year over year, research efforts are critical to ensure an understanding of the supply chain, build theory, and identify new topics of study.

Based on the above, it is important that researchers focus on topics within the ancillary supply chain. Because of new research, practitioners in CTASC organizations can better serve their pharma customers, grow their businesses, increase competitive advantage, and deliver value not only to the pharma organizations but to the patients that they serve.

For ease of presentation and to demonstrate the outcomes of this research, I conducted a two-part investigation that utilized a quantitative approach to analyze results and understand what elements influenced outcomes of the CTASC. Ultimately, this research attempted to understand the contributing factors that lead to the overall success of the supply chain.

Success in this research was defined as having the right product, in the right quantities, at the right country and site location so that treatment is available to the patient without the possibility of harm and delay of treatment.

Study I of this research focused on the external characteristics of customer, country/site, products, and therapeutic area and the findings indicated that magnitude, stability, and product characteristics had a direct influence on the overall success of the supply chain. These findings initially appeared to be counterintuitive, as one would expect that as variables change by size and scope, success will be impacted. But as indicated in this research, pharma has a higher level of scrutiny on larger trials that have huge investments and where success of the trial is critical. Alignment of the pharma organization and the CTASC is necessary if success is to be achieved.

Study II of this research focused on the internal characteristics of the supply chain to understand how organizational culture influenced the ability of the firm to acquire and use the knowledge it gathers. Internal historical CTASC surveys were analyzed to understand how the operating teams within the supply chain responded and applied knowledge. Responses were analyzed using a quantitative approach based on data gathered from Survey Monkey. Confirmatory factor and interaction analyses determined that moderation occurred during the pre-trial phase – where organizational culture and effective knowledge management influenced success. Ultimately, the overarching goal of this research was to determine how external and internal characteristics of customer, product, country, knowledge management, organizational culture, therapeutic area, and type of shipment influenced overall outcomes of the CTASC organization during pre, in,

and post phases of the clinical trial and supporting evidence from this research identified variables that influence success of this complex supply chain.

CHAPTER 2: LITERATURE REVIEW & CONCEPTUALIZATION

Defining the Supply Chain

Supply Chain Management (SCM) is defined as all activities involved in delivering a product from raw material through customer, and including raw materials, parts, manufacturing/assembly, warehouse/inventory, order, distribution management, systems technology and customer service. SCM coordinates and integrates these activities in a seamless process (Lummus & Vokurka, 1999). Supply chain (SC) organizations must manage the process from the manufacturing of goods to the delivery of such goods to customers. Systems, resiliency, integrated processes, and unique characteristics embedded in the firm broaden the definition of SCM and help firms to design programs that deliver successful outcomes. So how might these broad and differentiating definitions of SCM assist the CTASC in determining pathways to deliver successful outcomes?

I posit the CTASC brings uncertainties, complexities, and pressures that are unique. While it has been well settled that "the greater uncertainty in the (supply) chain will affect the performance of the (supply) chain," this is most evident when examining the CTASC (Reddy, et al., 2008). Identifying the characteristics that contribute to increased uncertainties and complexities and managing these throughout the supply chain will influence outcomes (McAdam & McCormack, 2001; Wang et al., 2004; Wang et al., 2008; Lambert and Cooper, 2000; Fisher et al., 1997; Prajogo et al., 2016; Gunasekaran et al., 2001; Mentzer et al., 2001).

Country Characteristics

Academic and practitioner research shows that certain country characteristics have a significant impact on supply chain success. Regulatory and customs delays are the most prominent characteristics influencing supply chain success with some countries displaying greater variations in these characteristics than others. The preeminent countries possessing such characteristics that influence supply chain success are Argentina, Russia, China, Colombia, and India, where numerous challenges lead to formidable failures that influence the progress of the trial (Abdelkafi, et al., 2009; Bamberger and Patel, 2017; Fisher, et al., 1997; Qi et al., 2009). Border strikes, trade barriers, and government corruption are but a few of the challenges that the CTASC must address. Managers of clinical supply chains should realize that those factors, which lead to success in one country today, might fail tomorrow as there is no single set of characteristics that are universal for success (Lamberti et al., 2016; Gatica et al., 2003; Lambert and Cooper, 2000). Ultimately, it is the responsibility of the CTASC organization and its' managers to proactively prepare to respond and learn from these experiences.

Countries such as Brazil, Chile, Colombia, Mexico, Peru, Costa Rica, Ecuador, Guatemala, and Panama are troublesome to the CTASC because of product restrictions, delays in clearances, and uncertain in-country procurement practices. In terms of country characteristics having a negative influence on the supply chain, Argentina is one of the most complex countries in Latin America. Office products (printed documents), measuring devices (rulers, scales, and data loggers), and electronic equipment (laptops and iPads), are highly regulated by governmental agencies (Bamberger & Patel, 2017).

These regulations influence logistics, causing substantial delays and creating additional complications in the supply chain. Among other elements, development of critical forethought for global distribution of drug supply is necessary to "overcome regulatory challenges and avoid hiccups," critical to supply chain success (Ketchen et al., 2014; Lis et al., 2009; Pedroso & Nakano, 2009; Wiengarten & Ambrose, 2017; Cooper et al., 1997; Coronel & Fregni, 2011).

Clinical trials are becoming progressively complex. Pharma organizations look to enroll "naïve patients" in their clinical trials. A subject is considered "naïve" if s/he has never undergone treatment for an illness. For example, in the world of sexually transmitted infections, the term is most often used to refer to people who are HIV-positive and who have never taken any antiretroviral therapy for their infection. Subjects who have taken one form of HIV medication are considered "treatment experienced", which leads pharma organizations to expand clinical research across the globe and in remote locations. The following chart is presented to illustrate the region of the world, the reasons pharma organizations are keen to conduct clinical trials in the region, and the challenges that the CTASC must address daily in these regions:

Table 3

Benefits and Challenges of Conducting Clinical Trials

Region	Benefits & Challenges of Conducting Clinical Trial	Challenges for CTASC
Latin America	Growing Population Qualified Medical Professionals Strong patient/doctor relationship High incidence of disease Naïve patients Diversity in the population Strong enrollment rates with 50% less drop outs Long approval processes Language translation issues Special licenses required	Medical devices must be licenses & registered MOH controls all medical devices & registrations In-country purchasing requirements necessity Regulatory guidelines change often & without notice
Russia & Ukraine	Large and available population Genetic diversity, naïve patients and high urban proportion Highly motivated & compliant patients High incidence of disease Possibility of turbulent political & economic climate Deficiency of modern medicine Special licenses required Numerous regulatory requirements & long approval processes	Limitations to where supplies and equipment can be sent Extremely complicated customs clearance processes & numerous delays Medical devices require certificates of compliance obtained in Russian Federation Strict accounting & reporting of all supplies & equipment In-country customs brokers required for clearance of all materials
China	Large patient pool & lower cost for services High incidence of disease Numerous naïve patients Delays in approval processes Research sites located in overcrowded hospitals Issues with accurate record keeping & data management	Medical devices must be registered in country Import licenses required Many import restrictions and many items banned for entry Numerous and unannounced trade barrier

In summary, there are numerous benefits to the pharma organization hosting clinical trials in remote regions of the world. Genetic diversity, naïve, compliant and highly motivated patients, and a high incidence of disease are a few benefits that increase pharma organizations' ability to recruit patients and complete clinical trials in such regions. Although the benefits in remote regions of the world can be a significant incentive for pharma organizations to host clinical trials in remote regions of the world, along with these benefits come several challenges that the CTASC must address to achieve success.

Customer Characteristics

Significant amounts of research have focused on various aspects of customer characteristics, including customer relationships, customer engagement, and the overall influence of these characteristics on firm success. Research has looked at customer partnerships, sharing of critical information, customer size, customer engagement, responsiveness, score carding, and customer collaboration in order to understand how these characteristics influence satisfaction and success (Brewer et al.,2000; Godsell, et al., 2006; Grewal et al., 2017; Slater & Reddy, 1997; Campbell and Cooper, 1999; Anderson et al., 2008; Reinartz et al., 2004). Differences in customer characteristics are often associated with differences in what customers value, the return on investment received from a relationship, the longevity of the supplier/customer, and the overall outcomes of the relationship (Anderson et al., 2008).

Understanding how to manage customer relationships has become an important topic in research, as firm success is a direct result of the effectiveness in the relationship (Reinartz et al., 2004). Customer relationship/engagement management is a process by

which provider firms can measure the effectiveness of their programs and subsequently build and adjust their models in response to their customers. These models can change the interaction between the customer and the provider firms, which has a direct impact on success (Reinartz et al., 2004; Beckers et al., 2018; Vivek et al., 2012; Venkatesan, 2017).

Employing on-going customer engagement and understanding the characteristics of the customer served by the CTASC firm are essential in today's marketplace. These relationships are ever-evolving and require extreme focus by the CTASC organization, as organizing the firm and triggering conversations to promote customer engagement are important assets that firms apply for success (Venkatesan, 2017).

The CTASC possesses the strict requirement to engage its' customers to understand, acknowledge, and adjust its' processes for preferred outcomes of success. Provider firm monitoring of the internal and external supply chain characteristics is necessary to understand those essential elements critical to the overall success of the supply chain. There is no time like the present for understanding these customer characteristics, engaging the customer in executing the supply chain, and in evaluating the performance of the supply chain so that success is delivered on all occasions (Lings, 2000).

Product Characteristics

"Supply chains must be engineered to match product characteristics and customer requirements," with the need to re-engineer the supply chain to address product lifecycles (Aitkin et al., 2003). An apparent example of the need to address product characteristics is when CTASC organizations modify the chain to address the expiry and calibration supply requirement at clinical sites; as traceability and calibration of devices are

fundamental requirements in CTASC logistics and considered a "clinical necessity" (Simpson, et al., 2006).

Fisher et al., (1997) suggests that during the design phase of a supply chain, provider firms must consider the characteristics of the products they plan on moving through the chain to mitigate the risks to all associated parties. Research has arrived at multiple conclusions when examining the impact of product characteristics on the supply chain (Huang et al, 2002; Randall & Ulrich, 2001; Selldin & Olhager, 2007). The classification of a product can be "functional", "innovative", or "hybrid", and these classifications have a direct impact on the supply chain. Functional products, as the name would suggest, are simple, readily available, and possess a long life-cycle. Functional classifications of products typically lend themselves to a high success rate in the clinical supply chain. Innovative products, on the other hand, are new or reengineered products recently introduced to the marketplace. These classifications of products will have issues in global markets with limited supplies available. Finally, hybrid products, which are a cross between functional products and innovative products, are products with multiple outsourced components. Hybrid products may present issues in global markets as regulatory inspectors have the potential to restrict entry to their countries because of product design, construction, or componentry (Huang et al., 2002; Wang et al, 2004). Coupled with the characteristics of a product, it is also essential that we consider product quantity as this may also have a direct influence on clinical supply chain success. Product shortages, or a low quantity of a given product, have the potential to have dire influence on the supply chain. One example of this potential impact on the supply chain can be seen by examining saline solution. The product characteristics of sodium chloride

are quite simple as the product is inexpensive, the packaging is transparent, and its components are simply salt water. Yet, while the characteristics of the product may be functional, manufacturing of the product occurs in a sterile and regulated environment that must be pyrogen-free and free of particulates. In September of 2017, Hurricane Maria devastated a major saline producer in Puerto Rico (Huang et al., 2002; Mazer-Amirshahi and Fox, 2018; Marucheck et al., 2011). This natural disaster led to extreme saline solution shortages, of which such product shortages are still present today. This illustration demonstrates how a functional product severely and negatively affects the supply chain, with the contributing factor being the quantity of product available within the marketplace.

When considering product characteristics, the clinical trial supply chain resembles spare part supply chains (Fleishhacker et al., 2015). Products are diverse in nature and come from many sources all of which have the potential to derail the success of the trial. The need for cross-coordination in the clinical supply chain with a greater need for upfront product planning and risk mitigation are imperative proactive measures that must be included in the initial planning stages of supply chain execution (Lamberti et al., 2016).

Therapeutic Area

A *Therapeutic Area (TA)* is a knowledge field that focuses on research and development of treatments of diseases and pathologic findings, as well as the prevention of conditions that negatively impact the health of the individual *(NCI Thesaurus)*. Life science organizations focus their studies on a specific TA and develop research protocols that address favorable outcomes for the disease. Examples of TAs of study in global

clinical trials are cardiology, dermatology, endocrinology, gastroenterology, hematology, metabolism, oncology, and women's health.

Literature Review Summary

Much research has contributed to aspects of a supply chain originating from customer, product, and country characteristics. Supporting evidence has shown that the customer plays an important role in the overall success of a supply chain. Dimensions of customer characteristics including such components as size, responsiveness, collaborative efforts, value, customer relationship, and engagement models have been observed to be predictors of overall success (Brewer et al., 2000; Grewal et al., 2017; Slater & Reddy 1997; Campbell and Cooper, 1999; Anderson et al., 2008; Reinartz et al., 2004; Beckers et al., 2018; Vivek et al., 2012; Venkatesan, 2017). Considerable research has also provided evidence to support the fact that product characteristics are predictors of success. Documented evidence indicates the need to re-engineer supply chains to address product lifecycles, availability, and product design so that success is realized (Huang et al., 2002; Mazer-Amirshahi and Fox, 2018; Marucheck et al., 2011; Fleishhacker et al., 2015; Fleischacker & Zhao, 2011; Randall & Ulrich, 2001; Selldin & Olhager, 2007). Finally, many researchers have focused on country characteristics as being predictors of successful outcomes. Many countries pose considerable threats to supply chain success and supporting evidence has documented the predicted outcomes. Supply chain organizations must give considerable forethought so that global distribution efforts can overcoming hiccups, regulatory challenges, and governmental concerns (Ketchen et al., 2014; Lis et al., 2009; Chen at al., 2012; Wiengarten & Ambrose, 2017).

Ultimately, the literature seems to have reached a consensus: numerous elements and characteristics influence the success of the supply chain. These include, but are not limited to demand, uncertainty, geographical distance, product characteristics, product variety, and costs. Interestingly, research also reveals that customers themselves have the potential to compromise the success of the supply chain at any point, thus resulting in challenges, stoppages, and failures in the supply chain (Reddy et al., 2008; Wiengarten & Ambrose, 2017; Selldin & Olhager, 2007; Fisher et al., 1997; Qi et al., 2009; Randall & Ulich., 2001).

Conceptualizing the CTASC: Case Study Overviews

Even though there exists robust and rigorous academic research on the topic of supply chain management, a gap in the literature highlighting the ancillary supply chain is evident. One of these such gaps concerns the concept of equipment management. It is the responsibility of the CTASC to perform the following functions:

- properly position calibrated and standardized supplies across the globe
- maintain the quality of the equipment by tracking and fulfilling site specific expiration and calibration requirements

Figure 1 illustrates the CTASC process for identifying and sourcing a glucometer which is a device that measures glucose levels in patients and is a critical requirement for monitoring blood levels in all diabetes trials. This product is manufactured for use within one country as noted below and the device is available with several product options. It is essential that the CTASC sourcing team selects the exact product match for each country included in the trial.

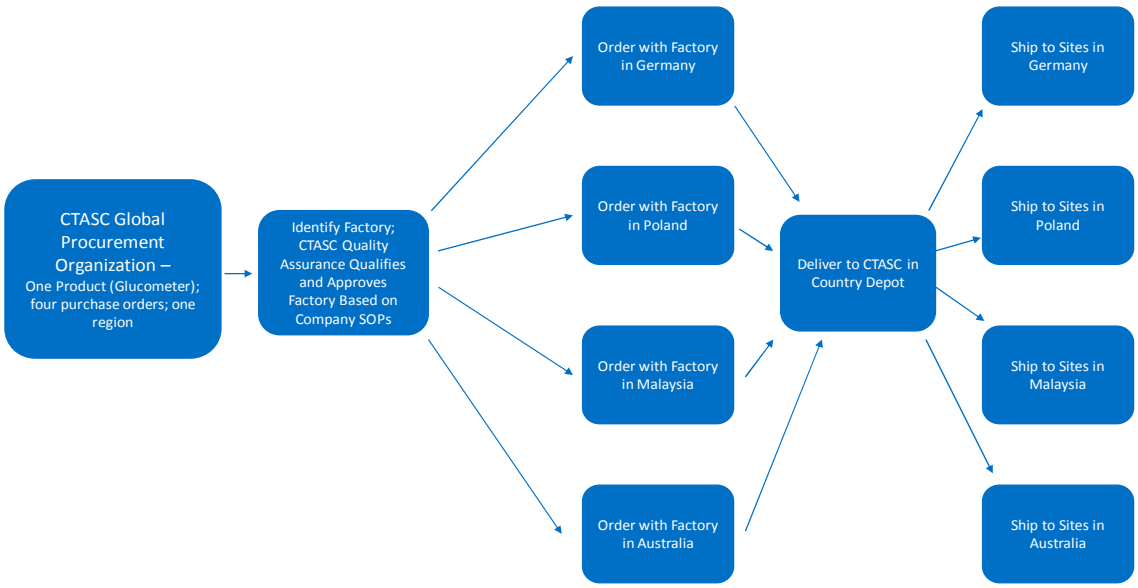

Figure 1. Sample Product Flow within the CTASC.

These functions consistently aim to deliver the right product, at the right place, at the right time, to diverse global clinical trials sites throughout the world are daunting and challenging endeavors and additional research is warranted.

As an illustration, infusion lines are required by for clinical trial use, such as oncology and hematology, to administer the drug to the patient because the study drug cannot be formulated as a pill or it would not survive gastric conditions. Lines are manufactured using materials that have the potential to interfere with the drug during the infusion process, causing adverse effects to the patient and compromising the results of the clinical trial (Materials such as polyethylene (PD), polyvinylchloride (PVC), or co-extruded PE/PVC (Co-Ex.) are infusion line components). Medical experts with CTASC organizations are responsible for identifying products based on the TA under study and the components of the drug being administered. The CTASC organization must identify

the infusion line based the TA and the specifications provided by the customer and perform the following:

- identify factories
- review the material composition in the line
- select the correct product
- determine countries where the line is approved for medical use
- source the item

If the product is not available or licensed in each country, the CTASC begins the process to locate alternate in-country supplies and/or equipment.

The following case studies are included to provide a better understanding of the complexities that occurred for two trials managed by the CTASC organization. Case Study Number One features a large, global cardiology clinical trial that took place in numerous countries throughout the world and enrolled thousands of patients. This Case Study is provided to illustrate a corroborative and collaborative approach between the supply chain and the customer who provided significant preparation time prior to FPFV so that the CTASC SME's analyzed the product that resulted in a well-documented supply plan. Case Study Number Two depicted a protocol where timelines were extremely short, a small number of countries and patients, limited customer knowledge about ancillary supplies, resulting in limited information and several issues. These Case Studies were selected from the 222 closed trials included in this research.

Table 4

Components of Case Study #1 and #2

Case	Therapeutic Area	# of Supplies	# of Countries	# of Sites	# of Patients
#1	Cardiology	48 Unique Items	36 – Argentina, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Israel, Italy, Mexico, Netherlands, New Zealand, Poland, Puerto Rico, Romania, Russia, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, UK, Ukraine, USA	2,200	30,000
#2	Metabolism	37 Unique Items	15 – Belgium, Canada, Czech Republic, Germany, Hungary, Italy, Netherlands, Spain, Sweden, Poland, Russia, France, Austria, Mexico, USA	65	1,000

Conceptualization Case Study #1

The pharmaceutical customer contacted the CTASC organization well in advance of the protocol launch and the pre-trial collaboration between the two firms was extensive. The customer supplied a protocol synopsis containing the following key trial components approximately sixteen (16) weeks prior to protocol launch:

- Therapeutic Area
- Investigator Meeting Team Participation
- Number of Patients
- Number of Regions and Countries
- Equipment and Supplies Required
- Start Date including First Patient First Visit (FPFV) time line for all regions, countries & sites
- End Date including Last Patient Last Visit (LPLV) timeline for all regions, countries & sites
- Importer of Record Requirements (summary of the provider firm requirements to provide export documentation for all countries)
- Summary of provider firm requirements for reclamation and disposition of equipment and supplies

As noted above, the successful relationship in this case study is defined as having the right product, in the right quantities, at the right country and site location so that treatment is available to the patient without the possibility of harm and delay of

treatment. Information is openly shared between the CTASC organization and the customer in a pre-planned and proactive environment.

Internal Readiness to Execute Trial Phases

As indicated above, the customer provided all necessary information so that the provider firm was able to build a supply plan prior to scheduled trial launch. An organized and documented training program was administered to all dedicated clinical supply chain staff, approximately twelve (12) weeks prior to the protocol launch. The training program consisted of the following modules:

- Types of equipment & supplies required by region and country
- Equipment expiry and calibration monitoring requirements and reporting guidelines
- Project Management Team assignment – duties and responsibilities
- Site training and documentation requirements for all equipment
- Country regulatory reviews for all products prior to release
- Trial launch date (Start Up Phase) – including ERP set up, inventory management, distribution schedules, depot identification, expiry, lot and calibration management, etc.
- Investigator meeting – dates, locations, and agenda
- Review of FPFV timeline per country, region and site
- Communication and escalation plans
- Establishment and review of technology programs with appropriate accesses granted

- Internal, external and joint company team meetings during the trial
- Anticipated maintenance phase timeline
- Effectiveness survey guidelines (5-point Likert Scale)
- Site including (LPLV) and total study close out plan

During the trial, the customer required two modifications to the original plan. The first modification occurred because one of the countries included in the original protocol was unable to enroll the designated number of patients due to patient recruitment issues. This required the provider firm staff to suspend all deliveries, retrieve products previously delivered, and officially close out the sites in that country (based on company Standard Operating Procedures). Due to strict deadlines, it was necessary to reassess, revise, and complete all plans and activities in a very restricted timeline requiring reassignment of additional dedicated staff to support the task. The second modification occurred because the customer needed a six (6) month extension of the study, which was previously unanticipated. This unanticipated extension meant that some of the products and equipment utilized in the study were set to either expire or exceed calibration dates, ultimately leading the CTASC organization to coordinate and schedule the recalibration of equipment in the field, as well as the sourcing of new unexpired products, both of which had to be accomplished with an extremely abbreviated timeline.

Conclusion

This Case Study serves as an example of a successful engagement in which the customer shared information well in advance of execution, collaborated effectively, outlined responsibilities/escalation pathways, and operated in a transparent manner. An

example of this can be found in one of the countries selected to participate in the study: India. In India, sites were first identified by the pharma organization, at which point the CTASC organization identified and sourced products specific to India. However, soon after the CTASC organization engaged in its' sourcing efforts, the pharma organization announced that patients were not enrolling in the trial as quickly as anticipated and as required for the trial to progress. It was at this point that the pharma organization made the decision to remove India from the trial and this decision was readily communicated to the CTASC organization. This advance notification from the pharma organization was imperative to the success of the trial, as the CTASC organization could ensure that product orders were cancelled, any previously received stock was returned to the suppliers and all pending shipments were stopped either before release to sites or while in transit. Ultimately, this saved time and reduced the budgets considerably.

In summary, success was based on early customer engagement, collaborative efforts, effective release of critical information, and transparent operations. Early engagement between the pharma and the CTASC organization enabled the supply chain to complete the following in advance of SIV and FPFV:

- ERP set-up including site listings, inventory management, distribution schedule, and reporting requirements
- Product analysis including confirmation of in-country regulatory and licensure requirements Maintenance programs
- Timelines and dosing schedules analysis
- Initial Qualification (IQ), Operational Qualification (OQ/) and Performance Qualification (PQ) schedules for all equipment throughout the world

- Timely sourcing and procurement activities
- In-country sourcing in several troublesome countries
- Receipt of incoming stock and quality assurance activities
- Depot set up
- Site training

While customer, country/site, and product characteristics were influential in the success of the trial, this case appears to demonstrate that customer characteristics have a profound impact on the success of the CTASC. Although countries and product characteristics provided significant challenges and pre-planning by the CTASC, customer characteristics appeared to contribute to the overall success of the supply chain.

Conceptualization Case Study #2

The customer reached out to the supply chain firm in a panic. The trial was about to enroll its first patient in 15 days without any ancillary supply requirements at site locations. Pre-trial collaboration between the parties was minimal. The customer did not provide a protocol or protocol synopsis for provider firm review but acknowledged that 15 countries would enroll patients in approximately sixty-five sites. Country and site listings were not available at the time of supply planning. The customer's project manager believed that one thousand patients would eventually enroll in the trial. The customer project manager had little understanding of ancillary supplies and could not suggest the types of supplies required for the study. As a result, the provider firm developed a supply plan based on its experiences in managing the therapeutic area. The customer quickly accepted the supply plan and requested that the provider firm begin to execute immediately.

Internal Readiness to Execute Trial Phases

The provider firm began to execute the pre-trial phase immediately. Training of the internal project management team took place based on requirements set forth by firm Standard Operating Procedures (SOP). Appropriate documentation of training occurred, and technology systems were updated with available information. Project managers immediately procured the initial supplies required to enroll the first patients. Since the provider firm requested a rush delivery of supplies, it incurred additional costs for the expedited processes. The project managers waited for the new site, country and supply information and did not execute any additional purchase orders for future enrollment. Rather, the project managers waited for the customer to confirm the exact countries, the site addresses, and the accuracy of the supplies required to complete the supply plan. The customer confirmed the requirements within twenty days and project managers proceeded to raise applicable purchase orders.

Many challenges influenced the success of the supply chain at each phase of the clinical trial. The customer continuously changed and modified requests while the provider firm cancelled factory orders and then resubmitted revisions to accommodate the numerous requests. Additionally, several regulatory issues arose during each phase of the trial and a delay in shipments resulted. There were considerable cost escalations throughout each phase and these cost increases negatively affected the customer's financial allocation for the trial. In addition, there was an absence of accurate specifications of supplies, resulting in the destruction of large amounts of incorrect supplies.

Conclusion

The impact of inability to engage the customer in advance of SC execution caused failures in the clinical supply chain. Issues such as inaccurate country information, uninformed and untrained sites, unrealized supply variations, and numerous modifications to the protocol caused considerable challenges for the provider and the customer firm. Costs were exorbitant and uncontrolled, patients went untreated, timelines were delayed, and the overall supply chain success in all phases of the trial were affected because of these characteristics. As a result, the provider firm demonstrated that it was unsuccessful during pre-and in-trial phases.

CHAPTER 3: RESEARCH CONTRIBUTION

Research Gaps

This research will now address gaps in the supply chain literature as they relate to clinical trial ancillary supply chains:

1. As this study has highlighted, much research has focused on clinical trial drug supply chains (Fleishhacker and Zhoa, 2011; Fleishhacker et al., 2015; Chen et al., 2012; Lainez et al., 2012; Papageorgiou et al., 2001). And while ample research and literature exists in clinical trial supply chains, primarily as it relates to pharmaceuticals, there is a present opportunity to expand supply chain research to another specialty; the CTASC. I posit that indeed the CTASC is unique and complex, and containing characteristics that do not exist in other supply chains. This research attempts to highlight these factors for additional growth. How would a deeper understanding of the internal and external characteristics of the CTASC influence outcomes? How might current theories and models of supply chain execution apply to the CTASC? How do internal factors within the CTASC organization influence outcomes? How will these findings broaden academic and practitioner research findings?
2. Sertkaya et al., 2016 examined cost drivers of pharmaceutical clinical trials in the United States. They observed that per study, overall costs are impacted by the therapeutic area, regulatory concerns, and the phase of the trial. Although the focus of this research is not centered on early costs vs. future profitability, how might these findings relate to the characteristics identified in the CTASC?

This study also concluded that pharma organizations with internal governance committees report decreased study complexity where early engagement and planning were critical to the outcome. How would outcomes of the CTASC differ if it was engaged in this structure? How will mechanisms evolve that will promote early engagement and planning for the supply chain organization?

3. Positioning inventory and planning for demand failure were research topics of investigation (Fleischhacker and Zhao, 2011; Feischhacker, et al., 2015). How might certain external characteristics of the CTASC such as product and customer complexity, timelines and the location where the trial takes place influence outcomes? How might inventory management models as suggested by these researchers apply to the CTASC?

I posit that customers providing early and complete trial information, are process and patient focused, are focused on trial outcomes and timelines and not completely cost conscious, and understand the issues facing the ancillary supply chain, will experience outcomes that are more successful than those who do not. I believe that the clinical trial therapeutic area of focus moderates the outcome of the supply chain. An example of the moderating effect of the Therapeutic Area (TA) is illustrated by the TA as well as the study drug.

Based on the above, I hypothesize:

H1A: Country/Site characteristics will influence supply chain success during the pre-trial phase

H1B: Country/Site characteristics will influence supply chain success during in-trial phase

H1C: Country/Site characteristics will influence supply chain success during post-trial phase

H2A: Customer characteristics will influence supply chain success during the pre-trial phase.

H2B: Customer characteristics will influence supply chain success during the in-trial phase.

H2C: Customer characteristics will influence supply chain success during the post-trial phases.

H3A: Product characteristics will influence supply chain success during the pre-trial phase.

H3B: Product characteristics will influence supply chain success during the in-trial phase.

H3C: Product characteristics will influence supply chain success during the post-trial phase

H4: The therapeutic area of study will moderate the overall success of the trial.

Research Contribution

There is no time like the present to expand the clinical trial global supply chain literature focusing on comparator and study drugs to the newly evolving ancillary supply chain industry. This research originated with the assumption that the CTASC is complex and unique with scant existing academic and practitioner research, as compared to standard supply chains. I explored current research to understand the elements of supply

chain success in the pharmaceutical industry to determine if existing theory was applicable to the ancillary supply chain. My research has revealed that the emergence of a CTASC -- a chain that manages the end-to-end process including protocol, regulatory and product analyses, sourcing, inventorying and distributing of diverse products, product maintenance, and quality oversight during the course of the trial, and the reclamation/disposition of all such products at the close of the trial -- is unique, complex, and difficult to manage with many opportunities for potential failure to occur. This research focuses on identifying the previous research and determining its significance to the CTASC, but it also expands this knowledge by focusing on internal and external characteristics that the customer and the supply chain brings to the table. Along with this research, however, many questions arise and come into view. How is the CTASC unique when compared to other supply chains? How do the propositions and theories that evolved from research in the clinical trial drug supply chain apply to CTASC organizations? Pharma organizations continue to highlight the need to reduce overall costs and time to market via outsourcing and open innovation strategies (Gassmann, et al., 2018; Chesbrough et al., 2018; Chesbrough & Van Alstyne, 2015). Since these goals will continue to challenge the health science industry for years to come, clinical trial supply chain organizations must deliver new processes and innovations to add value to their strategic relationships. Will other areas embedded within the CTASC emerge from initial exploration of the characteristics of the supply chain? The answers to this and many other questions will undoubtedly emerge from this research, and as a result, will begin to expand the knowledge base that will guide supply chain industry professionals. Contributions to the CTASC will open new avenues of research in the supply chain

industry that will assist practitioners and academics alike in their quest to gain knowledge, develop new theory, deliver increased efficiency and value to customers and create competitive advantages for businesses.

CHAPTER 4: DATA COLLECTION METHODOLOGY

This research attempted to develop new knowledge and theory in supply chain literature by focusing on the CTASC. I outline the characteristics of three independent variables: customer, country/site, and product, and the moderating effect of the TA under study and their influence on the overall success of the CTASC during the pre, in, and post phases of the trial. Success is defined as having the right product/equipment, at the right facility, in the correct quantities, and ready to service patients as they arrive for treatment at clinical sites throughout the world, during all phases of the supply chain. A review of the literature helped to identify relevant variables and highlight gaps in the ancillary supply chain research. This approach is particularly useful in understanding the variables and drawing conclusions which will expand the body of clinical trial ancillary supply chain knowledge (Golafshani, 2003; Christopher & Peck, 2004). Quantitative methods are appropriate for validation of this research (Straub et al, 2004; Durcikova et al, 2018).

Data Collection

This study collected data from an anonymous global supply chain organization specializing in ancillary supplies. A total of 222 samples were randomly selected from a pool of 1,850 clinical trials and the selection was restricted to those trials in the CTASC organization database that were classified as "closed" (a closed clinical trial is one in which all phases of the protocol have been completed).

I selected a dataset from the CTASC organization's database of 222 from a pool of 1,850 closed clinical trials. This total was limited to 222 trials for ease of analysis and was selected via a computer-generated random sample. The CTASC organization houses a rich database that includes thousands of data points from more than 8,000 studies and

information is gathered from various points throughout the operation. The Phase III trial is a large global clinical trial (increased numbers of patients, countries and sites) that follows Phase I and II where a drug efficacy has been shown with minimal or tolerable side effects and is generally the step before a new drug product is approved for sale to the public. The data included studies managed by the pharmaceutical organization and did not include studies lead by Contract Research Organizations (CROs) and hence represent a subset of available possibilities. An example of a study classified as closed is as follows:

1. Patient enrollment and data collection including treatment regiments are completed and closed; and,
2. Clinical Trial Professionals are beginning to assemble data to submit to the appropriate regulatory agencies; and,
3. The CTASC has reclaimed, dispositioned, and submitted certificates of removal and/or destruction for all products remaining at the site to the pharma clinical trial management team (This process includes the sale, donation or destruction of all remaining supplies and equipment); and,
4. All CTASC finances are completed and closed (all invoices are prepared and submitted to the pharma organization).

This dataset included seven unique customers with trials focusing on 20 unique therapeutic areas. The size of the trial ranged from small (less than 100 patients with sites in 1 to 2 countries) to large (more than 5,000 patients with sites throughout the world). A total of 5,431 products in the data with a total of 3,954 unique items

researched, procured, and released to clinical sites. The following Table 5 illustrates the types of products required:

Table 5

Sample CTASC Products

Item	Regulatory Challenges
	Centrifuge is considered a medical device in many countries. If classification is not determined during supply plain pre-planning stages and proper licensing is not obtained and submitted in advance of shipment, country customs will deny access.
	Data loggers are devices used by the clinical site to ensure the temperature readings for freezers and refrigerators comply with protocol/drug requirements. Units are calibrated prior to shipment based on specifications with the need for recalibration during the course of the trial.
	Blood pressure devices are considered a medical device in many countries. If classification is not determined during supply chain pre-planning stages and proper licensing is not obtained and submitted in advance of shipment, country customs will deny access.
	Patient cooler bags are used to transport drug from clinical site to patients homes. Unit must hold temperature for specified period of times based on protocol specifications and are lab tested to confirm. Failure to obtain compliance documents prior to supply chain planning has the potential to have a detrimental impact on the trial and the patients served. In addiiton, some countries will deny entry if units are constructed with vinyl materials. Careful planning is neccesary to comply.

Table 5 (continued)	
	Glucometers are used to measure patient glucose readings and are considered a medical device. Devices are manufactured based on country specific guidelines (unit for the German market cannot be used in Poland). Careful product/country analysis during the supply plan stages is required to achieve a successful global supply chain.
Note. This example is standard practice for all countries, all regions throughout the world. It is best practice to purchase directly from the source of production, the factory.	

Of the 222 trials, 78% of the trials had ancillary supply costs ranging from $10,000 to $2,999,999 with 22% of the trials studied with costs exceeding $3,000,000. Costs breakdowns were as follows:

Table 6

Breakdown of Costs

Range of Cost	Percentage of Trials
$10,000 to $99,999	5%
$100,000 to 299,999	10%
$300,000 to $499,999	17%
$500,000 to $599,999	25%
$600,000 to $799,999	10%
$800,000 to $2,999,999	11%
$3,000,000 +	22%

Data analysis focused on the 222 closed trials and the total number of patients, products sourced, shipments, patients, countries and sites. The dataset also included total number of emergency shipments required by each trial. A clinical site requires emergency or unplanned shipments for several reasons and of the 222 trials included in this study, 40% of all shipments were classified as emergency or unplanned shipments

and as such, were not included in the original supply plan developed prior to study start-up.

Table 7 is a summary of the data collected during this study for the 222 trials observed:

Table 7

Components of Size

Category	Totals	Comments
Number of Customers	7	
# of Trials and Status	222	All trial classified as closed (no additional work performed by CTASC)
Total # of Patients	323,525	Average # of patients per trial: 1,457
Total # of Products	5,431	
Total # of Unique Products	3,954	73% of all products sourced and shipped to clinical sites were unique, one-time buys
Total # of Products with Regulatory Restrictions	2,481	45% of all products sourced and shipped to clinical sites had regulatory restrictions requiring special handling and/or documentation
Total # of Products Requiring In-Country Sourcing	1,597	Based on regulatory restrictions, 20% of all products sourced did not receive customs clearances and required in-country sourcing
Total # of Shipments	236,468	
Total # of Emergency shipments	94,793	40% of the total number of shipments were emergency shipments and required immediate fulfillment and release to the clinical site
Total # of Countries	88	Average number of countries per trial 25
Total # of Sites Serviced by the CTASC	23,107	Average number of sites per trial 104
Total # of Depots Utilized by the CTASC for the 222 studies	12	Depot management in critical areas of the world can influence the SCO need to achieve better, faster and cheaper processes for its customers

CHAPTER 5: DATA ANALYSIS

To analyze the data, results from the 222 closed studies were imported into SPSS. The independent variables associated with the characteristics of customer, product, and country/site were identified and used in the data analysis. It is important to note that it was assumed that each component within a variable type had equal weight. The components of each variable are noted in Table 8 below:

Table 8

Components Breakdown

Type of Variable	Components
Customer Characteristics (IV)	• Customer size • Project size • Number of shipments requested by the customer • Number of changes requested by the customer • Number of days for receipt of customer information
Country/Site Characteristics (IV)	• Number of countries • Number of sites • Number of emergency shipment requests • Number of depots required
Product Characteristics (IV)	• Number of products • Number of products with regulatory restrictions • Number of in-country purchases
Therapeutic Area (TA) (Moderator)	• Designated TA under study
Pre-Trial (DV)	• Percent of needed ancillary supplies on site before FPFV
In-Trial (DV)	• Percent of resupplies required at sites during the trial
Post-Trial (DV)	• Number of contacts required for dispositioning of supplies remaining a site after LPLV

Several analyses on the independent variable (customer, country, and product) and dependent variables (project success during pre, in, and post phases) were performed utilizing the following measures:

Table 9

Measurements

Measurement	Purpose
Linear Regression	To determine if predictor variables predict outcomes and to forecast the impact of changes
Factor Analysis	To determine the relationship between variables
Cronbach's Alpha	To determine internal consistency
R-Square Analysis	To determine the variance in the DV explained by the IV
Varimax Rotation	To determine the total amount of variation explained by the factors
Kaisen-Meyer-Olkin (KMO) & Bartlett's Test of Sphericity	To determine if there are underlying factors causing variance
ANOVA with Friedman's Test	To determine differences between ordinal DVs
Tukey's Test	To determine differences in the samples

Conceptual Model

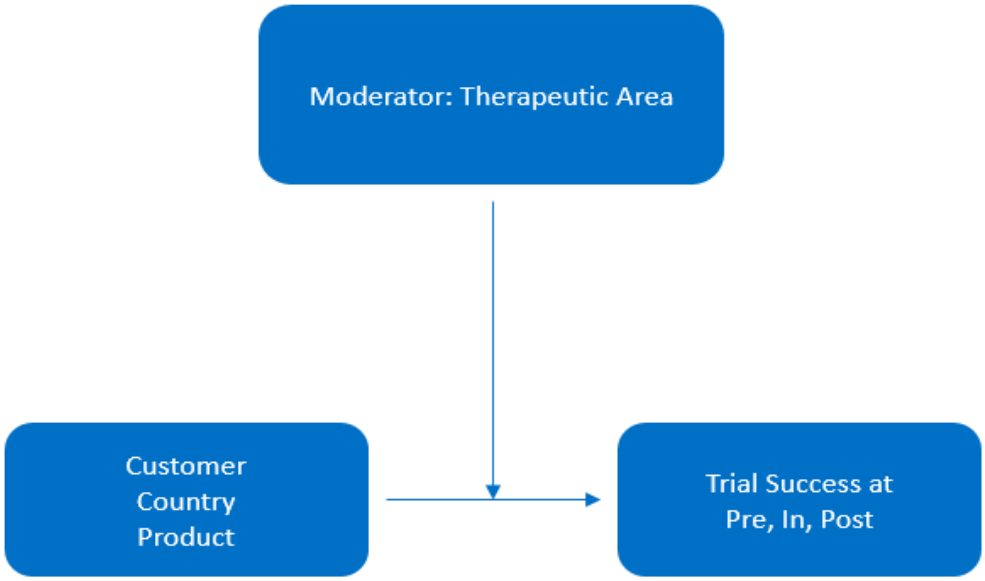

Figure 2. Conceptual Model Part I.

Three independent variables for customer, product, and country/site were assessed as noted in the thirteen components in Table 7. CFA with Varimax Rotation was used to analyze the influence of the one, moderator, Therapeutic Area. (I posit that the TA moderates the overall outcome of the trial and is included in this analysis as it is an external factor.) The analysis yielded three items with initial eigenvalues greater than one with eigenvalues of 9%, 7% and 5% of the variance, respectively. Kaiser-Meyer-Olkin measure of sampling adequacy was .89, above the recommended .6 value and Bartlett's Test of Sphericity was significant at .000. Communalities were above .3 for four of the components.

Since the data did not appear to be in a normal/parametric distribution, the Friedman Test was chosen as an alternative to one-way ANOVA to test for differences

between large and small groups or categories included in the database. Results of the Freidman test showed that there was a statistically significant difference in the size of the trial, number of changes, and the number of delays (days) for the in-phase of the trial.

The factor loadings results seem to not support the independent variables I had expected to find. Instead, I found significance in magnitude (size components), stability (number of changes during the trial), and product characteristics as these factors had a direct influence on the success of the supply chain.

Magnitude, or size of the trial, appears to influence the overall success of the supply chain, where the larger trial has a negative impact on successful outcomes. Magnitude or size factors in the dataset are as follows:

- Number of patients
- Number of sites
- Number of products
- Project size (dollar value)
- Total number of shipments
    - Number of emergency shipments
    - Number of unplanned shipments
- Number of countries
- Number of denied shipment

Stability of the project appears to influence the success of the trial where an increase in the changes to the supply plan requested by the customer at any phase of the trial have a negative impact on success. Stability factors included:

- Number of changes requested by the customer during the trial

- Number of countries added or subtracted from the trial during any phase of the trial
- Number of products added or subtracted from the trial after completion of the supply plan and prior to FPFV

- Number of days for the customer to provide information for planning the supply chain

Table 10

Factor Results

Factor	Average
Magnitude	.76
Stability	.73
Product	.81

Results of the Pearson correlation seems to support positive relationships between several of the measures in the model and the overall success of the trial. In retrospect, the high Pearson correlations seem understandable and expected as some of these measures may be evaluating similar areas. For example, larger patient populations would require more shipments. With this assumption in mind, the correlations noted below, may not be an accurate measure of the relationship.

- Number of sites and number of shipments: .94
- Number of patients and number of shipments: .91
- Number of sites and number of emergency shipments: .91
- Number of sites and number of patients: .83
- Number of patients and number of emergency shipments: .97
- Number of days to receipt information and number of shipments: .85

The results of the discriminant function analysis of .000 and Wilks' Lambda indicate that the predictors significantly discriminate the groups.

The following constructs did not load with an eigenvalue of >1:

- Customer Characteristics
    - Proposed or forecasted number of shipments
    - Number of days to receive information from customer
- Country Characteristics
    - Number of overall attempts to retrieve product during the post phase of the trial
    - Number of first, second, and third attempts by CTASC to retrieve product during the post phase of the trial
    - Country location based on region of the world
- Product Characteristics
- Forecasted number of countries for potential of denied shipments
- Number of depots

This research attempted to understand how the independent variables of the customer, product, and country/site characteristics influenced the dependent variables of overall success of the clinical trial ancillary supply chain. I hypothesized that each independent variable would influence the overall results and I applied quantitative methods to test my hypotheses. I also presented a case study extracted from the provider firm to illustrate how the independent variables influence the overall success of the trial.

Linear Regression

Linear regression tested the model and aspects of magnitude, which indicated stability as a potentially significant threat to success. In other words, it would appear the greater the magnitude of the trial -- increased number of patients, countries, products, and project size -- the larger the impact on overall trial success. Stability of the project appeared to influence the success of the trial--where an increase in changes requested by the customer to the supply plan throughout the trial appears to be a negative impact on success. For example, medical devices such as EKG machines, syringes, needles, monitoring devices, patient items such as diabetes supplies for the monitoring of glucose levels, and pregnancy tests, as well as some lab equipment, seemed to impact the overall success of the trial when these supplies were required across the globe. Many regulatory agencies restrict entry of these types of products into their countries, thus affecting the outcome of the trial. Interestingly, the TA of study during the trial was not a valid component at any phase of the trial and did not influence the outcome of success.

CHAPTER 6: DISCUSSION OF RESULTS

This research investigated the relationship between the independent variables of the customer, product, and country/site characteristics, and the dependent variable of the overall success at all phases of the clinical trial. Although prior research has not focused specifically on the CTASC, it has focused on the independent variables included in this study. This research appears to support previous research findings that indicate that certain inherent country, product, and customer characteristics have significant influence on supply chain success, despite that the items of the independent variables I originally proposed did not load as expected. Even though provider firms tend to focus on developing supply plans to overcome risk and deliver overall success, other factors have the potential to influence the outcomes.

Country Characteristics

Research has found that country characteristics are key predictors of the success of a supply chain. The research points out the fact that certain "troublesome" countries throughout the world negatively influence success of the supply chain. My research identified magnitude (or size) and stability as factors of customer characteristics that seem to influence the supply chain. Magnitude and stability would seem to partially support this hypothesis if the increase or change occurred within those countries of the world where many restrictions, regulations, and the potential to cease the supply chain existed.

Customer Characteristics

As research has shown, aspects of customer characteristics influence the success of the supply chain as organizations engage, collaborate, respond, and develop

relationships. Although these factors are important within the ancillary supply chain, other components seem to come into play. This research partially supported the hypothesis that customer characteristics influenced the success of the supply chain. Rather, stability or the number of variations required by the customer during the trial, and especially during the pre-phase of the trial, appeared to have influenced the success of the chain. Results from my research seem to support the fact that as the number of changes increased, the success of the overall supply chain decreased.

Product Characteristics

Research has discussed the influence of product characteristics on firm performance and the success of the supply chain. Research has attempted to develop product categories to explain the impact of certain characteristics on success and utilize these categories to develop models and programs in efforts to drive success across the supply chain. Research has examined product shortages, manufacturing requirements, and the need to engineer the supply chain specifically for the products it serves.

Again, results from quantitative analyses seemed to support the findings that magnitude relating to products pose the potential to influence success outcomes. It is speculated that as the number of unique and regulated products increased, overall success at each phase of the trial diminished. As the number of in-country purchases increased (product characteristics and/or regulatory restrictions forced in-country sourcing), the number of global depots increased, and overall success factors decreased. Therefore, my research seems to partially supports my hypothesis that product characteristics influence the success of the overall supply chain in all phases of the trial. In retrospect, the high Pearson correlation seems understandable and expected. An increase in the number of

patients seemed to increase the number of shipments required but will trials that experience an increase in the number of shipments also experience an increase in the number of patients? Going forward, I would consider looking at shipment averages per patient to better understand if a correlation exists.

Therapeutic Area

Results of this research did not show the statistical significance for the TA moderating the outcome of the CTASC during the pre, in, or post phase. There was no evidence that the TA under study had any influence on the overall outcome of the trial.

Magnitude Findings

Results of statistical analysis in Study 1 identified magnitude of the trial as having a potential influence on the overall success of the trial. At first glance, this finding appears to be counterintuitive as commonsense points to the fact that the larger the trial – higher number of patients, products, countries, project value– the greater the potential of influence on successful trial outcomes. However, factors in the pharma industry seem to indicate that larger clinical trials are particularly important to their organization and as a result will receive higher priorities, attention and focus as follows:

- Larger clinical trials have a much larger investment and as such pharma organizations seek considerably higher returns on these investments.
- Larger clinical trials are planned well in advance of trial launch and approximately twelve to thirty-six (12-36) months prior.
- Pharma leaders across the organization are highly focused on the progress and outcomes of the larger trial.

- There exists an industry "race to be the first to market" for the new and innovative therapy under investigation by pharma organizations. This race comprises very large, global clinical trials with numerous countries and sites, patients, and products. At times, many pharma organizations are testing similar competitive compounds expected to deliver outstanding clinical results with a potential high yield return on investment. This race to be the first to market results in greater and increased scrutiny, attention, and reporting processes across all levels of the pharma organization and at all phases of the trial and the supply chain.

CHAPTER 7: CONCLUSION

The CTASC operates as an outsourced model within the pharma industry. Outcomes of the supply chain have the potential to influence the flow of the global clinical trial as designated supplies are necessary to treat patients. This research focused on a dataset of closed trials where the pharma organization conducted the trial. Significant findings of this research found that magnitude, stability, and product characteristics were factors that had a direct influence on the success of the supply chain.

Limitations of the Study

There are other variables that were not considered during this research and some of these can be highlighted as follows:

- How would the level of experience from the pharma global trial manager influence outcomes of the supply chain?
- This study focused on the clinical trials managed by the pharmaceutical organization. In many cases, pharma organizations outsource clinical trial management to Clinical Research Organizations (CRO). How would CTASC outcomes be influenced when the trial is managed by an outsourced Clinical Research Organization (CRO) especially one with experience in the TA of the drug being studied?
- TA did not seem to influence the outcome of the supply chain. It is my impression that the complexity of the TA would moderate outcomes of the supply chain and expanded research is warranted.
- Further research should be conducted to include several CTASC organizations that manage the supply chain for a variety of customers including pharma,

CROs Clinical and biotech organizations. Other variables should be identified in future research to determine the impact on the overall success of the CTASC.

PART II: DRIVERS OF SUCCESS IN THE GLOBAL CLINICAL TRIAL ANCILLARY SUPPLY CHAIN

CHAPTER 8: INTERNAL FORCES: KNOWLEDGE MANAGEMENT AND ORGANIZATIONAL CULTURE

Much research has focused on knowledge management (KM) and organizational culture (OC). The concept of creating an organization able to adjust to changes in the market and develop networks to support sharing of knowledge has been studied by numerous researchers. In addition, many researchers have linked OC to the ability of the organization to effectively share and manage its knowledge (Hult, et al., 2002; Foss, et al., 2010; Schoenherr & Chandra, 2014; Tseng & Lee, 2014; Zack and Singh, 2009; SM Tseng, 2009; Grant, 1996; Foss, et al., 2009; Dinur et al., 2009; Esper et al., 2010; Lilleoere & Hansen, 2011; Pedroso & Nakano, 2009; Bartsch & Maurer, 2013 et al., 2011; Wei & Miraglia, 2017; He & Wei 2009; Park et al., 2004; Al-Alawi et al., 2007; Zheng, et al., 2010; Mello & Stank, 2005; Hoff et al., 2004).

Knowledge, "a high value form of information" (Shih et al., 2012) and the internal culture of the organization, will support or prohibit the flow of learnings to overcome barriers and promote strategic advantages (Bartsch et al., 2013; Park et al., 2004). This research focuses on the moderating influence of KM and OC in the CTASC organization.

Research Focus

An opportunity exists to expand research to better understand and/or determine the moderating influence of KM and OC on the CTASC organization. CTASC team members face diverse and demanding customers and manage projects that include numerous project complexities and abbreviated timelines, all while facing new, updated,

and sometimes conflicting knowledge streams. As new information is acquired, this knowledge must be applied and disseminated across the organization prior to the execution of the supply chain. Part 2 of this research investigates how KM and OC moderate the overall success of the supply chain at the pre, in, and post phases of the global clinical trial. This research also attempts to understand how the TA and the type of shipment moderate overall supply chain success.

CHAPTER 9: LITERATURE REVIEW

Knowledge Management (KM)

"Knowledge Management" (KM) is defined as the management function that creates or locates knowledge, manages the flow of knowledge within the organization, and ensures that the knowledge is used effectively and efficiently for the long-term benefit of the organization (Darroch, 2005). Knowledge and the management thereof, is one of the core intangible assets of the firm that contribute to its' overall success. A firm that effectively manages its knowledge and supports this initiative across the organization will ultimately perform better and have a greater likelihood of success (Darroch, 2005; Darroch and McNaughton 2002; Demarest, 1997).

I speculate that effective KM across an organization leads to learning, a by-product of KM, which will ultimately improve the organization and the CTASC it serves. Research has supported the concept that an organization that manages it knowledge is one that encourages its' members to learn, seek continuous improvement, and transform their knowledge into learnings to deliver success to the firm. Organizations that encourage this type of knowledge acquisition and collaboration tend to avoid stagnancy, realize improvements in overall responsiveness, and any success or failure provides an opportunity to transfer knowledge across the organization. These organizations operate in an environment where continuous improvement correlates with responsiveness and embodies the notion that every experience -- good or bad -- is an opportunity to contribute to successful outcomes (Darroch, 2005; Darroch & McNaughton 2002; Demarest, 1997).

Knowledge sharing in successful supply chain organizations is critical in the execution of an efficient operation – delivering the right product, to the right place, at the right time. Researchers have looked at a variety of theories to explain the management of knowledge in complex supply chains. As suggested by chaos theory, imposing strict processes, rules, principles, and guiding existing knowledge are beneficial in uncertain and complex supply chains (Shih et al, 2012). Since characteristics of the CTASC exhibit elements of uncertainty, diversity, and complexity, imposing processes as noted above may yield improved performance and success.

Performance and success are encouraged by structuring, bundling, and leveraging KM across the supply chain (Patnayakuni et al., 2006; Darroch, 2005; Mehralian et al., 2015; Harraf et al., 2015; Narasimhan & Narayanan., 2013). As such, the literature has shown that a firm's knowledge exists within the management of documents, operating procedures, as well as environmental and market discoveries (explicit knowledge), which develop and remain embedded in the memory of its people (tacit knowledge). In many cases, the acquisition of local knowledge in supply chain organizations must flow across the organization in a reverse effect from subsidiary back to parent, and the firm must evolve as a "listening post" -- receiving, filtering, and transmitting knowledge in a reverse flow. Structuring, bundling, and leveraging the knowledge inflows and outflows transfer across the organization, and have a direct impact on the firm and its ability to drive success across the chain (Meyer et al., 2011). Links develop among internal and external networks, knowledge sharing and management, and social capital within an organization. These embedded resources occur within, are available through, and derive

from the network of relationships possessed by individuals or organizations (Inkpen et al., 2005).

The current global ancillary supply chain market is emerging and ever-changing and the firm, therefore, must develop the ability to effectively embed resources from networks, knowledge sharing, and social capital, which will require structuring, bundling, and leveraging knowledge across the organization. The firm's ability to manage complex and often conflicting knowledge streams, perform effectively in response to new sources, and assimilate the management of knowledge across the organization will ultimately lessen perceived market complexities and the need for rapid integration of new knowledge and processes (Sayuti, 2011). So how might the emerging CTASC apply current theory in KM to its internal operations and where might potential gaps appear?

Although the acquisition and transfer of knowledge serves as building blocks within the CTASC, management of knowledge is an extremely fluid process. As in all supply chains, knowledge enables the organization to address challenges and manage complexities within the supply chain (Blome et al., 2014). Unlike the typical supply chain, an inconsiderable amount of competitors exist in the ancillary space, therefore, overall competitive advantage is based on performance at the country and protocol level. This means that the CTASC organization must manage the supply chain faster, cheaper, better, and on time goals that support their customers and the patients enrolled in global clinical trials.

Organizational Culture (OC)

Just as organizational experiences provide the opportunity to learn and share, the composition of a firm's strategic internal and external network can promote or inhibit firm performance. As organizations and supply chains emerge and grow, there is no single component of knowledge that adds to the value or overall success of the organization (McLaughlin et al., 2008; Paton & McLaughlin, 2008; Lund 2003). From a resource intra-corporate perspective, strategic knowledge networks that manage the flow of information may provide sustainable success and a competitive advantage to manage the complexities of the global CTASC organization. Social interaction among internal business units structures the facilitation of knowledge acquisition, sharing, and adoption -- a direct benefit of social capital. To realize success, research suggests that management practices must align across the organization to help create a sustainable business advantage. Focus on the firm and its resources while deemphasizing the individual elements and characteristics of its' players delivers success and competitive advantage (Eisenhardt & Martin, 2000). Although focus on the firm and its' resources are elements of success, other research has indicated the importance of the individual. Understanding the role of individual subject matter experts (SMEs) within the firm and their ability to support knowledge acquisition and sharing within the firm further enhances success and drives competitive advantage. It is the firm's responsibility to oversee the knowledge acquired by SMEs and disseminate it across the organization to support the knowledge management efforts (Hutchinson et al., 2008).

"Organizational Culture" (OC) plays a critical role in how teams willingly, openly, and readily acquire, share, and transfer information as it becomes available.

Research has found that OC guides the way individuals, groups, and business units connect and interact within, across, and outside the organization. OC comprises the attitudes of the individuals, the values of the organization, and the knowledge acquired across the organization. Aspects of OC are fluid and may vary with new leadership and strategic initiatives imposed by the firm and may be strong or weak based on value alignment, controls, and internal and external dynamics (Serrat, 2017; Al-Alawi et al., 2007). OC often represents the character of the organization and depicts how people act, perform, and communicate (Tseng, 2017; Dodek & Heyland, 2010). OC also helps to shape the behavior of its people, its teams, its leaders, and ultimately their performance (Zheng et al., 2010).

A review of the literature suggests that the culture of the organization influences the ability of its' people to gather and share knowledge ultimately affecting a firm's ability to succeed and innovate (Hult, 2002). The organization's ability to generate new ideas and approaches, and management's ability to leverage and manage its' knowledge base for the supply chain, are essential for value creation (Narasimhan & Narayanan, 2013). OC may differ in terms of the degree to which these principles are embedded into the organization, as well as the desire to succeed. It is imperative that the concept of innovation is accepted as a basic value both across and throughout the organization. As such, OC can stimulate or derail outcomes within the organization. Factors such as acceptance, the quality of information, time of dissemination, and the surrounding culture can create the desire to exceed customer expectations and surpass market competitors (Kundsen & Madsen, 2001).

Finally, OC has the potential to strengthen and weaken over time by internal and external variables, including location of and age of the firm, firm leadership, and elements of gender, growth patterns, financial stability, and market conditions. Research suggests that a firm's culture can provide competitive advantages to the firm, be instrumental in KM, and may play a role when analyzing and orchestrating the firm's resources (Kundsen & Madsen, 2001; P. Sharma, 2017; Al-Alawi et al., 2007; Hult et al., 2007).

OC ebbs and flows across the CTASC organization and the ideals, attitudes, beliefs, and values of each contributing team within the CTASC organization, has the potential to strengthen and weaken, and since individual and diverse teams oversee each clinical trial, OC exists on many levels within the CTASC organization and variations of culture will differ across the firm.

A thorough investigation on how KM and OC influence the CTASC organization is essential to building new theory, advancing and improving the ancillary supply chain, and helping practitioners achieve success.

Linking the Two: Knowledge Management and Organizational Culture

In today's world, new knowledge seems to flow across organizations at lightning speed. CTASC organizations are presented with new, complex, and conflicting knowledge sources as they execute projects and as their ancillary supply chains become more daunting. The cultural orientation of an organization plays a key role in the management and execution of the CTASC and a positive cultural orientation will create customer value, contribute to positive outcomes, and ultimately provide competitive advantage. Findings have indicated that KM is not only antecedent to organizational

success, but it also serves as a mediating role in the culture of the organization and can be an intervening mechanism. This in part may result from the fact that culture determines organizational belief, values, and norms and these factors influence how knowledge is shared throughout the organization (Zheng, et al., 2010; He & Wei, 2009). Key factors of OC are important in the knowledge sharing process. Trust, rewards, absorptive capacity, and common cultures have been identified as key factors in the knowledge sharing process (Tseng, 2009). Fundamentally, linking the CTASC organization's ability to effectively manage knowledge by overcoming barriers to transferring and sharing is linked to culture of the organization (Wei & Miraglia, 2017).

CHAPTER 10: RESEARCH CONTRIBUTION

Research Gaps

Numerous researchers have studied KM and OC to determine the influence on success within the firm. An opportunity exists to expand existing research within the CTASC organization. This research expands the analyses of Study 1 to understand if KM and OC moderates the overall success of the trial and provides the opportunity to enhance and contribute to the CTASC literature as follows:

1. Synergies exist between the success of the firm and OC and KM (Hult, et al., 2002). How might these constructs act independently to moderate successful outcomes of the CTASC? Would these constructs moderate success equally across all phases of the clinical supply chain or might their moderating influence prove more impactful at one phase – such as the pre, in or post-trial phase? Understanding when and if these moderating influences occur would provide great value to practitioners and academics alike.
2. A learning organization is one that encourages its members to learn, seek continuous improvement, and transform their learnings to deliver success to the firm (Darroch, 2005; Darroch & McNaughton 2002; Demarest, 1997). Research suggests that a firm's culture can provide competitive advantages to the firm, be instrumental in KM, and may play a role when analyzing and orchestrating the firm's resources (Kundsen & Madsen, 2001; P. Sharma, 2017; Al-Alawi et al., 2007; Hult et al., 2007). An important research contribution would yield an understanding of the when and at what levels KM and OC moderate the success of the CTASC.

3. The OC determines how existing knowledge will be acquired and distributed across the organization. OC can be considered an impediment to leveraging KM across the organization and researchers suggest diagnosing these hurdles in order to improve outcomes (De Long & Fahey, 2000). How might the characteristics of an KM and OC influence the success of the supply chain during the pre, in, and post-trial phases? Do higher levels of KM and OC offer improved successful outcomes than lower levels? The opportunity exists to expand grow research to understand how these factors moderate the success of the CTASC.
4. The CTASC organization manages several clinical trials that study an assortment of therapeutic areas. Each TA brings a unique set of challenges that include variations in products characteristics, magnitude, and stability. How might the TA moderate the success of the supply chain? Would this moderating influence occur at each phase of the trial or at one point in the chain? Understanding the moderating influence of a TA would contribute to current research and help practitioners proactively manage their supply chain.
5. Emergency shipments often are required by clinical sites throughout the world. The CTASC must respond to these requests for emergency shipments in such a way so that service to patients is not jeopardized. Does the need for the CTASC to respond to emergency shipments moderate the success of the supply chain? Does an increase in emergency shipments improve successful outcomes or would this increase negatively impact overall success? Again, understanding the moderating influence of emergency shipments on

successful outcomes will help practitioners in their quest to improve successful outcomes of their supply chains.

Research Contribution

Part I of this research has provided insight into the drivers of success during three phases of the CTASC, a chain dedicated to the global management of ancillary supplies to clinical sites. As an emerging and ever evolving supply chain, these research findings offer a starting point for academics to continue to build theory. It also offers important insights to practitioners to assist them in improving their models and the successful outcomes of their supply chains.

Part II of this research continues to analyze the dataset of 222 closed clinical trials to determine moderating factors that influence success. It is hypothesized that KM, OC, TA, and type of shipment moderate success during the pre, in and post-trial phases of the CTASC. Continuing to expand this research to understand the moderating impact of these constructs will contribute and enhance learnings and contribute as follows:

1. Contribution to academic research by continuing to expand an understanding of the drivers of success by examining the moderating influence of the constructs included in this research:
    a. Building and extending KM and OC by applying current theories and applying them to the CTASC. Understanding how these constructs impact success would expand current theory.
    b. Understanding how high versus low levels of KM and OC influence success during all phases of the supply chain.

c. Introducing the construct of TA to supply chain research as a moderating factor of success.
d. Examining type of shipment as a construct in supply chain research as a moderating factor of success.
e. Opening new areas of research to build theory and gain knowledge in the CTASC.

2. Contribution to practitioner research by offering new insights that will guide managers to develop mechanisms to achieve success:
   a. Expanding research topics focused on the CTASC and these constructs will assist practitioners in improving their operations and will help deliver success to their customers.
   b. Understanding how and when these constructs moderate success will help practitioners improve their models and gain competitive advantage in the CTASC.
   c. Providing practitioners with the understanding of the importance of KM and OC will improve relationships with their pharmaceutical customers that will help their teams deliver success.

CHAPTER 11: CONCEPTUAL MODEL

My research has found supporting evidence that product characteristics, magnitude, and stability of the clinical trial impact successful outcomes. Literature has provided supporting evidence that the ability of a firm to effectively manage its' knowledge impacts successful outcomes across the organization (Darroch, 2005; Darroch & McNaughton, 2002; Demarest, 1997; McLaughlin et al., 2008; Paton & McLaughlin, 2008). Much research has focused on the culture of an organization and empirical evidence has provided evidence that OC has the potential to shape, guide, and support its people; it can stimulate or derail outcomes within the organization as well as strengthen or weaken over time (Tseng, 2009; Kundsen & Madsen, 2001; Hult et al., 2007). Based on these findings, note the following conceptual model:

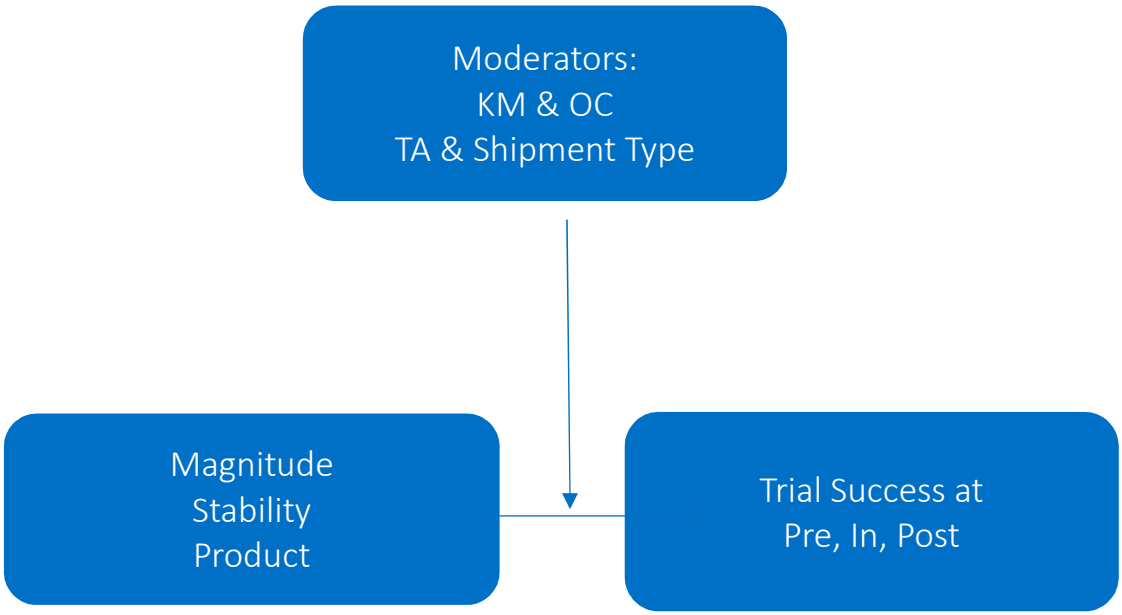

Figure 3. Conceptual Model Part II.

Hypothesis Development

H5A: The impact of CTASC success is moderated by the organization's ability to capture, share, and apply new knowledge streams during the pre-trial phase.

H5B: The impact of CTASC success is moderated by the organization's ability to capture, share, and apply new knowledge streams during the in-trial phase.

H5C: The impact of CTASC success is moderated by the organization's ability to capture, share, and apply new knowledge streams during the post-trial phase.

H6A: The organizational culture of the customer firm will have a moderating influence on the success during the pre-trial phase

H6B: The organizational culture of the customer firm will have a moderating influence on the success during the in-trial phase

H6C: The organizational culture of the customer firm will have a moderating influence on the success during the post-trial phase

Therapeutic Area

In Part I of this research I attempted to understand the influence of the therapeutic area (TA) however, the data did not support that this construct influenced outcomes of the supply chain. The TA under investigation in a clinical trial has the potential to moderate outcomes and based on this I will continue to analyze the influence of the TA in Part II. I am proposing that classifying and ranking the TA based on the occurrences in the 222 closed trials and performing additional statistical analyses may uncover the moderating influence on supply chain success.

H7: Therapeutic area will have a moderating influence on success during the pre, in and post-phases of the clinical trial.

Classification of Shipment – Emergency or Unplanned vs Planned Shipment

I suspect that the classification of shipments utilized by the CTASC in the 222 trials included in the data set has a moderating influence on overall success of the supply chain. Two types of shipments were included in this dataset – the Planned Shipment and the Emergency Shipment. These shipments are defined as follows:

1. Planned Shipment -- A shipment that is forecasted to take place at each phase of the trial. The forecast is based on the information that was provided by the customer prior to protocol launch.
2. Emergency Shipment -- A shipment that is a special request by the customer for immediate release of materials to global clinical sites. Emergency shipments are requested by the pharma organization for several reasons and some examples of these as follows:
    a. Enrollment in the trial is competitive where sites compete for patients and proceed with the trial based on the number of patients that are identified and enrolled. Emergency shipments are required when sites enroll more patients than anticipated thus requiring additional supplies.
    b. Misuse of the supplies by the on-site clinicians because of incorrect distribution and/or non-adherence to the protocol.
    c. Replacement supply requirements because of damaged or expired goods.

I anticipate that an increase in emergency or unplanned shipments during the trial will have a negative moderating influence on overall supply chain success.

H8: The type of shipment, planned or emergency/unplanned, will have a moderating influence on success during the pre, in, and post-phases of the clinical trial.

CHAPTER 12: DATA COLLECTION METHODOLOGY

Data Collection

KM and OC, the constructs at the heart of Phase II of this research, were assessed via two independent surveys. Data collection originated from historical surveys collected from Voice of the Teams (VOT) documents facilitated through Survey Monkey and administered to "servers" and "customers." Servers are those individuals who manage the clinical trial supply chain on behalf of the CTASC organization. Customers, as the term indicates, are representatives from the pharmaceutical organizations' clinical trial teams and who awarded the contract to the CTASC firm.

The surveys were designed by a group of developers within the CTASC that included quality control, human resources, operations, and process improvement team members, and the surveys were designed to assess team performance. Prior to release, the developers issued pre-tests to 10 senior project managers within the CTASC to obtain feedback on clarity, time to complete, and relevance to job assignments. Based on CTASC contractual agreements, customers were asked to review and approve the survey. Seven senior procurement and clinical operations managers participated in the pre-test/review process. The developers received two suggestions for server modifications of server items and three suggestions for deletions of customer items. Items were modified and deleted as requested and the survey was released.

The CTASC Data Analytics Team followed a standardized process for survey administration to maintain consistent and reliable results. An email invitation request to participate in the VOT was sent to servers and customers 10 days prior to the close of each trial during the period January 2017 to December 2017. The email invitation to

participate included a letter of instruction for the respondent describing the number of items in the survey, the rating system, the survey, trial due date close-out schedule, contractual or performance reminder for completion, and the promise of anonymity. The respondent's manager was copied on the invitation to participate email serving as notification of the requirements for completion. A separate email notification was also sent to each respondent's manager announcing trial close out and survey completion requirements. Additional notifications were sent via email to respondents and their managers at the five and again at the two-day mark, as reminders that the survey due date was approaching. The email notifications included a Survey Monkey link to the site. For example, the survey launched on June 10 (reminder notifications occurred on June 15 and again on June 18) and closed on June 20. See Appendix C for sample invitation to participate email.

Upon completion, analyses of survey results were processed by the CTASC Data Analytics Department. Results were shared with developers, servers, customers, managers, and organizational leadership team members.

A Five-Point Likert Scale was used for the surveys reviewed in this research. There were five categories of responses organized in rank from highly agree (1) to totally disagree (5) (Lee & Paek, 2014). Negatively worded items were reverse coded and then included in the reliability. Since the server and customer respondents exist in an environment where time sensitive and pressured work conditions are the norm, surveys were designed with these considerations in mind. Selection of a Five-Point Likert Scale addresses these circumstances and prevents frustrations and demotivation on the part of the respondents. Based on results of the pre-test responses, surveys completed by servers

and customers were completed with results submitted in a short period of time (less than 20 minutes), were easy to understand, and were based on work that was completed in each study.

It should be reiterated that contracts between the pharmaceutical organization and the CTASC include a feedback loop that mandates completion of the survey by both parties, prior to the official close-out of the trial. As a result of this mandate, response rates for each group as noted:

Table 11

Historical Survey Responses

Component	Total Surveys Administered	Total Responses
Servers	222	222 or 100%
Customers	222	222 or 100%
Total Historical Surveys	444	444 or 100%

Model Survey Items

The following Knowledge Management Survey was administered to servers within the CTASC organization.

1. There is a free flow of relevant information across the CTASC organization
2. I know where I can get support if I am unsure about new regulatory requirements
3. The CTASC organization often offers training programs and workshops that increase my ability to manage my trial
4. The CTASC organization readily shares newly acquired information with me and my team
5. I received no regulatory change notifications during my trial and did not require additional support from my manager

6. I received approximately 10 to 25 regulatory change notifications during my trial where I needed my manager's help to modify my plans to execute properly
7. I received more than 25 regulatory change notifications during my trial where I needed my manager's help to modify my plans to execute properly
8. The best way to describe my study is that it is very chaotic, and the customer made numerous changes throughout the trial that forced me to seek manager's help and/or research the KM database
9. My supervisor always assists me when I face any problem related to new information
10. The company KM system is easily accessible and helps me to do my job
11. The company's KM system is up-to-date and current on all global regulatory and compliance changes in the marketplace
12. There were approximately 2,000 sites and 5,000 patients at the close of my study and these numbers increased substantially as the trial progressed
13. My study included numerous products and many of these products were not licensed in all regions of the world. This required me to do additional research which increased my workload
14. My study was large, and the budget exceeded $3,000,000. This required me to use the company's KM database to find the answers and this increased my overall workload

The following Organizational Culture Survey was administered to the pharmaceutical global clinical trial managers who partnered with the CTASC organization.

1. I would describe my clinical trial partner (CTP) as being very collaborative and readily shared information with me during the pre and in phases of the trial
2. I would describe my CTP as being very collaborative and readily shared information with me during the post phase of the trial
3. My CTP is very knowledgeable and experienced in CTASC and understood the importance of early engagement with me and my team during the pre and in phases of the trial
4. My CTP openly shared information so that I could manage my project more effectively during the pre and in phases of the trial
5. My CTP was open to new ideas that delivered better results
6. Mutual trust between the CTP and me existed throughout the relationship
7. My CTP was sometimes stressed because of the demands of the trial
8. My CTP valued the work that I did to support the clinical trial
9. My CTP and I held scheduled weekly meetings to discuss issues, challenges and upcoming events during the pre and in phases of the trial and provided me with the necessary support required
10. My CTP and I held scheduled weekly meetings to discuss issues, challenges and upcoming events during the post phase of the trial and provided me with the necessary support required

11. My CTP and I held scheduled bi-weekly meetings to discuss issues, challenges and upcoming events during the pre and in phases of the trial and provided me with the necessary support required
12. My CTP and I held scheduled bi-weekly meetings to discuss issues, challenges and upcoming events during the post phase of the trial and provided me with the necessary support required
13. My CTP included several clinical operations managers in our meetings when issues and challenges arose and to support and suggest best actions forward
14. My CTP and I did not have planned meetings
15. I believe my CTP and I had a very effective communication process where we freely discussed successful and unsuccessful events

In summary, data methodology utilized to collect information for this research originated from servers' and customers' responses from the period January 2017 through December 2017 and at 10 days prior to study close out. The CTASC had a 100% response rating for survey completion as servers' requirements and customers' contractual agreements called for survey completion as the final step in the close-out process. These facts significantly contributed to the large amount of responses available for this research which would expect to have a positive impact on the results obtained.

CHAPTER 13: DATA ANALYSIS

Data from historical results were exported from Survey Monkey and the CTASC data management platforms and imported into Microsoft Excel and IBM SPSS Version 25. SPSS was used for all the analyses including confirmatory factor analysis (CFA), descriptive statistics, regression analysis/interaction analysis, and correlations. The statistical analysis commenced with descriptive statistics and CFA using the principal component method and direct oblimin to seek communality and to reduce the set of items included in the KM and OC surveys.

Descriptive Statistics

Descriptive statistics was the first step in the data analysis.

Table 12

OC Descriptive Statistics

Survey Number	Mean	Std. Deviation
OC1	3.5	1.272
OC2	3.93	0.989
OC3	2.49	1.079
OC4	3.29	1.301
OC4	2.96	1.36
OC6	2.69	1.455
OC7	2.55	1.271
OC8	2.33	0.921
OC9	4.36	0.964
OC10	4.56	0.589
OC11	2.74	1.271
OC12	4.01	0.977
OC13	3.2	1.602
OC14	2.75	1.641
OC15	2.82	1.231

Table 13

KM Descriptive Statistics

Survey Number	Mean	Std. Deviation
KM1	2.14	0.927
KM2	1.91	0.916
KM3	1.88	0.702
KM4	1.78	0.783
KM5	3.22	1.598
KM6	3.64	1.438
KM7	3.93	1.419
KM8	2.76	1.320
KM9	2.62	1.173
KM10	1.80	0.728
KM11	2.40	1.036
KM12	3.95	1.476
KM13	2.10	1.510
KM14	3.23	1.371

Confirmatory Factor Analysis and Construct Analyses

The second step in the statistical process was to perform CFA utilizing the principal component method and direct oblimin. The principal component method was used to determine if the larger set of variables could be reduced to fewer latent variables that share a common variance, in other words, reducing dimensionality (Bartholomew et al., 2011). Critical factorability of correlation criteria was utilized to support the statistical analyses applied in the study to understand the components of each item. These analyses included correlation matrix, Kaiser-Meyer-Olkin measure of sampling, and communalities to confirm any shared common variances that may exist in the model (DiStefano and Hess, 2005).

It was observed that 12 of the 14 KM items and 12 of the 15 OC items correlated at a minimum of 0.3 with at least one other item suggesting reasonable factorability. The correlation matrix indicated that four items (two in KM and two in OC) failed to fall within the minimum of 0.30 -- KM1and KM8 and OC3 and OC10.

Results from the Total Variance Explained for OC and KM indicate there are five components with Eigenvalues greater than one and these factors explained (OC: 30%, 14%, 11%, 8%, and 7%) and (KM: 27%, 15%, 12%, 8%, and 7%) the variance in the model. These factors explained 70% of the variance for OC and 69% of the variance for KM.

Principal Components Analysis indicated three factors. Results from the Kaiser-Meyer-Olkin measure of sampling adequacy was 0.83 above the recommended value of .6 confirming that patterned relationships exist within the dataset. Cronbach's Alpha Bartlett's Test of Sphericity indicates a significant level of $p < .05$ and Kaiser-Meyer Olkin Measure (KMO) of sampling adequacy above .50 or 0.854 for OC and 0.669 for KM.

Eight items loaded on factor 1 identified as Component 1, six items loaded on factor 2 identified as Component 2, and six factors loaded on factor 3 identified as Component 3. These three groupings were highly correlated among three dimensions of knowledge management and organizational culture. Component 1 identified a sense of a shared culture between servers and customer. Component 2 identified a sense of shared communication and transparency between servers and customers. Component 3 customers felt educated and supported by servers.

Table 14

Components of Study 2

Description	Component 1: Sense of Shared Culture	Component 2: Shared Communication and Transparency	Component 3: Education and Support
OC14: My CTP and I did not have planned meetings	-0.949		
OC13: My CTP and I invited several clinical operations to our meeting when issues and challenges arose to support and suggest best actions forward	0.938		
OC6: A mutual trust between the CTP and me existed throughout the trial	0.921		
OC5: My CTP was open to new ideas that delivered better solutions	0.903		
OC15: I believe my CTP and I have a very effective communication process where we freely discussed successful and unsuccessful events	0.768		
OC8: My CTP valued the work that I did to support the clinical trial	0.740		
OC2: I would describe my CTP as being very collaborative and readily shared information with me during the post phase of the trial	0.596		
OC1: I would describe my CTP as being very collaborative and readily shared information with me during the pre and in phases of the trial	0.54		

Table 14 (continued)			
OC11: My CTP and I held scheduled weekly meetings to discuss issues, challenges and upon coming events during the pre and in phases of the trial. This provided me with the necessary support I needed		0.661	
KM10: The company's KM system is easily accessible and helps me to do my job		0.542	
KM8: The best was to describe my study is that it is chaotic, and the customer made numerous changes forcing me to seek manager's help		0.506	
KM11: The company's KM system is up-to-date on all global regulatory and compliance changes in the marketplace		0.499	
OC12: There were approximately 2,000 sites and 5,000 patients in my study and these numbers increased as the trial progressed		0.563	
KM9: My supervisor always assists me when I face any problem related to new information		0.381	
KM3: The CTASC organization offers training programs and workshops that increase m ability to manage my trial			-0.792
KM2: I know where I can get support if I am unsure about new regulatory or compliance requirements			-0.765
KM4: The CTAS organization readily shares newly acquired information with me and my team			-0.727
KM5: I had no regulatory or compliance changes during my trial and I did not need additional help from my manager			0.34

Table 14 (continued)			
KM13: My study included numerous products… This required me to do additional research which increased my overall workload			-0.486
OC3: My CTP is knowledgeable and experienced and understood the importance of early engagement with me and my stud team during all phases of the trial			-0.309

The factor analysis indicated that five KM items were eliminated for failing to have a primary factor loading (KM1, 6, 7, 12, 14). One of items was like others in the matrix and was also eliminated (KM7). Likewise, four of the items for OC failed to meet the minimum criteria and were eliminated (OC4, 9, 3, 10). The formation of three factors or components resulted and herein identified as Component 1 or C1, *sense of shared culture,* Component 2 or C2, *shared communication and transparency,* and Component 3 or C3, *education and support.*

Based on findings obtained from Confirmatory Factor Analysis, this research will proceed with the next data analysis step to understand the relationship of KM, OC, TA, and type of shipment and their moderating influence on the CTASC during the pre, in, and post-trial phases.

Regression and Interaction Analysis

As noted, results of the pattern matrix yielded three factors or components identified as sense of shared culture, shared communication and transparency, and education and support. The components were divided into three sub-sets of low, median, and high to adjust for the variance in the data. SPSS was utilized to analyze the

interaction and to understand the relationship of the three component findings and their moderating effects of magnitude, stability and product on the success supply chain during the pre, in, and post-trial phases. I began the interactions by examining the correlation of the independent variable of each component identified in the factor analysis and then included only those variables that showed a positive or negative correlation. The next step in the process was to address multicollinearity in the model by centering all variables to reduce the covariance between them. Correlation and regression tests were run to determine if collinearity was addressed in the model.

The following chart is a summary of the findings:

Table 15

Summary of Findings

Product Term	Pre	In	Post
Product C1[a]	.808 p<.05	N/S	N/S
Product C2[b]	.698 p<.05	N/S	N/S
Product C3[c]	N/S[d]	N/S	N/S
Magnitude C1	.911 p<.05	N/S	N/S
Magnitude C2	.923 p<.05	N/S	N/S
Magnitude C3	N/S	N/S	N/S
Stability C1	.944 p<.05	N/S	N/S
Stability C2	N/A	N/S	N/S
Stability C3	.941p<.05	N/S	N/S

[a] C1=sense of shared culture
[b] C2=shared communication & transparency
[c] C3=education and support
[d] No Significance Found

Product Characteristics

Product characteristics totals were loaded into SPSS to compare interactions with the three components identified in the factor analysis. Cronbach's Alpha was utilized to determine reliability and internal consistency. Results indicated Cronbach's Alpha

of .868 for the three components at the pre-trial phase, .772 for the in-trial phase, and .788 for the post-trial phase indicating high internal consistency.

Correlation analyses were calculated to assess the direction of the relationship between product characteristics and a sense of shared culture during the pre-trial phase of the supply chain. The correlation indicated a strong relationship among the variables and this hypothesis was supported as with $F(3,218) = 136.95$, $p<.05$ with regression analysis accounting for (65%) of the total variance. An analysis of the relationship between product characteristics and shared communication and transparency also indicated a strong relationship among the variables $F(2,219)=104.21$, $p<.05$, with regression analysis accounting for (49%) of the total variance in the model. The correlations were in an acceptable range for the pre-trial phase for a sense of shared culture and shared communication and transparency factors.

Magnitude

Cronbach's Alpha analyzed the internal consistency of the three factors or components for magnitude for the pre, in, and post-trial phases. Results yielded .804 for the pre-trial phase, .804 for the in-trial phase and .802 for the post trial phase indicating reliability or internal consistency of the scale. Correlation analysis was calculated to assess the direction of the relationship between magnitude and a sense of shared culture during the pre-trial phase of the supply chain. The correlation indicated a strong correlation between the two variables with $F(2,219)=533.618$, $p<.05$ with regression analysis accounting for (82%) of the variance.

Data analysis also found significance when comparing magnitude and shared communication and transparency. Correlation analysis was computed to assess the

relationship the relationship between magnitude and Component 2. There was a strong correlation between the two variables $F(3,218)=418.505$, $p<.05$ and (84%) of the variance being accounted for in this model. The correlations were in an acceptable range for the pre-trial phase for a sense of shared culture and share communication and transparency and therefore supporting culture and shared communication.

Stability

Similar data analyses were conducted on the impact of stability and the three factors or components during the pre-in and post-trial phases. Cronbach's Alpha results yielded .820 for the pre-trial phase, .808 for the in-trial phase and .800 for the post trial phase indicating a strong reliability among the components. Pearson's R correlation coefficient was computed to assess the relationship between stability and the three factors or components. There was a strong correlation between the stability of the trial and a sense of shared culture with $F(3,218)=598.64$, $p<.05$; this regression accounting for (94%) of the variability. Also, there was a strong correlation between stability and the component education and support with $F(2,219)=840.77$, $p<.05$, regression analysis accounting for (89%) of the variance. The correlations were in an acceptable range for a sense of shared culture and education and support during the pre-trial phase and as such supports a shared culture and knowledge management.

Therapeutic Area

I attempted to utilize a fractional factorial to determine the moderating influence of the therapeutic area TA on successful supply chain outcomes. Prior to running this analysis, the 20 unique TA's were ranked from lowest to highest. The dataset of randomly selected closed clinical trials included one Pain Management one Women's

Health TA, three Hepatic Disease, five Endocrine, six Urology, six Rare Diseases, six Ophthalmology, seven Gastroenterology, seven Respiratory, eight Rheumatology, nine Dermatology, ten Cardiology, 10 Neurology, 10 Infectious Disease, 11 Hematology, 12 Vision Care, 14 Immunology, 18 Vaccine, 21 Oncology, and 58 Diabetes/Metabolism. The random sampling of the 222 closed trials included a broad range of diverse therapeutic areas and data analysis did not yield significant results that captured the moderating influence of the therapeutic area on the overall success of the supply chain. H7 was not supported.

Table 16

Summary of Therapeutic Areas

Therapeutic Area	Totals
Pain Management	1
Women's Health	1
Hepatic Disease	3
Endocrine	5
Urology	6
Rare Diseases	6
Ophthalmology	6
Gastroenterology	7
Respiratory	7
Rheumatology	8
Dermatology	9
Cardiology	10
Neurology	10
Infectious Disease	10
Hematology	11
Vision Care	12
Immunology	14
Vaccine	18
Oncology	21
Diabetes/Metabolism	57

Planned vs Emergency Shipments

Descriptive statistics was completed in SPSS to determine if the type of shipment moderated the overall success of the supply chain. Results of descriptive statistics for planned shipments (M = 424.40, SD = 1609.49), emergency shipments (M = 516.1441, SD = 1628.47) and total shipments (M = 1337.75, SD = 3233.47). Results indicated a non-significant moderating effect of the type of shipment influencing success of the overall supply chain. H8 was not supported.

CHAPTER 14: DISCUSSION OF RESULTS

I begin this discussion with a summary of the hypotheses and the results of the analyses:

Table 17

Summary Results of Data Analyses

Hypothesis	Results Found	Summary
H5A H5B Success is moderated by knowledge management during the pre-trial phase	*Product and C1[a]:* $F(3,218) = 136.95$, $p<.05$ (64%) of variance explained *Magnitude and C1:* $F(2,219)=533.61$, $p<.05$ *82%) of variance explained* *Stability and C1:* $F(3,218) = 598.64$, $p<.05$ (89%) of variance explained	Interaction effect is significant. Moderation was partially supported -- product and C1 Moderation was partially supported – magnitude and C1 Moderation was partially supported – stability and C1
H5B Success is moderated by knowledge management during the in-trial phase	Not significant	Moderation was not supported
H5C Success is moderated by knowledge management during the post-trial phase	Not significant	Moderation was not supported

Table 17 (continued)		
H6A Success is moderated by the organizational culture of the customer firm during the pre-trial phase	*Product and C2*[b]*:* *F (2,219)* = 104.21, *p<.05* (49%) of variance explained *Magnitude and C2* *F(3,218)* = 418.5, *p<.05* (84% of variance explained) *Stability and C3*[c] *F(2,219)* = 840.77, *p*<.05 *(*89%) of variance explained	Interaction effect is significant. Moderation was partially supported – product and C2 Interaction effect is significant. Moderation was partially supported – magnitude and C2 Interaction effect is significant. Moderation was partially supported – stability and C3
H6B Success is moderated by the organizational culture of the customer firm during the in-trial phase	Not significant	Moderation was not supported
H6C Success is moderated by the organizational culture of the customer firm during the post-trial phase	Not significant	Moderation was not supported
H7 Therapeutic area will have a moderating influence on success during all phases of the clinical trial	Unable to test	Moderation was not supported
H8 The type of shipment planned or emergency, will have a moderating influence on success during all phases of the clinical trial	Not significant	Moderation was not supported
[a] C1= sense of shared culture [b] C2=shared communication & transparency [c] C3=educated and supported		

Through my research and the resulting data analyses, it is clear the pre-trial phase of the clinical trial supply chain is the most impactful for overall supply chain success. As this is the phase where culture, effective communications, and KM are most strongly emphasized it is the phase where the greatest chance for success. And as the saying goes, failing to effectively plan for successful outcomes is truly a plan for failure.

Significant empirical research addressed the topics of OC and KM and my research is supported by these findings during the pre-trial phase (Hult, et al., 2002; Foss, et al., 2009; Schoenherr & Chandra, 2014; Zack and Singh, 2009; Tseng, 2009; Grant, 1996; Dinur et al., 2009; Esper et al., 2010; Lilleoere & Hansen, 2011; Pedroso & Nakano, 2009; Bartsch et al., 2013; Wei & Miraglia, 2017; He & Wei, 2009; Park et al., 2004; Al-Alawi et al., 2007; Zheng, et al., 2010; Mello and Stank, 2005; Hoff et al., 2004). My research has discovered that a strong interaction between the customer and server allows for substantial dissemination of information, enabling both parties to capture relevant information to build the optimal supply chain from the start, and to build success throughout the program. When components of the supply chain are prepared for in advance and knowledge is openly shared between the parties, the customer and the server can identify, implement, and track progress throughout the lifecycle, ultimately contributing to the success of the chain. As supported by previous research, knowledge, "a high value form of information" (Shih et al., 2012) and the internal culture of the organization, will support or prohibit the flow of learnings to overcome barriers and promote strategic advantages (Bartsch et al., 2013; Park et al., 2004). Furthermore, application of previous research in adaptive design theories in clinical trial execution, may provide the flexibility required by the CTASC to respond to necessary modifications

that will achieve optimal supply chain preparedness (Lis et al, 2009; Fleischhacker & Zhao, 2011; Fleischhacker et al., 2015; Gaydos et al, 2009; Chow and Chang, 2008).

Alternatively, a lack of these elements constitutes a lack of preparation which can lead to issues in the supply chain. It is important to note that without pre-planning preparation, all supply chain activities inherently will not be digested by the customer and the server and events will be reactionary instead of planned and controlled. The importance of the pre-trial phase and the relationship between customer and server cannot be understated and/or underestimated. Again, findings in drug supply research that stress the importance of upfront planning and risk mitigation support the importance of focus on pre-planning the chain in advance of executing the chain (Lamberti et al., 2016).

Applying these findings to the real-world points to the fact that pre-trial phase of the CTASC is considered a critical period. It is the time when there are numerous modifications to the original protocol, overall scope of the trial may change based on availability of patient enrollment, and the customer is hyper-focused on servicing the patient at the first visit to the site. This is the phase when original product characteristics are adjusted based on modifications to the original protocol, where new countries and sites are added to the trial, and where timelines are altered to match patient enrollment at clinical sites. This is an extremely active phase, where information flows between servers and customers and is the time when large amounts of new knowledge are received and shared among teams and between organizations. Missed amounts of important information, breakdowns in communication, and unmatched cultures will negatively impact the successful outcomes.

Based on the data analyses, this research has resulted in significant findings. It has provided supporting evidence that an organizations' ability to capture, share, and apply new knowledge, will moderate the success of the CTASC. It has also supported the assumption that a delineated shared culture between servers and customers will moderate successful outcomes. Based on the evidence from this research, these moderating effects occur only during the pre-trial phase and findings did not support a moderating effect during the in or post-trial phases of the supply chain.

This research highlights the fact that the complexity and scope of the trial is defined by the planning work in the pre-trial phase. As a clinical trial is in development, considerable pressures are placed on the teams of both the CTASC and the customer to coordinate efforts, design optimal study processes, and to lay the foundation for success as the trial launches and is administered globally.

As evidence has shown, product characteristics, magnitude, and stability of the trial have a direct influence on the success of the chain and are important variables to consider. Many drug supply research findings have supported these findings. For example, as research has shown, the countries where the trial takes place pose a significant threat to clinical trial success. As many researchers have discovered, countries such as Argentina, Russia, China, Colombia and India contribute to extreme challenges throughout the trial (Abdelkafi, et al., 2009; Bamberger and Patel, 2017; Fisher, et al., 1997; Qi et al., 2009). Variations in product, magnitude, and stability have the potential to impact the success of the supply chain and careful attention to these variables must be addressed by servers and customers at the onset of the program. Finally, it is the

responsibility of the CTASC organization and its' managers to proactively prepare for variations and modifications so that success is realized.

This evidence supports the importance of planning activities during the pre-trial phase of the supply chain and the moderating influence of culture, open communication, and the ability to integrate before a program is launched. Conversely, the lack of significance during the in and post-trial phases of the supply chain appears much less impactful to the success of the program and is supportive of these findings.

In conclusion, my research shows that the pre-trial phase of the supply chain for a clinical trial is most critical as it relates to the CTASC and the overall success of the trial for both the servers and customers. Communication, transparency, and knowledge management between the two organizations appear to moderate successful supply chain outcomes, most specifically during the important pre-trial phase. As the organizations need to collaborate in order to design programs, and the CTASC is reliant on the customer for inputs related to product, magnitude, and stability, a strong organizational culture of transparency and communication is critical to ensure key deliverables and success.

Finally, these findings appear to show that KM and communication are significantly related to success at the pre-trial phase of the supply chain and evidence did not show support during the in-trial and post-trial phases of the supply chain. I find these results to be both interesting and surprising as they suggest that there is a critical need to acquire knowledge and diffuse it during the pre-trial phase. It appears to show that during in-trial phase of the supply chain most of the critical information as it relates to various aspects of the protocol and subsequent supply chain responsiveness have been

shared across the organization and the project is well underway. These findings are akin to the fuzzy front-end of product development where it is crucial to acquire customer knowledge and communicate that knowledge across all functional areas of the organization involved in the development of the project to achieve success.

CHAPTER 15: CONCLUSION

Research Contribution

The purpose of this dissertation was to begin to develop new theory in an area where gaps in the literature existed. This research highlighted the significance of the CTASC in the pharmaceutical industry and compared the chain to existing models in drug supply where few similarities exist (Lis et al, 2009; Fleischhacker & Zhao, 2011; Fleischhacker et al., 2015; Gaydos et al, 2009).

Review of the many complexities of the CTASC and subsequent data analysis discovered what seemed to be supporting evidence that variations in product characteristics, magnitude or size of the trial that include number of patients, countries and sites, products and shipments, and the overall stability of the trial that include changes in the number of countries, products, and days to receive critical information, have a direct influence on the overall success of the supply chain. Although previous research has supported many of these findings (Fisher et al., 1997; Huang el al., 2002; Randall & Ulrich, 2001; Aitken et al., 2003; Selldin & Olhager, 2007) minimal studies have focused on the CTASC.

My research then proceeded to understand the moderating effects of culture, communication, education and support knowledge and their influence on supply chain success and statistical analyses of these factors supported their moderating influence during the pre-trial phase. Interestingly, supporting evidence did not show moderating influences during the in- or post-trial phases of the supply chain.

Implications

This research presents a significant contribution to academics and practitioners:

1. From an academic perspective, this research opens the door for new avenues of exploration in the CTASC. Since supporting evidence appeared to indicate that product characteristics, magnitude, and stability of the trial had a direct influence on success, new theory can begin to emerge. How might product characteristics, magnitude, and stability be controlled prior to supply chain activity? Would control of these variables influence supply chain outcomes and therefore generalizability of this research?
2. A strong correlation seemed to support the moderating influence of KM and OC at the pre-trial phase of the supply chain. One might consider the moderating impact of the variable with product, magnitude, and stability controls?
3. Selection of the dataset included in this research resulted from a random sample. Academic research may focus on classifying the dataset based on one outcome. For example, how might results differ in the dataset consisted of trials within a specified size or magnitude? By extending this research to include other variables and or limiting the scope of the dataset to a specific subset new and exciting results may be achieved.
4. From a managerial perspective, this research offers CTASC organizations the opportunity to benefit from the findings of this research. As this study has speculated, the pre-trial phase is paramount to subsequent supply chain success during later phases. Focusing on activities that take place during the

pre-trial phase may offer opportunities for improvement and success of their supply chains.

5. Managers may look at the way knowledge is gathered and shared throughout their organizations. Improvements in these areas may yield additional rewards and successes.
6. Managers may attempt to understand how organizational culture moderate relationships between servers and customers. Understanding this relationship, educating their teams, and developing processes to respond to cultural aspects of the relationship may yield favorable results for the supply chain.

Research Limitations

This research experienced limitations and these are noted as follows:

1. The results of this study were based on data collected from a single source. Larger databases from several CTASC organizations may yield different results.
2. The random sampling of clinical trials was extremely diverse, and an investigation focused on smaller or larger trials may be considered.
3. Survey respondents were selected from two sources – server within the CTASC and customers within the pharmaceutical. This sample may not be fully representative of the industry of CTASC organizations and results would be stronger if other researchers were able to duplicate results with another sample of clinical trials.

4. The study did not consider the profiles of the respondents including age, years of experience, types of certifications and level of education, etc. These factors may have an influence on results.

Suggestions for Future Research

Based on the research opportunities and the limitations of this study, the need for future research is suggested. These suggestions may include:

1. The customer in this research project was the pharmaceutical organization. How might results differ if the customer in a future study was a Clinical Research Organizations (CRO)? Would these results be generalizable to this type of customer?
2. It would be interesting to consider the profiles and demographics of the respondents. Age, gender, levels of education, types of certifications, years of clinical trial and/or supply chain experience were not considered in this study. These variables may influence the success of the chain.
3. Magnitude, product characteristics, and stability were identified as predictors of success. These predictors are broad topics and many research projects can evolve if individual research projects were to focus on one of the predictors
4. KM and OC were identified as potential moderators of success. Again, there are multiple facets to KM and OC. An individual research projects focusing on one of these moderators may yield varied conclusions.
5. The TA moderation was not supported in this study. I would expect that classifying TA area based on complexities and research focusing on a smaller sample set would yield interesting and supportive results.

6. This study did not find supporting evidence that planned or emergency shipments moderate overall supply chain success. A study focusing on smaller or larger clinical trials may deliver new findings.

The CTASC is in its infancy. As such, there are numerous topics that would no doubt bring value to academics and practitioners that would expand theory and deliver new knowledge to this supply chain. It is my hope that this research spurs others to explore this extremely complex, diverse, and ever-changing supply chain. Developing new theories and expanding knowledge will benefit academics and practitioners alike but more importantly will help those patients looking for new medicines to extend their lives and cure their diseases.

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APPENDIX A:
DEFINITIONS

Customer:

The CTASC customer, sometimes referenced as “sponsor”, is the pharmaceutical, biotechnology and/or clinical research organization (CRO) that has outsourced the clinical supply chain by engaging the CTASC firm in an end-to-end management model.

Server:

The server is the CTASC team member who serves the customer and manages the supply chain during a clinical trial.

End-to-End Management Model:

A model within the CTASC that manages a clinical trial by performing the following functions as part of the outsourced model:

- Protocol Supply Analysis
- Sourcing/Procurement of Supplies
- Regulatory Analysis and Compliance for import/export of supplies to clinical sites
- Inventory Management
- Management of Installation Qualification and Operational Qualification (IQOQ) services for all lab equipment
- Calibration/recalibration of all equipment/supplies
- Expiry management of supplies in inventory and at global sites
- Supply and resupply of materials at all global sites

- Reclamation and disposition of goods remaining at the clinical sites at trial close out
- Close out activities including site audits, inventory disposition, destruction and/or redeployment of materials

Product:

The product is an assortment of non-drug items required by the clinical sites to conduct the trial. Products can range in size, scope and classification including medical devices (syringes, EKG machines, blood pressure devices), patient items (glucose monitoring devices, pregnancy tests, cookbooks, home medical devices), lab equipment (centrifuges, freezers, refrigerators), etc.

Country/Site:

The country is the place in the world where the trial will take place. The site is the location within that country that will administer the protocol and receive patients.

Success:

Success is having the right product, in the right quantities, at the right country and site location so that service is available to the patient without the possibility of harm and delay of treatment.

APPENDIX B:
SAMPLE SURVEYS

Rating Scale:

1. Highly Agree
2. Agree
3. Neither Agree or Disagree
4. Somewhat Disagree
5. Totally Disagree

Historical Survey: Knowledge Management (14)

1. There is a free flow of relevant information across the CTASC organization.
2. I know where I can get support if I am unsure about new regulatory requirements.
3. The CTASC organization often offers training programs and workshops that increase my ability to manage my trial.
4. The organization readily shares new acquired information with me and my team.
5. I received no regulatory change notifications during my trial.
6. I received approximately ten (10) to twenty-five (25) regulatory change notifications during my trial that required that I make changes in planning and execution.
7. I received more than twenty-five (25) regulatory change notifications during my trial that required that I make changes in planning and execution.

8. The best way for me to describe my study is that it was very chaotic, and the customer made numerous changes (more than ten changes) throughout the study.
9. My supervisor always assists me when I face any problem related to new information.
10. The company knowledge management system is easily accessible and helps me do my job.
11. The company's knowledge management system is up-to-date/current on all global regulatory changes in the market place.
12. There were approximately 2,000 sites and 5,000 patients in my study.
13. My study included numerous products and many of these products were not licensed in all regions of the world.
14. My study was large, and the budget exceeded $3,000,000.

Historical Survey: Organizational Culture (15)

1. I would describe my customer as being very collaborative and readily shared information with me during the pre and in phases of the trial.
2. I would describe my customer as being very collaborative and readily shared information with me during the post-phase of the trial.
3. My customer is very knowledgeable and experienced in CTASC and understood the importance of early engagement with me and my team during the pre and in phases of the trial.

4. My customer openly shared information so I could manage my project more effectively during the pre and in phases of the trial.
5. My customer was open to new ideas that delivered better results.
6. My customer trusted me and the work that I delivered.
7. My customer was sometimes stressed because of the demands of the trial.
8. My customer valued the work that I did to support the clinical trial.
9. My customer's clinical trial project manager and I held scheduled weekly meetings to discuss issues, challenges and upcoming events during the pre and in phases of the trial.
10. My customer's clinical trial project manager and I held scheduled weekly meetings to discuss issues, challenges and upcoming events during the post phase of the trial.
11. My customer's clinical trial project manager and I held scheduled bi-weekly meetings to discuss issues, challenges and upcoming events during the pre and in phases of the trial
12. My customer's clinical trial project manager and I held scheduled bi-week meetings to discuss issues, challenges and upcoming events during the post phase of the trial.
13. My customer included several clinical operations managers in our meetings when issues and challenges arose and to ensure that timelines were not negatively influenced.

14. My customer's clinical trial project manager and I did not have planned meetings to discuss issues, challenges and upcoming events during any phase of the trial.
15. I believe my customer and I had a very effective communication process where we freely discussed successful and unsuccessful events

APPENDIX C:
SAMPLE EMAIL NOTIFICATION FOR INVITATION TO PARTICIPATE IN TRIAL CLOSE OUT

Survey

Subject: Trial _____Close Out

Dear _____,

All activities for Trial _____ will close on _____ and we request that you complete the Voice of the Teams Survey. This survey includes a total of 14 or 15 items (servers or customers) and you are asked to help us to evaluate performance and implement process improvement programs to continue to deliver exemplary services to you. Completion of this survey is indicated by our contractual agreement with our organization (for customers) or are a part of your supply chain performance evaluation (for servers) and is a final step in the trial close out process. Please click on the link below and complete this survey by _____. Once results are tabulated, we will share them with your leadership teams.

Thank you for helping us to better serve you!

APPENDIX D:
HISTOGRAMS FOR MODERATOR COMPONENT VARIABLES

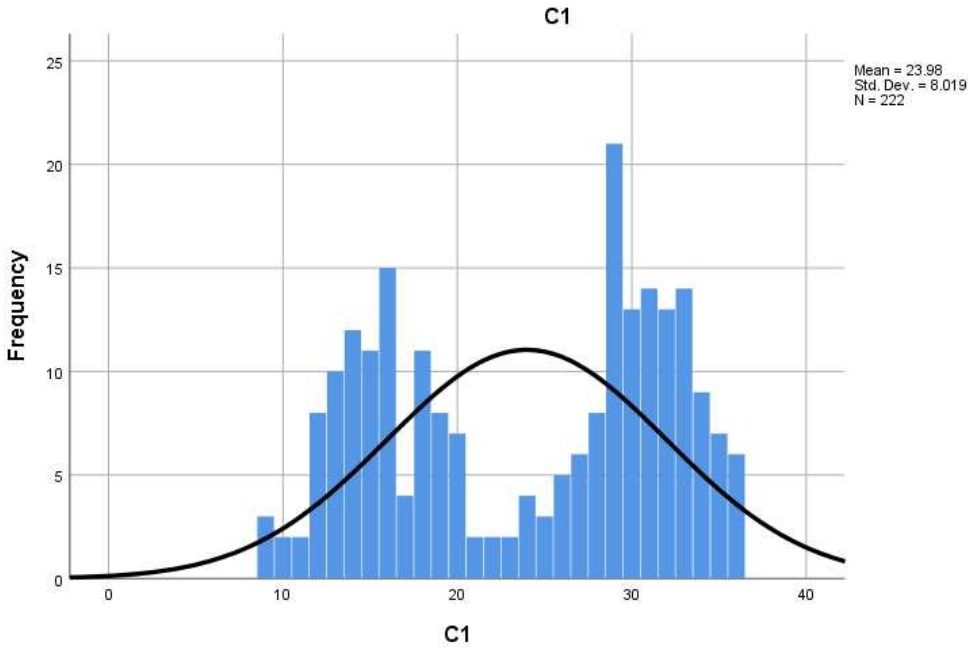

Figure 4. Histogram for Component C1.

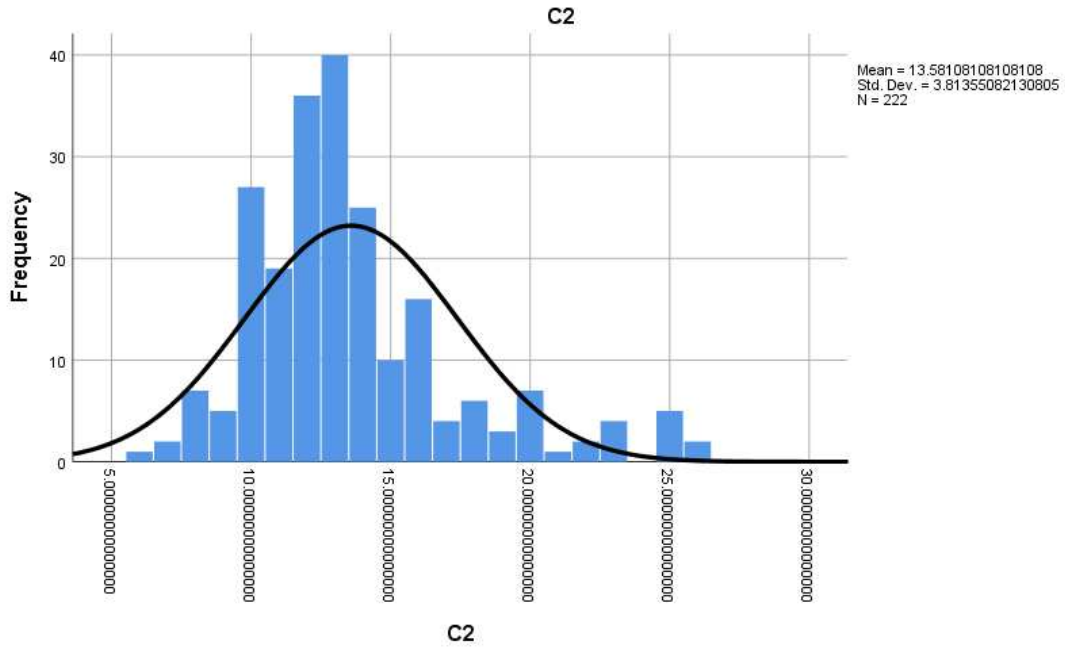

Figure 5. Histogram for Component C2.

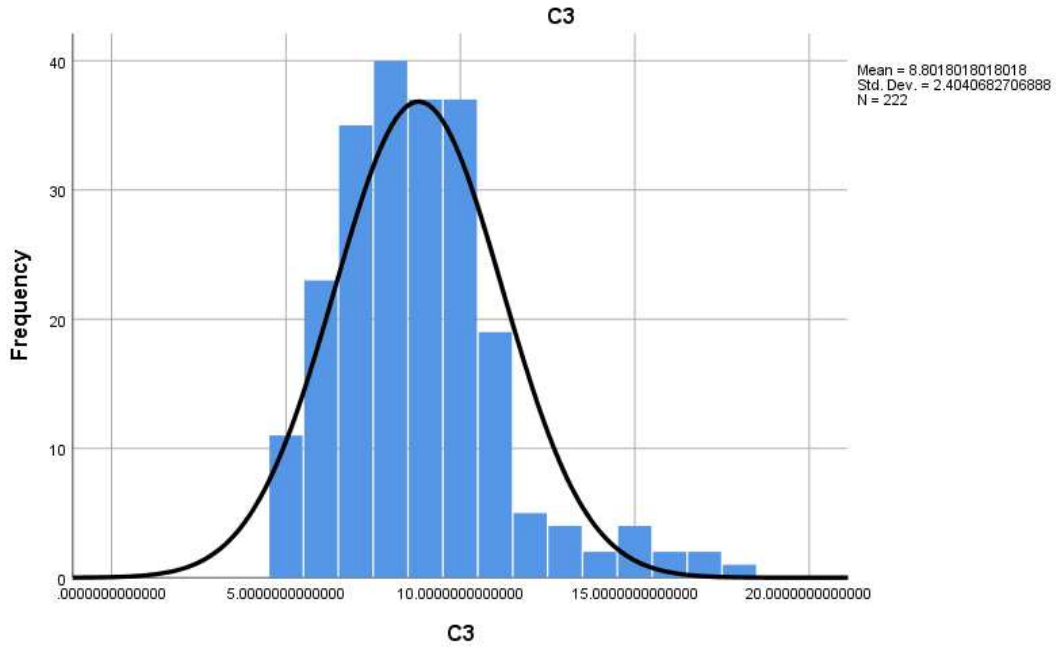

Figure 6. Histogram for Component C3.