Clinical Research competencies are enhanced when there is synergy and strong internal cohesion, with the appropriate level of clinical expertise in recruitment of participants and undertaking a study from initial stages, to conclusion. When a study sponsor approaches a site to conduct a clinical trial, the site must convey accurately that it has the resources and capability to undertake a study. The clinical research site should be able to demonstrate competencies in meeting minimum clinical and research capabilities in conducting a study. Explicit and optimal utilization of available resources and capabilities to meet clinical, regulatory, ethical, and other mandates will reflect this capability. The United States Food and Drug Administration regulatory process is demanding, exacting, time consuming and complicated. Clinical research sites must conform to regulatory clinical research standards. The interaction and collaboration of researchers in different roles and functions in a clinical research study may necessitate studying the factors that promote or constrain inter-professional synergy. The complex human interplay of many diverse and dedicated professionals, comprising clinical site coordinators, researchers, physicians, and research subjects, engaged in furthering the development of medical device and pharmacologic advancements. The increased complexity of clinical research, diminishing financial returns, increased regulatory oversight and the immense complexities, appear to be constraining drug development. There are challenges and opportunities in achieving clinical trials efficiencies as well, which is a topic of significance for the following patient benefit and economic reasons:

- Key cost drivers of pharmaceutical clinical trials in the United States are in constant escalation mode, and recent higher estimates indicate surpassing the billion $ threshold (Aylin, Hui-Hingham, & Trinidad,2016). Reith, Landray, Devereaux, Bosch, and Granger (2013), have warned, that in a clinical research study, weak internal cohesion, infrastructure, and planning may inhibit researchers in successfully conducting of clinical trials, which is to the risk and detriment of patients.
- The escalation in drug development costs and the burdensome regulatory system, has led to many existing and new interventions of significant promise to be waylaid and not evaluated (Reith, Landray, Devereaux,Bosch,& Granger, 2013).

When a study sponsor approaches a site to conduct a clinical trial, the site must convey accurately that it has the resources and capability to undertake a study. In this regard, “the most critical factors are an organization's previous experience with a site, site experience, performance, and capabilities, including sufficient staff and resources to conduct a study (Lamberti, Chakravarthy, & Getz, 2016). Conducting high-quality clinical trials requires rigor in study design, execution, and that the requisite prowess in implementation is in place to best ensure accurate conclusions are drawn from the study results (Sharpe et al.,2009). The clinical research site should be able to demonstrate competencies in meeting minimum clinical and research capabilities in conducting a study.

Background and Introduction

Clinical Research is a combination of many diverse and dedicated professional talents. A clinical research site usually comprises of coordinators, researchers, physicians, and research subjects, engaged in furthering the development of medical device and pharmacologic advancements. The increased complexity of clinical research, diminishing financial returns, increased regulatory oversight and the immense complexities, appear to be constraining drug development. There are challenges and opportunities in achieving clinical trials efficiencies as well, which is a topic of significance for the following patient benefit and economic reasons:

Clinical Research Competencies, Clinical Research Site.

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Explicit and optional utilization of available resources and capabilities to meet clinical, regulatory, ethical, and other mandates will reflect this capability. The FDA regulatory process is demanding and exacting, time consuming and complicated. Clinical research entities therefore must often re-invent internal functioning, and innovate extensively to conform to regulatory and legislative clinical research standards.

**Gaps in Literature**

The interaction and collaboration of researchers in different roles and functions in a clinical research study setting warrants research, to understand the factors that promote or constrain synergy. With the constantly evolving nature of CR, currently there is a knowledge deficit. A common theme expressed by researchers, is the imperative to understand innately, the challenges in single and multi-network sites in respect of efficiencies related to coordination, synergies and clinical trials management activities (Rosas, 2014). CRSS often fail to cover the actual costs of research, as “US clinicians, practices, and health care systems are increasingly opting out of the latter” (Califf, 2009).

Continuous and ongoing improvement to meet evolving needs must be demonstrated with suitable track record of successful clinical research execution by a CRS. For instance, a site may show to a sponsor how “By making infrastructure improvements that promote efficiency, sites will be able to better serve patients by more rapidly translating basic scientific discoveries into clinical care” (Baer et al., 2010). However, researchers by their own admission, have indicated that with the continuing and evolving nature of clinical research, further research is an imperative to understand human dynamics within research. The gap in knowledge presents an opportunity for a research study to understand ways to promote efficiency and improve infrastructure at research sites. With the identified current knowledge deficit, a study as recommended, may be of significance.

A gap detected in contemporary research on clinical research cohesion. Is further reinforced by different views expressed in literature. Rosemary, Flaherty, Sarsfield, O’Brien, and Anderson, K. (2014) noted that additional research would serve to enhance collaborative communication among faculty, deans, clinical administrators, and service chiefs, citing a gap in the literature on collaboration among schools of nursing and health services agencies (2014). From an exhaustive review of recent literature, it may be evident, that this gap extends to inter-professional collaboration in clinical research.

Søreide, Alderson, Bergenfelz, Beynon, and Connor (2013) found that surgeons in research networks and trial centers need greater international collaborations, and noted barriers to collaboration in these areas. The paucity of information on collaboration in clinical settings is perhaps profoundly stated by one eminent Central African researcher, “there is still a gap in terms of enabling local researchers to make themselves known to other researchers” (Furtado, Franzen, Loggerenberg, Carn, & Grahek, 2014). The researchers argued, that in the absence of collaboration, skills and knowledge of research sites are effectively isolated. These views denote a gap in literature, and represents an important reason why studying the factors which promote or constrain collaboration in clinical research settings may contribute in some way to successful clinical research outcomes. Furtado, Franzen, Loggerenberg, Carn, and Grahek (2014) expressed the grave implications for a lack of collaboration in the form of a) frustration at research sites, b) loss of trained staff as the study ends. Furtado et al., concluded that a stable site and the knowledge residing within, with the confidence, and training of the site will ultimately help clinical researchers improve site infrastructure and skill bases, thus enabling application and translation of personal research, to alleviating local health issues, also identified as an international priority by WHO.

The aim of this recommended research endeavor is to map and assess human dynamics in a CRS. Professional researchers in clinical research may advance or constrain study outcomes and success. The complex human interplay of many diverse and dedicated professionals, comprising clinical site coordinators, researchers, physicians, and research subjects, engaged in clinical research is not fully understood and merits further study. The hypothesis is a specific statement of prediction, and that is not the objective of recommended study. Since not all studies have hypotheses, a groundwork for a future study is designed and proposed to be exploratory.

**Research Problem**

The overarching research problem is that clinical research sites must cope with intense scrutiny and copious FDA and other regulations, which often limits clinical discovery, lowers financial success and often impedes successful research execution (Reith, Landray, Devereaux, Bosch, & Granger, 2013). Many researchers have cited the knowledge deficit in the drug industry efforts at compliance, from pre-clinical, to post launch is a contributory cause. Knowledge from clinical research benefits humankind where vigilance is required to ensure the choices made by patients, physicians, administrators, and policy makers and others in the clinical research enterprise are compliant with regulatory and other mandates. The inculcation of good clinical research practices and standards during initial study start up, is essential for the trial to proceed with clear preparedness to meet regulatory and other standards. Harmony among researchers is crucial to achieve clinical research goals and successful trial/study execution (Rosas, 2014). As stated, weak internal cohesion, infrastructure, and planning increases costs of clinical trials and lowers success, and sets back the quest for advancement in human health.

The appropriateness and rationale for an exploratory quantitative method, with a descriptive and correlational design is supported, based on an extensive review of pertinent literature. Collaboration and continuous and ongoing learning was found imperative and mandatory for clinical researchers in an era of disconcerting change. There was little to no studies found on the factors which constrain or advance clinical researcher collaboration within CRS’s, and synergies necessary to negotiate the burdensome and often opaque regulatory maze of guidelines and directives researchers must comply with. The exploratory outlook of a future and recommended research study hence may be deemed important, to examine the positive and negative factors that advance or constrain internal team efforts within clinical research sites, using a quantitative method and a descriptive design. A comprehensive description of the proposed research plan and data collection methodology is detailed herewith. Consistent with the goals of studying internal cohesion in a CRS, an exploratory research study, using a quantitative method and a descriptive design can be undertaken, based on the researched design from extensive personal experience,
and the best research practices as may be pertinent on the proposed and recommended study. No hypothesis will be necessary, since the aim is to explore (Trombim, 2006).

**Research Questions and Aims/Objectives**

A clinical research site should be able to demonstrate to the meeting of minimum requirements and advancement of human health. The Tufts Center for the Study of Drug Development (CSDD) noted that significant amendments to protocol elongate study cycle times (Lamberti, Chakravarthly, & Getz, 2016), connoting the importance of an optimally networked and coordinated research operation. The judicious utilization of available resources and capabilities to meet clinical, regulatory, ethical, and other mandates, and management strategies may aid in ensuring coordination and synergy between clinical research staff in diverse geographic. The research problem prompts the following important questions, denoted as RQ1, RQ2, and RQ3 respectively:

**RQ1:** What factors promote positive interaction between clinical research staff?

The aim of RQ1 will be to identify and examine the positive factors that advance team efforts within a clinical research site.

**RQ2:** What factors adversely impact cohesion between different members of the clinical research team?

The aim of RQ2 is to identify and examine the negative factors that constrain cohesion and team efforts within a clinical research site, using a quantitative method and a descriptive design orientation.

**RQ3:** How do researchers overcome inconsistencies’ in the current regulations, guidelines and the lack of consensus between agencies? - “the rules issued by the FDA and the National Institutes of Health (NIH) often diverge or even conflict” (Emanuel et al., 2004).

The aim of RQ3 is to understand the challenges of clinical researcher to negotiate the ever-changing regulatory environment landscape.

Researchers must display continuous efforts to improve clinical trial successes, which also hinges on the coordination between diverse clinical stakeholders, jointly with regulatory agencies, IRB’s, and others, keeping close adherence to regulatory tenets, and mandated practices and protocols. The aim must be to also understand the challenges in streamlining standards and requirements and coordination in CRS’s in an organizational management context, and to analyze existing practices.

**Further Discussion on Study**

Observance to regulatory compliance must not be construed as obstacles and impediments, rather opportunities to undertake a clinical research study that contributes to the advancement of human health and upholds the rigor and quality standards necessary. When patents, investors, decades of research, and—most importantly—patients’ lives are at stake, a one-size-fits-all approach simply will not work (Goldman, 2004). Furthermore, the complexity in regulations, and that agencies are either at loggerheads, or do not interact and collaborate with clinical trials, to develop shared guidelines and communications, may further exacerbate the problem. The key capability must be to achieve a disposition that favors constant innovation across every facet of the research endeavor with the focus on unifying and standardization. The starting point may well be in undertaking and organizational study, to aid in with the mapping of human dynamics within clinical research. The aim of a recommended and proposed study therefore will be to examine the positive and negative factors that advance or constrain internal team efforts within a clinical research site, using a quantitative method and a descriptive design orientation.

Thinking strategically, mapping of existing clinical research processes within a CRS may aid in the understanding of strengths, opportunities, and weaknesses in practices and approaches, for achieving clinical research goals. The objective of a future recommended study will also be in understanding how management can be improved within clinical research settings, as it is the glue, which binds most operations and holds true of the collaboration within a CRS as well. The study of clinical study execution may add to the body of existing knowledge, and is also a personal choice, as the aim is to study management strategies in a clinical trial environment.

**Settings**

Clinical research is truly global, and increasingly conducted in globally dispersed sites. The research setting for this study therefore will be researchers who are in the US, or in any international location, with internet access an essential requirement to participate, after meeting the stipulated inclusion and exclusion criteria. Potential participants can be employed in a CRS, and recruited through internet searches, by requesting participation and indicating the academic nature of the study to increase response rate and drive completion of a survey. Requests for participation will commence from an organizations’ ‘Contact us’ details, to seek email addresses, request for the study to be placed on the organizations Bulletin Board, and other creative ways to solicit participation. Once a participant agrees to participate, contact can be initiated though email and provided with a secure link and password to participate.

The permission to recommend the Interprofessional Team Collaboration Scale (AICTS), suitable for studying and assessing healthcare collaboration (Orchard, King, Khalili, & Bezzina, 2012) has been obtained for reference in this paper by the writer. The AICTS has been used in clinical settings and for a future study, permission must be obtained from the developers of the research instrument, if a study does not involve this author/researcher. The AICTS instrument and survey(s) should ideally be hosted for a period of 60 days on a secure web survey host, by selecting an online organization offering encrypted hosting capabilities. Using a Web browser, this tool can facilitate the administration of the chosen instrument(s) using the intuitive survey editor interface. With the powerful options, available through a good Survey host, it will be possible to collect answers to all questions, control the flow with custom skip logic, and even randomize answer choices to eliminate bias. In addition, the features provided by the secure survey administrator will also provide complete control of instrument format, colors, and layout.

Invitations to participants may be solicited by utilizing a link to the survey, while the automated e-mail notification and list management tools will serve to track respondents. It will be possible to instantly analyze and view results as collected in real-time, and then to also selectively pursue individual responses. The capabilities of the survey host will likely facilitate displaying responses and in downloading the raw data into Excel, which is conducive for transference into SPSS for statistical analysis.
Sampling

The population of the study will best be all clinical research professionals at clinical research sites and CRO’s in the US, and globally. Clinical research studies are increasingly global, and the largest possible respondents to the survey may be of value in a descriptive study. Participants for the study may be identified and recruited using internet search strategies. Potential participants for the study will be also recruited using a convenience sampling. As responses to surveys are typically very low, the strategy will be to identify, reach, and select participants from the population of clinical researchers, in US based and internationally located CRO’s and CRS’s. With a convenience sample, the potential recruitment of qualified participants may yield knowledge that could transcend geographic boundaries, while the shift of clinical research to overseas locations may also add to the potential contribution the results of this study may hold. The importance of probability sampling, is recognized, however, as stated the global reach is deemed more important with a study of this nature and outlook.

Participant Selection: Inclusion and Exclusion Criteria.

Included in this section will be a description of the target population and details about how they may be selected. Qualified and eligible participants will be recruited from leading Contract Research Organizations (CROs), and in Clinical Research Sites (CRS). Study participant and organizations can be identified, and recruited using a directory of clinical research companies. A CRO conducts clinical trials for pharmaceutical, biotechnology, and medical device industries in clinical studies, to expedite the drug development and will serve as inclusion criteria as well. An estimated 70 individuals can be the targeted recruitment goals of researchers from professional CRO organizations, CRS’s, and clinical research associations.

The inclusion criteria to participate in the study may be clinical researchers, comprising of physicians, nurses, data analysts/statisticians, Clinical Research Associates (CRA’s), and others serving in a CRS/CRO. The minimum experience of having participated in at least two clinical studies and holding a bachelor’s degree can constitute minimum eligibility requirements to participate in the study. The participant screening, eligibility and demographic component of the survey is at the beginning of the research instrument (Appendix A). Inherent in the design of the survey, is that when a participant does not meet the inclusion and exclusion criteria, ability to proceed further, is denied and the survey terminated.

The possible participants can be recruited with a personalized invitation, by utilizing a link to the survey, while the automated e-mail notification and list management tools will help to track respondents. The powerful filtering capabilities of most survey hosts can also facilitate downloading the raw data into Excel, which can then be manually transferred to SPSS for further statistical analysis. The invitation to participate can also include specific details regarding the purpose of the study, informed consent, and how to complete the survey. To undertake a study depicting the highest standards in informed consent, and adherence to the Belmont principles, and ensure anonymity and confidentiality, each participant should be assigned a unique identification number.

Research Method and Design Appropriateness

Method Rationale

The recommended research will involve a quantitative method, with a descriptive and correlation design, with data collection by administering the Interprofessional Team Collaboration instrument. A quantitative methodology may be chosen, using a sample of 50 to 75 participants, drawn from a global population of CRO’s and CRS’s. This sample size may be conducive to generalizing the study findings to the population and to also serve to use the numerical survey data for empirical examination (Dobrovolny & Fuentes, 2008). The rationale for the chosen methodology after careful consideration, is based on the premise, that it will serve to understand participant views expressed in a survey, at a deeper level (Nimon & Oswald, 2013). Quantitative research is also an appropriate method given the nature of the proposed study, as this entails using a statistical approach to uncover participant views, with an objective analysis of the data (Williams, 2011).

The aim in recommended research, must be to conduct a study involving a convenience sample, to examine cohesion in CRO’s and CRS’s in the US, and internationally. The challenges in achieving cohesion within a clinical research site are universal with a diverse set of professionals combining talents in the execution of a study. The goal will be to understand the drivers and barriers to collaboration, where regulatory guidelines are constantly evolving. The rejection of a qualitative and a mixed-methods approach are driven by a) the smallness of sample in a qualitative study, b) the needles elongation and complexities of a mixed-methods study, and inability to generalize to a CRO/CRS population with the findings of studies using these methods. Finally, choosing the quantitative method over a mixed method, and qualitative research respectively, may serve the aims of a recommended study, as it may offer a suitable option to gather pertinent clinical research information from a large sample drawn from targeted population (Masue, Swai, & Anasel, 2013).

Suitability of Design

The major variables to be studied in a clinical research setting in this study, recommended, is by using the stated research instrument, and are: a) Independent Variables (x₁, x₂, & x₃) of Partnership, Cooperation, and Coordination respectively, and b) the Dependent Variable (y) Interprofessional Team Collaboration. As an extension of the descriptive design, the invocation of a correlational research design will involve utilization of the inferential statistical technique of correlation to determine the views on collaboration may vary based on the research professional, experience, and other characteristics. A correlational study is non-experimental and suitable to answer research questions as opposed to conducting an experience to determine cause and effect, which is not intended. The assessment of the correlation between the various variables and factors can be undertaken to evaluate how the demographic characteristics of the population, i.e. how the clinical research function, qualifications, and experiences shape views. Two variables are correlated if a change in the value of one signifies a change in the other. Careful thought is given to the statistics and measures of association, depending upon relevance to the study and the research instruments intended for use: 1. Pearson chi-square, likelihood-ratio chi-square, linear-by-linear association test, Pearson’s r.
2. Spearman’s measure of correlation could be measure correlation for ordinal data, as this measure, Lind, Marchal, and Mason (2002, p. 273), have observed, facilitate describing the relationship between sets of ranked data. These authors also have noted that skewness and measures which show data spread and variation, can serve as a useful indicator, which can be measured using descriptive statistics.  
3. Kendall’s tau_b is also a measure of association, useful in paired observations.

Correlational techniques aid in assessing the direction, and strength of associations between ordinal variables (Rowley, 2014). In summary, the quantitative research method and the descriptive design aligns with the nature and purpose of the proposed study. The statistical analysis helps to compare numerical data gathered from a survey to promote objective measurements that are beneficial for examining larger generalizations to CRO and CRS settings.

**Research Instrument**

A common view held by many healthcare professionals, is that the nature of their profession entails collaboration and teamwork. However, the degree and extent that this occurs in clinical research needs more extensive studies, borne out through the gaps in literature and the relative absence of studies in this domain. The aim of a study based on deep personal experience, and specifically undertaken for this publication, may be of significance to clinical researchers, notably to examine the positive and negative factors that advance or constrain internal team efforts within a clinical research site, using a quantitative method and a descriptive design.

After extensive research, an instrument suitable to assess actual level of collaboration practice within clinical research study settings was found. The instrument can be viewed in the Appendix. The research developed by the authors cited herein, is the Assessment of Interprofessional Team Collaboration Scale, suitable for healthcare collaboration assessment (Orchard, King, Khalili, & Bezzina, 2012). The AITCS has been developed after extensive testing, and refinement, as the authors have contended that there is “a paucity of literature and measurement tools addressing interprofessional collaborative team performance and the nature of effective teamwork processes and patient roles within collaborative teams”.

A gap in literature is apparent, with the relative absence of research studies on this topic. Knowledge is limited collaboration among health care teams. Instruments are therefore needed to assess collaborative relationships. The features of the AITCS, is that it consists of 47 items within 8 subscales (partnership, cooperation, coordination, and shared decision making) and with a 5-point Likert scale. While it was used in in the Canadian healthcare settings, the instrument can be adapted to clinical research with very minimum of change. The instrument and internal consistency estimates for reliability of each subscale ranges from 0.80 to 0.97, with an overall reliability of 0.98, which makes the AITCS a reliable and valid instrument (Orchard, King, Khalili, & Bezzina, 2012). The instrument developers further have stated that the psychometric analysis of this instrument supports its value in measuring collaboration within healthcare teams, when patients are a part of the equation.

The AITCS is a diagnostic instrument, designed to score and measure interprofessional collaboration among team members (Orchard et al., 2012). It consists of 23 statements considered characteristic of interprofessional collaboration (how teams work and act). Scale items represent three elements considered to be key to collaborative practice. These subscales are: (1) Partnership—8 items, (2) Cooperation—8 items, and (3) Coordination—7 items.

The scoring of AITCS data is relatively straightforward. Respondents will indicate their general level of agreement with items on a 5-point rating scale that ranges from 1 = “Never”; 2 = “Rarely”; 3 = “Occasionally”; 4 = “Most of the time”; to 5 = “Always”. These ratings produce scores from 23 to 115. The survey takes approximately 10 minutes to complete. As stated, descriptive statistics can be used to compute response rates, the mean, median and mode. The demographic data will aid in evaluating correlations, into how the responses to the degree and extent of collaboration is influenced by gender, qualification, experience, and professional specialization in clinical research. Lind Marchal and Mason (2002) noted that in determining the strength (or weakness) of relationships, there is absolutely no relationship between the two sets of variables, when Pearson’s r is zero. A coefficient of correlation r close to 0 (say, .08) will likely show that the relationship is quite weak. The same conclusion is drawn if r is -.08. Coefficients of -.91 and +.91 have equal strength; both indicate very strong correlation between the two variables. Thus, the strength of the correlation does not depend on the direction (either – or +), in estimating the degree of correlation (Lind, Marchal, & Mason, 2002, p. 460). Lastly, the research instrument has been used in healthcare settings and is a standard, tried and tested instrument with high internal consistency and overall reliability. The AITCS a reliable and valid instrument which will provide consistent results when administered to a different sample of clinical researchers. The study results, of a study as recommended herein, will hence be likely replicated in other studies.

**Internal and External Validity**

In quantitative studies, ensuring validity and reliability are imperatives with suitable measures and research steps, as the aim is often to achieve consistency and repeatability of results. In this context, the appropriate scales in the research instrument must also measure to measure what is intended. The quest to achieve reliability and validity can suffer when the threats lie in the research design. A discussion on the possible threats to the study’s internal and external validity will be appropriate here. Suitable safeguards and measures in the research design will aid in minimizing such threats, to potentially render these inconsequential.

**Threats to Internal Validity**

Internal validity manifests when the variables and elements that measure the same general construct produce similar results (Roe & Just, 2009), which for a proposed study is interprofessional collaboration. High internal validity in a study is an imperative for a study of merit, and to ensure the any influence on the dependent variable are attributable to the independent variables, and not extraneous variables. Important risks to internal validity may include non-random selection inducing bias of participants, history, instrumentation errors, maturation, data contamination, and others, which will be discussed individually:

- **History:** External events can adversely affect internal validity when these cause discernible changes in the dependent variable occur, and are not related to changes in the independent variable. These events are not deemed to pose a threat to validity in a proposed study of this nature, however vigilance and awareness will be necessary to
monitor in sphere of clinical trials in all geographies participant selection. Prior events to conducting this study, will not be a factor, as in descriptive research, there is no treatment, or events in the environment likely to influence clinical researcher views.

- **Maturation:** Maturation is often considered a potential threat to internal validity, and would also not be a relevant factor as there will not be any anticipated physical or psychological changes in the participants in a study based on the method and design proposed. The short duration and time span, and that participants can be recruited from geographically dispersed US and international clinical research sites precludes maturation as a factor that will lower internal validity.

- **Statistical regression:** Statistical regression is a possible threat to internal validity, and represents the effect when the results display “a tendency for subjects selected on the basis of extreme scores to regress towards the mean on subsequent tests” (Michael, n.d.). No tests need to be involved in this recommended study, which can involve a quantitative method and an exploratory design. Since a participant should have the opportunity to take the survey just once, and there will not be any measurements a second time.

- **Selection:** Selection bias can be a threat to internal validity. In the proposed study, volunteers from different geographies, and no method of selection, other than meeting the inclusion/exclusion criteria, will minimize this threat. A threat to internal validity in selection of participants in a non-random sample predominantly surfaces with the effect of treatment, as there lies the potential of other confounding factors to influence results. To minimize threats to internal validity, participants of the study must be selected, from a large pool of CRO’s CRS’s and CR organizations/associations. The recruitment will represent one of convenience, as participants who are easily accessible will be recruited. Factors affecting internal validity include prior events to conducting this study, which will not be a factor, as in descriptive research, there is no treatment, and events in the environment likely to influence clinical researcher views.

- **Testing:** Testing can pose a threat to internal validity. In this study, however, the effect of experience with a pretest will not also be a threat, as the instrument has been widely used in healthcare settings, will be administered just once to an individual participant. Participants will therefore not be acquainted to the instruments through prior testing. For this reason, the threat of the familiarity of participants with the research instrumentation, and the nature of it will also not arise, since there will not be pre-to posttest actions in a descriptive study in studying inter-professional collaboration. Since there is no testing and treatment, this threat is not relevant in this study.

- **Instrumentation:** Instrumentation can potentially constitute a threat to internal validity, notably when there is measurement involved in pre- and post-test stages. In this study, however, there would not be any pretest and posttest. As stated, a) the instrument has been widely used in healthcare settings, b) will be administered just once to an individual participant, c) there will no pre-to posttest measurements. Since there is no testing and treatment, this threat is not relevant in this study. The AITCS is a reliable instrument, used in healthcare settings, and designed to score and measure interprofessional collaboration among team members. The use of a reliable and specific instrument and using the data collection procedures described, using a secure and trusted survey host, will serve to negate instrumentation errors. The survey may be hosted for a limited period of fifteen days, as a step to reduce maturation effects during the data collection phase of the study. Direct communication with study participants should be only in the form of the initial invitation, and subsequent reminders, to increase response rate, to ensure integrity of the data.

- **Mortality:** The mortality and attrition of participants is of potential significance in clinical research and other studies, conducted over an elongated period. For the proposed study, the completion time is estimated to be under 20 minutes, and mortality will not be a threat. The research will involve recruiting clinical researchers from CRS’s and CRO’s worldwide using an exploratory design, with a survey used in healthcare settings, which has served to assess collaboration among healthcare professionals.

- **Design contamination:** Design contamination represents a possibility in control group studies. The intervention in such studies can provide advance knowledge, or awareness to other participants of the intervention being received by those not in the control group. There is therefore no fear of design contamination. Since this study as recommended, will not involve a control group and any intervention, and as participants will be unknown to each other in geographically separated locations, there will be no threats to internal validity.

- **Compensatory rivalry:** Compensatory rivalry threats may surface when a study has a test and a control group. This study as described and detailed, should entail an exploratory, correlational design, involving a survey, which also precludes this threat. Compensatory rivalry is also possibly when a study is conducted with one, or a few organizations and participants and there is potential interaction among them, which is not true of the asynchronous setting of this recommended online survey based study.

- **Resentful demoralization:** Resentful demoralization is a threat when the test and control groups express dissatisfaction in some aspect of the treatment received as research subjects. As stated, there would be no groups of this nature in this research, and therefore this threat will not represent a limitation to the validity of the study.

In summary, to minimize the above listed threats to internal validity, participants of the study must be selected, from a large pool of CRO’s CRS’s and CR organizations/associations. The recruitment should represent one of convenience, as participants who are easily accessible must be recruited.

**Threats to External Validity:**

External validity represents the extent the research design corresponds and relates to the target audience (Maddux & Johnson, 2012). The instrument is specific to healthcare and as recommended, should be customized to a US audience, and therefore will necessitate minor change to replace the healthcare professionals listed, specifically with clinical researchers. External validity is an indicator of the extent the study findings are generalizable to the population, from the sample used. A threat to external validity may lie in making erroneous generalizations, which will not be the case here, as limitations will be expressed as well as opportunities for further research and study in the realm of collaboration in clinical research. The external validity threat of aptitude (Leedy & Ormrod, 2010), and treatment interaction will not arise in a disconnected global population of clinical researchers, from which participants will be drawn by
convenience and chance. The risks to external validity often arise when the sample is not truly a representation of the population. This risk should be avoided by specific recruitment of clinical researchers, who will be screened and qualified to determine eligibility to participate in the study, using the stipulated inclusion and exclusion criteria, with further elaboration below:

- **Interaction of selection and treatment:** Selection and treatment can threaten validity of a study. With the absence of any treatment in a study as recommended, with an exploratory descriptive research design, and the absence of pre-test and post-test effects, should not represent threats. However, cognizance of individuals averse to collaboration will be factored in, and a scrutiny of data for this threat will be undertaken.

- **Interaction of testing and treatment:** Setting and treatment may affect external validity, and are typically associated with physical settings. In a proposed and recommended study, the online environment presents the opportunity to complete the survey at the participant’s convenience and at home. There will also no interaction foreseen among participants in view of the dispersed locations, and confidentiality in participant recruitment.

- **Interaction of history and treatment:** History and treatment can represent a threat to external validity if concerted events take place during a study. It is highly improbable that CR events will occur simultaneously across global CRS’s, and CRO’s, to cause a threat to external validity. In the rare possibility that this may occur, appropriate actions must be taken to mitigate any possible risk posed.

- **Reactive arrangements:** Reactive arrangement are a possibility when the behavior of participants change with the knowledge of participating in a clinical or scientific study. In this study, participants will be recruited with full disclosure, and awareness of participating in a study. Furthermore, the audience will be researchers, who are well acquainted with the nature of a study, and therefore this should not warrant being considered a threat in this study. Reactivity and cause-effect relationships if any found during the study, may add to the existing body of knowledge on collaboration amongst clinical research professionals. The aim is not to make any claims of generalization, as exploratory studies serve in expanding the understanding of a topic, and it is impossible to formulate hypotheses without some exploratory studies, (Crawford, 1997).

- **Multiple treatment effects:** Multiple treatment effects pose a threat to external validity in studies involving participants receiving multiple treatments. As stated, there would be no treatment in this study.

Environment/Setting is also an external validity threat, and may beg the question, if the results can transfer, apply, and be relevant to another setting. While the instrument for this study is specific to healthcare, the challenges in interprofessional team collaboration are unique to clinical research in view of intense regulations that must be followed, and data shared. The recruitment of clinic researcher participants must follow specific inclusion and exclusion criteria, to mitigate this threat, while claims of generalization will not be made to other non-CR settings. A threat to external validity denoted as temporal, may not be relevant, as the results will hold true given the regulations for CR are enshrined in protocols, mandates, and rigorous expectations, in the US and globally. Situational specifics will also not represent or a threat, as there will be no conditions of time, location in an asynchronously administered survey that will not infringe on participant situations, to have any bearing on generalizability.

In conclusion, to further minimize threats to external validity, the recruitment of study respondents should entail a consistent process. As discussed, there must be measures to assure of participant confidentiality and anonymity as described, with selection of clinical researchers actively involved in research, to minimize bias from respondents who may have unrelated roles and functions. In the interest of enhancing external validity, the variables will also be operationally defined. For the proposed study, the expectation of high external validity may thus be inferred, as the convenience sample and application of specific screening and eligibility criteria will serve to increase the quality of participants from a carefully identified population.

**Conclusion**

The collaboration imperatives in clinical research are generally understated and understudied. With the great focus and emphasis on research design, ethical recruitment of participants, and in the overall efficient conduct of clinical research study, perhaps the synergy and internal cohesion is relegated to the back-burner. Organizational management principles and strategies must be brought into play with the clinical research expertise when undertaking a study, from the initial stages, and to its logical conclusion. Arguably, an organization must know its strengths, and negate weaknesses, however to achieve that introspective assessment warrants mapping of existing cohesion, synergies, and management competencies, in addition to strong clinical and research capabilities. The aim of this discourse, is to recommend and present a systematic and organized mapping and assessment approach of human dynamics in a clinical research site, ideally before a clinical research study commences. As discussed, a lack of collaborative teamwork may constrain clinical research quality and successful outcomes from a management perspective.

The complex human interplay of many diverse and dedicated professionals, comprising clinical site coordinators, researchers, physicians, and research subjects, in clinical research merits further study. Clinical research sites must cope with intense scrutiny and copious FDA and other regulations, and unless inter-professional collaboration is optimized, the positive implications of a study and even clinical discovery may be at risk. The exploratory outlook of a research study may be essential to examine the team collaboration and cohesion at clinical research sites, and using a quantitative method and a descriptive design as recommended herein, which could yield new knowledge in this realm. A comprehensive description of a recommended research plan and data collection methodology detailed herein, may offer new opportunities for research. As in any research, the limitations of the proposed study method and design will necessitate management studies in multiple and different sites, and in different geographies. The recommendations in study internal cohesion in a CRS, using a quantitative method and a descriptive design is based on extensive personal experience in organizational management, a review of pertinent literature, and the best practices in clinical research management. Further discussion and collaboration in executing such studies are invited and solicited from the academic and clinical research community.
References