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Visualization Literacy and Decision-making in Healthcare

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Visualization Literacy and Decision-making in Healthcare

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Dedication

This work is dedicated to my spouse. Not only for your unwavering support and sacrifice throughout this process, but also the push towards continuous improvement through knowledge and the use of knowledge to make a difference. Tom- you inspire me to embrace knowledge as a gift and as an opportunity to serve others.

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Abstract

The ability of workers in the healthcare industry to analyze, interpret and communicate with health data is critical to decision-making and impacts both health and business outcomes. Optimal decision-making requires having real-time access to information that provides useful insights and that lends itself to collaborative decision-making. Data visualizations have the potential to facilitate decision-making in healthcare when presented as a dashboard. However, dashboards have shown varying results in both effectiveness and adoption. Data or graphical literacy challenges experienced by health team members could complicate strategic decision-making through an inability to correctly interpret or summarize the information presented in a dashboard. One assumption is that visualization literacy and its impact on how people process health data visualizations play a part in the effective interpretation of information to support decision-making.

To determine the impact of visualization literacy on the process of decision-making in a healthcare setting, we first developed and deployed a dashboard designed to provide important information for decision-makers on a clinical trial management team. We engaged Project Managers and Medical Managers in the project as key decision-makers on the team. The dashboard was integrated into the normal workflow of a clinical trial management team and designated as the tool used in the workflow to report on the trial status within the organization. Next, we administered a series of assessments to the key decision-makers. The assessments were designed to evaluate numeracy, visualization literacy, and the impact of both on the decision-making ability of participants. Decision-making was assessed using a common

workflow scenario supported by visualizations from the deployed dashboard. Additionally, we were interested in exploring indicators related to job satisfaction that was collected during the project period through a formal engagement survey.

We performed a general linear model to assess the relationship between the assessments and decision-making. Results of our project show a significant and clear relationship between visualization literacy and decision-making ability and an insignificant relationship between numeracy and decision-making ability. Job satisfaction scores for the participant group obtained through the engagement survey suggest favorable results. However, areas of opportunity for improvement illuminated through the survey included better tools and additional resources to support the execution of tasks, a better workload balance, and improvements in collaboration across departments and functions.

The results of this project contribute to the informatics discipline by demonstrating that information obtained from data visualizations produced through the aggregation of multiple sources of data can be effective decision-support tools if they are designed with user skills and abilities in mind. The results of the project suggest an opportunity to develop more useful and usable tools to improve job satisfaction as well as organizational business objectives related to workforce staffing, job competencies, and learning and development initiatives.

Keywords: Data visualizations, health data dashboard, numeracy, visualization literacy, organizational decision-making, clinical trial management.

Section 1: Introduction

Background

To complete the drug development lifecycle, the full cost of bringing a new drug to market was recently estimated in a range from $314 million to $2.8 billion (Wouters, McKee, and Luyten, 2020). Key cost drivers of clinical trials in the United States vary between therapeutic areas and can include clinical procedure costs, administrative staff costs, and study monitoring (Sertkaya, et al., 2016). It is widely accepted that 80% of all clinical studies fail to finish on time, and 20% of these are delayed for six months or more (Nuttall, 2012). Much of the time these delays are due to ineffective decision-making related to process cycle times, patient recruitment, or other key metrics that study teams currently monitor. To support timely and accurate decision-making, the industry has taken advantage of the rapid growth of technology and experienced a recent proliferation of data analysis and presentation, particularly in the form of data visualizations, as a solution.

Decision-Making Support. Real-time data visualizations for multiple medical sub-specialties have been studied from a data access, aggregation, and visualization aspect to support quality improvement (Mottes, Goldstein and Basu, 2019; Sim et al., 2017; Twohig et al., 2019). Various fields in health care have moved rapidly in the field of decision support with the development of dashboards. Huber and colleagues (2020) described the development and implementation of an interactive data visualization dashboard using a commercially available visualization tool to support decision-making for referring providers at the point of entry (Huber et al., 2020). The tool was ultimately employed to streamline research and quality improvement efforts. Similarly, Egan (2006) studied dashboard use in an intensive care situation and surmised that the capability to link physiological data with other selected data sets held promise for quality improvements, patient safety, and outcomes (Egan, 2006).

Clinical operations leaders across the field of drug development, and medicine in general, have continued to research software and underlying technology designed to support decision-making (Seow and Sibley, 2014; Vitacca and Vitacca, 2019). Data visualizations in the form of a project summary dashboard have the potential to facilitate clinical trial management as a dashboard facilitates summarizing and presenting data in a way that provides a quick analysis of the clinical trial's status. Data displays, such as a dashboard, can save time and costs related to decision-making as they possess the ability to synthesize a large amount of information produced from varying data points (Iftikhar et al., 2019).

In a similar manner to how clinical trial management uses information displays, Weiner and colleagues (2015) described a dashboard designed to integrate strategic and operational decision-making through the visualization of key performance indicators (KPIs) (Weiner et al., 2015). KPIs and their measurement against goals are important to ensuring the effectiveness of delivery in clinical trials and in measuring progress against organizational goals. Clinical trial management has also been studied as benefitting from tools designed to enhance timely decision-making focused on outcomes, quality, and patient safety (Farnum et al, 2012; Yang et al, 2018).

The success of a dashboard tool implementation designed to support effective decision-making is grounded in both the use of effective design principles, as well as an understanding of the importance of the dashboard to a user in solving both routine and unexpected challenges during a clinical trial. The creation of a tool that supports decision-making ideally will reflect and support the capacity for human information processing through the summarization of information that takes advantage of visual cognition in quickly creating awareness. Applying these concepts, in combination with the current ability to aggregate and display data from multiple source systems in real-time, make dashboards an interesting tool for decision support.

Varying results in use and adoption. Dashboards have been developed and implemented for healthcare decision-making with varying results in both effectiveness and adoption (Concannon et al., 2019; Toddenroth et al., 2016). Optimal dashboard design provides support for teams by enabling them to make decisions with a high level of accuracy and confidence (Sim et al., 2017). Effective management of a clinical trial requires having real-time access to information that provides useful insights into trial progress and that lends itself to collaborative decision-making. The information necessary to support effective management of a clinical trial is often captured from data points that are varied and complex as well as being generated using multiple systems employed during a clinical trial (Farnum et al., 2019).

Challenges can occur both from a data aggregation and integration perspective, as well as through the attempted provision of effective data visualizations that are both useful and usable to the clinical trial team. Compounding the challenge is the initial capture of the data points through processes that aren't always well-defined or optimized and may not be supported by underlying standards. The importance of having the ability to access, aggregate, and analyze data is evident when considering that organizations that lack a digital infrastructure show regular delays of at least one month, costing pharma and biotech companies up to $8 million per day (Hedin, Patil and Esiobu, 2020).

While the use of effective design principles could enhance the usability of a dashboard, adoption associated with the user's perception of the dashboard's suitability can provide a challenge. The dashboard must provide information that is not already obvious and must present the information in a way that is familiar to the user, follows their workflow, and is advantageous to quick decision-making.

Beyond Dashboard Design- Necessary Skill Sets. As institutions have been steadily introducing dashboards to measure quality and outcomes related to the provision of care in those institutions, the launch of dashboards as a tool has subsequently increased the necessity of the users possessing skill sets related to data and informatics. In clinical trials, data display formats and their impact on investigators' decisions to continue or stop clinical trials have been investigated primarily to assess the impact of the type of data display on decision-making (Elting et al., 1999).

The ability of workers in the healthcare industry to analyze, interpret and communicate with health data is critical to decision-making (Stadler, et al, 2016; Caban & Gotz, 2015; Shaw et al., 2015). While improved decision-making on behalf of a clinical trial team could effectively improve management of the costs and accelerate the timeline of drug development, simply providing technology or tools that displays relevant information may not be enough to solve decision-making challenges. While decision-making in healthcare is multi-faceted, health data literacy is an important component of decision-making, whether on behalf of a clinician, patient, or a clinical trial team. Benefits of improved decision-making in healthcare include patient safety and quality outcomes. Similarly, improved decision-making on the part of a clinical trial team includes improvements in the management of trial costs, quality, and acceleration of the timeline of drug development leading to enhanced safety and quality outcomes.

Numeracy and graphical literacy have been discussed and evaluated in the literature consistently over time (OTA, 1984; Kosslyn, 1989; Carpenter and Shah, 1998; Lipkus et al., 2001). Recently, numeracy and graph literacy as part of the larger topic of health literacy has received increasing attention as the two are intertwined (Rodriguez et al., 2013). Numeracy has been defined as "the degree to which individuals can access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical, and probabilistic health information needed to make effective health decisions" (Goldbeck et al., 2005, p. 375). Graph comprehension has been defined as the ability "to read and make sense of already constructed graphs" (Friel, Curcio and Bright, 2001, p. 145). While graphical literacy is often the focus of research, it is slightly different from visualization literacy which is a user's ability to use data visualizations and contrast and compare trends (Lee et al., 2019).

Designing visual aids that best support decision-making across a range of numeracy and graphical literacy skill sets has been built upon past research and has recently been considered in more depth (Garcia-Retamero, Cokely, 2017; Nayak et al, 2016). Yet, the essential connection between visual displays and graphical or visualization literacy of the intended recipients of the tool is not always considered when providing advanced technology tools for decision-making.

Levels of education required for licensure in the healthcare professions imply that, in general, healthcare clinicians are highly educated. Although it is frequently assumed, the level of education has not turned out to be predictive of high numeracy. Research by Lipkus and colleagues (2001) repeated previous research (Schwartz et al., 1997) in a highly educated population examining numeracy skill sets and risk interpretation and determined that highly educated participants have difficulty with relatively simple numeracy questions (Lipkus et al., 2001). The research implied that typical strategies for communicating risk may be flawed (Lipkus et al., 2001). Related work focused on medical personnel employed in emergency room situations and summarized the importance of addressing numeracy skills with the conclusion that poor numeracy skills among health professionals extend beyond medication error and can impact patient outcomes (Eley et al., 2014).

Current Practice

Clinical trial management teams in a Contract Research Organization (CRO) are hindered in making strategic decisions due to an inability to quickly access and review data in aggregate across the study lifecycle. Current practice states that many pharma, biotech, and CROs indicate a preference for and rely on spreadsheets to assess the progress of their trial making the aggregation and visualization of data across programs difficult (CenterWatch, 2018). Excel® spreadsheets, as the primary source of study data used to make decisions during a clinical trial, are commonly used in the process of trial management within the organization where this project was conducted. The static nature of a spreadsheet means that individual team members must forage for information that instantly becomes outdated by the time they have extracted, manipulated, and examined the information within their spreadsheets. It is not uncommon for team members to have different versions of trial information depending on where and when each member of the team obtained their data. While spreadsheets can be shared on a common drive, there is very little graphical information provided within the tool that would serve to establish a common baseline for all members of a trial management team.

Using disparate information from disparate sources leads to confusion and additional time spent investigating and harmonizing information across a team so that effective decisions can be made.

While the clinical trial industry employs highly educated individuals, there are little to no defined standard expectations for data literacy written into job descriptions or position profiles. Many of the roles across a trial team are populated by healthcare clinicians or staff with significant scientific or business backgrounds from both education and experience. Lee and colleagues (2017) state "data visualizations have become more popular and important as the amount of available data increases, called data democratization" (p. 551). It has been generally accepted that as the industry becomes increasingly digitized and the availability of data is democratized, staff have kept current with the skill sets necessary for the effective use of tools and data displays. Very few clinical research organizations evaluate new employees for their level of data literacy, nor do these organizations provide training other than on how the tools are ideally used and incorporated into staff workflows.

Problem Statement

In the clinical trial industry, trial delays significantly increase the cost of drug development. Delays are caused by ineffective decision-making due to a lack of accessible and timely information to support decision-making. If multiple source system data is summarized in health data visualizations and integrated into the workflow of a clinical trial management team, it is uncertain whether the key decision-makers that have been provided these workflow-specific tools have the necessary skill sets to interpret the information provided in the tool.

SMART Statement

Between fall 2021 and spring 2022, project leaders responsible for critical decision-making were assessed for visualization and numeracy skills followed by a decision-making assessment using a visual information display that has been recently implemented and integrated into their workflow. The data were analyzed to examine if a relationship existed between numeracy, visualization literacy, and decision-making supported by data visualizations illustrating trial progress. Organizational job satisfaction scores were reviewed to consider association with decision-making support and ability.

PICO

The population included in the assessments were project leaders who were responsible for making key decisions during a clinical trial. The intervention aimed at analyzing skill sets was the Visualization Literacy Assessment Test (VLAT) (Lee et al., 2016) and a subjective numeracy test. Both tests were compared to a decision-making assessment using a visual data display that was built and integrated as part of the decision makers' regular workflow. The key outcome was planned to be a comparison of visualization literacy to decision-making accuracy using a commonly deployed information tool integrated into the users' workflow.

Proposed Solution

Organizations that manage clinical trials are willing to invest in technology solutions such as data visualization dashboards. As such a comprehensive, complete, and easy to access information summary tool at the project level has been developed and was integrated into the clinical trial project leader's workflow. However, organizations have less insight into investing in learning programs that enhance or improve skills related to informatics and the interpretation of data displays or in modifying data displays to better accommodate existing user skill sets. The goal of this project is to determine if visualization literacy is associated with decision-making using data displays such as dashboards in a healthcare setting.

The model employed for this project involved a testing framework consisting of a visualization literacy assessment and subjective numeracy assessment followed by a decision-making assessment using data displays that are part of the participants' daily workflow. The purpose of assessing both numeracy and visualization literacy is to learn if decision-making might be influenced more strongly by one or the other. Job satisfaction is an interesting comparison as it could potentially be affected by the perception of how easy or difficult it is to accomplish a task as expected along with achieving expected outcomes as workflows incorporate increasingly digitized tools.

Section 2: Evidence-Based Practice Review

PubMed was used as the primary scholarly database for the search in consultation with a librarian from the Texas Medical Center Library. The database was selected to capture relevant literature from the primary fields of interest including data visualizations, organizational decision-making, clinical drug trials, and dashboards. Yale MeSH analyzer was initially used to support the selection of MeSH terms relevant to pre-selected articles obtained through previous searches or content expert suggestions. The initial search terms including both MeSH and keyword searches resulted in a target with the most relevant literature (n=208): (((graphical literacy) AND (numeracy)) OR ((clinical trials as topic[MeSH Terms]) AND (data literacy))) OR ((Information visualization) AND (Literacy)).

The final search terms were chosen based on reviewing similar content and through trial-and-error searches. Keywords from previously selected articles that were relevant were included in the search. Additional literature captured outside of the formal library search included references from other related literature (snowballing) and recommendations from content experts (n = 15). Duplicates were screened and removed by using the advanced search function within PubMed and combining the additional literature with the formal library search (n = 214). Additional filters were applied including Full Text, publication date within the last 10 years, and English with the result reduced to 166.

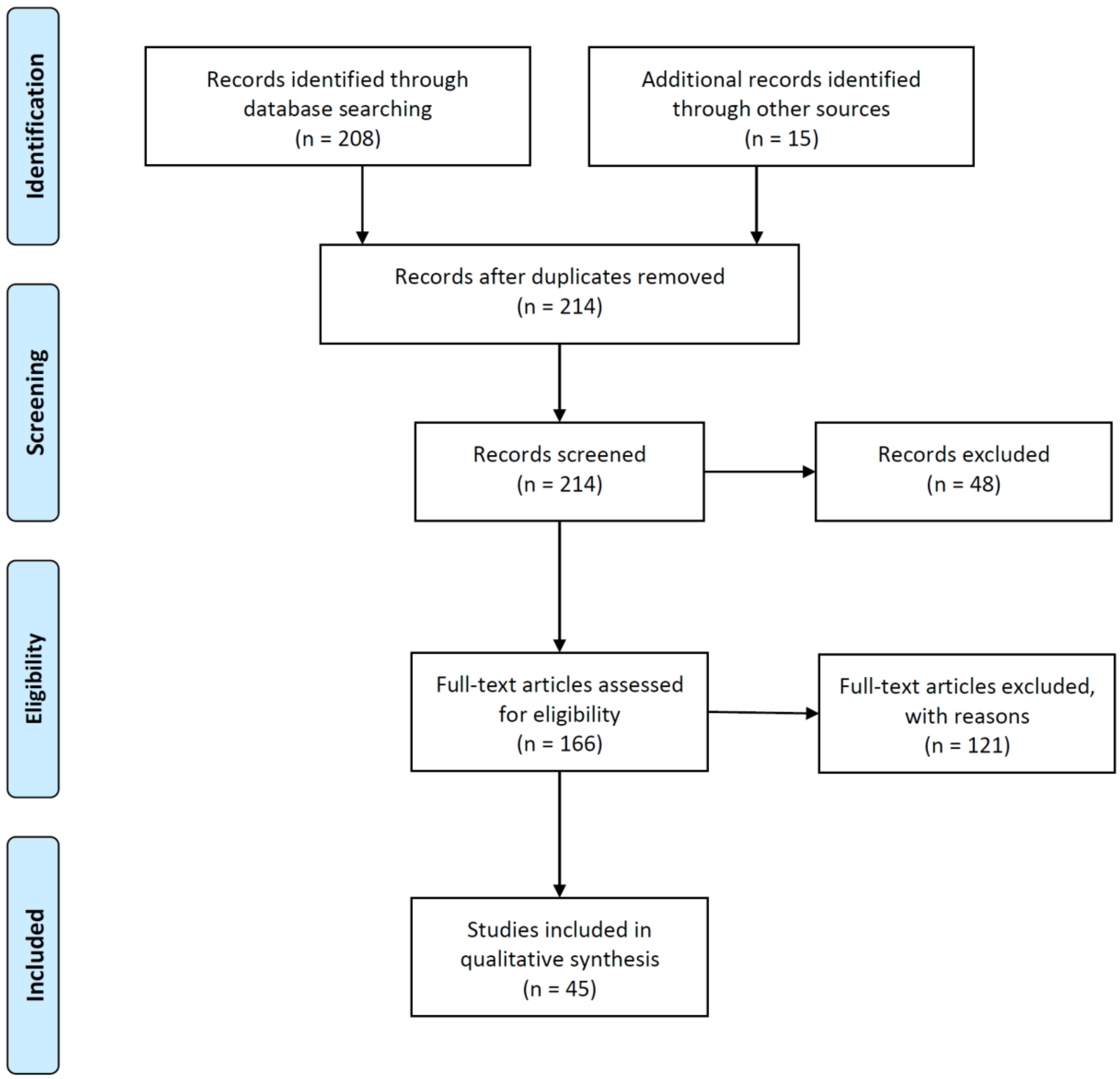
Next, records were screened by considering pre-defined inclusion/exclusion criteria. Criteria that were not available as a filter were screened through a review of the abstracts. Eligibility criteria are listed in Table 1. Articles were excluded that focused on education around one particular health topic, focused on one particular type of graphic or data display (i.e., a map), were focused exclusively on either very young (<12 YO) or very old (>80 YO) populations in respect to understanding a health diagnosis, or were deemed to be generally irrelevant to the topic.

Table 1
Article Eligibility Criteria

Inclusion	Exclusion
Article is written in English.	Article is written in a non-English language without translation.
Article is part of the peer reviewed literature.	Article is written for a publication without a focus on dissemination of knowledge.
Article is focused on data, graphical, or numerical literacy in broad relation to decision-making	Article is focused on one health topic, disease, or syndrome or does not include decision-making as part of the topic.
Article includes various types of health data displays or data displays in general.	Article includes only one type of health data display (e.g., map).
Article is focused on data displays in relation to decision-making.	Article does not include data displays as a primary source of information for decision-making.

After the primary search and screening of records, full text articles were assessed for eligibility (n=166). Following completion of an initial appraisal and overview of each article for quality of content, relevance of research design and relationship to the topic, a final selection was made for inclusion in the qualitative synthesis (n = 45). A PRISMA diagram illustrating a summary of the search is included as Figure 1.

Figure 1
PRISMA Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Evidence Summary. The evidence was organized into three domains that were integral to gaining supporting evidence for this project. The domains are:

- Decision-making and Dashboards
- Visualization Literacy
- Clinical Trials and Decision-making

A summary of the evidence using the Johns Hopkins Nursing Evidence-Based Practice tool is shown here:

Table 2
Evidence Levels

	Level I	Level II	Level III	Level IV	Level V
Decision Making and Dashboards	3	2	7	3	0
Visualization Literacy	4	3	1	4	0
Clinical Trials and Decision Making	2	3	3	5	4
Total	10	8	11	12	4

Decision-making and Dashboards. The basic premise behind the creation of data visualizations and dashboards is to support timely and efficient decision-making. It has been stated that *"*a rational decision-maker acting on better information should achieve a higher expected payoff*"* (Brynjoffsson, 2011, p. 5*).* Further, "improvements in technologies that collect or analyze data can reduce error in information" (Brynjoffsson, 2011, p. 6). An advantage of graphical visualizations are that the human brain is better at pattern recognition than it is at comprehending complex data and statistical models (Rasmussen and Vincente, 1989). Graphical displays and the complexity underlying their design and development have been discussed, including from the perspectives of divided attention, focused attention, and the relationship to problem-solving (Bennett and Flach, 1992).

The limits of human information processing were explored by Miller in 1956 in his publication in Psychological Review (Miller, 1956). In that publication, Miller describes the limitation of the unaided observer to process chunks of information and summarized that the human capacity is seven plus or minus two chunks for receiving, processing, and remembering (Miller, 1956). Subsequent additional research has been conducted including that by Cleeremans and Elman who surmised that optimal learning depended on reducing complexity in the information that more closely matched the human capacity for information processing (Cleeremans and Elman, 1993). Visual working memory and short-term memory limitations were described by Cowan (2001) and Luck and Vogel (1997). Additional research on the topic of cognitive capacity investigating the human limitation to process graphically displayed statistical interactions concluded that a structure defined on four variables is the limit of human processing capacity (Halford et al., 2005). Halford and colleagues found that any variable is impacted by the effect of other variables and that all of these must be formed into a single complex concept and in fact, anything beyond two variables creates a high processing load (Halford et al., 2005, P. 70).

In addition to the limits of human information processing capacity, consideration must be given to following good design principles of visualizations when creating dashboards. Experts in the field of information visualization describe the appropriate use of pre-attentive attributes in data display design including form, position, and color (Few, 2006; Tufte, 2001). If information visualization is the use of computer-supported interactive visual representations of abstract data to amplify cognition, six proposed ways that visualizations can amplify cognition include (Card, Mackinlay and Schneiderman, 1999, p.3):

1. Increasing the memory and processing resources available to the users.
2. Reducing the search for information.
3. Using visual representations to enhance the detection of patterns.
4. Enabling perceptual inference operations.
5. Using perceptual attention mechanisms for monitoring.
6. Encoding information in a manipulable medium.

While user-centered design principles can enhance the successful outcome of a dashboard implementation, understanding the multi-dimensional aspect of health information technology (HIT) is important in planning for successful outcomes. Conceptual models exist that describe the aspects of HIT and its adoption in complex systems such as Sittig and Singh's socio-technical model (Sittig & Singh, 2015). The socio-technical model has 8 dimensions that address the people, process, and technology-related concepts specific to the design, development, and implementation of HIT. The complexities of designing and building a dashboard to support clinical trial management lend themselves to such a model which is focused on complex adaptive systems. When considering the socio-technical model, user-centered design principles involving iterative processes focused on the user and their needs have the potential as a tool that supports the higher-level conceptual model.

Each technology must support users in the capture of relevant data points. Combining all the data housed within these systems is essential to the provision of information visualizations. However, that process amplifies the complexity and risk related to data quality and timeliness. Effective data visualizations that are both useful and usable could benefit from consideration of the principles of the socio-technical model to enable design success. The inclusion of the principles from the socio-technical model related to people, process, and technology can facilitate effective outcomes in the implementation of a clinical trial management dashboard.

While success has been demonstrated from a technical perspective in the ability to integrate data and visualize it in real-time using existing technologies and applications, limitations have been cited in those studies that strictly focused on building and launching the technology and that did not fully take advantage of employing theories and concepts that focused on outcomes from a user perspective (Concannon, Herbst and Manley, 2019; Toddenroth et al., 2016). Differences in user perspectives, data literacy skillset deficiencies within user groups, and confusion across user groups regarding the purpose of the dashboard were cited as potential reasons for the resultant critical user feedback and adoption of a dashboard designed to assist with insight and decision-making across public health research initiatives (Concannon, Herbst and Manley, 2019). The authors implied that the framework used to build the dashboard would be scalable across the larger enterprise but did not test the framework in that context or compare it to existing methods of data review (Concannon, Herbst and Manley, 2019).

Performing a cognitive work analysis in conjunction with the development of a data visualization could assist with the design of a data display created using a visualization tool (Effken et al., 2011). Cognitive work analysis has previously been studied to fit decision support tools, such as a health data display or dashboard, into a nurse's workflow (Effken et al., 2011). Cognitive work analysis specifies examination at five levels of the system including work domain, what decision-making procedures exist, how decision-making strategies are used, the social organization and collaboration, and worker skill level (Effken et al., 2011). The work domain analysis performed in the referenced article summarizing the use of a dashboard to enhance decision-making in a nurse's workflow highlighted the multiple competing priorities and constraints experienced by nurses as they struggle to improve quality and safety outcomes (Effken et al., 2011). The amount of data in an electronic format that nurses are exposed to supports the usefulness of dashboards as well as the need for further work on decision support tools that incorporate the data provided in the dashboards (Effken et al., 2011).

Research has shown that the adoption of digital technologies in healthcare could improve processes and outcomes (Laurenza et al., 2018). In addition, evidence exists in the literature defining constants that are related to technology adoption in healthcare including proper use and maintenance of the Information technology (IT) budget, the role of leadership, proper project management, a defined implementation process, and the significance of end-user involvement (Bernstein et al., 2007). Assessing performance using dashboards has demonstrated an increase in user productivity (Velcu-Laitinen and Yigitbasioglu, 2012).

A systemic review article looking across a range of projects focused on displays of patient information in critical care settings found only weak evidence suggesting information displays improve provider efficiency and process outcomes (Waller et al., 2018). The authors examined randomized controlled trials of physiologic and laboratory monitoring displays and found that they did not show improvement in outcomes despite previously showing positive results in simulated settings (Waller et al., 2018). The review concluded that important research translation gaps from laboratory to actual setting likely exist (Waller et al., 2018). Further, the authors found that the research design in existing publications of studies on the effectiveness of dashboards may in some cases be deficient as many did not include control groups, did not integrate data from multiple sources, and had no statistical analysis of the data, were not evaluated in a live setting, and did not have an experimental design or had a quasi-experimental design (Waller et al., 2018).

Another well-designed systematic review evaluating visual analytics for health informatics applications focused on characterizing the variety of evaluation methods and identifying best practices (Wu et al., 2018). Following PRISMA guidelines, a PICOS framework (Participants, Interventions, Comparators, Outcomes, and Study Design) was employed resulting in 76 study publications reviewed to characterize the variety of evaluation methods used within the health informatics community and to identify best practices (Wu et al., 2018). The review concluded that evaluation approaches are varied and that new studies should adopt commonly reported metrics, context-appropriate study designs and phased evaluation strategies (Wu et al., 2018). Moreover, opportunities exist for expanding evaluation practices and innovation concerning evaluation methods across health settings (Wu et al., 2018). A point of interest was a limitation discussed in the context of the review that was related to the reviewers' disagreement on inclusion criteria for 3 major points: the definition of a visualization system, the degree to which a system had to be implemented, and the extent of evaluation (Wu et al., 2018). A key opportunity cited by the authors is the lack of integration in efforts directed toward describing, contextualizing, and comparing evaluations between the fields of biomedical informatics and information visualization or visual analytics (Wu et al., 2018).

Visualization Literacy and Dashboards. The Committee on Health Literacy for the Council on Scientific Affairs of the American Medical Association (AMA) (American Medical Association, 1999) defines literacy as "an individual's ability to read, write and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential" (p.552). The Council's purpose in evaluating literacy in the United States was to assess the impact on patient health outcomes based on the patient's ability to function adequately in a healthcare setting (American Medical Association, 1999).

Related to the AMA definition and common in the literature is the term "health literacy" which is defined by Ratzan and Parker (2000) as " the capacity to obtain, process, and use basic health information" (as cited in Kindig, Panzer, and Neilsen-Bohlman, 2004) to make important and relevant decisions about one's health. Health literacy has been studied, particularly with chronic disease management and improved patient care and outcomes (Cavanaugh et al., 2009; Schillinger et al., 2002; Wallace et al., 2009).

Another descriptive term used to define a literacy skill set and sometimes used as an alternative to graphical literacy is the term "visualization literacy". Experts vary only slightly in their definition of visualization literacy from “the ability to use well-established data visualizations to handle information in an effective, efficient and confident manner”(Boy et al., 2014, p.3) to “*the ability to make meaning from and interpret patterns, trends, and correlations in visual representations of data*” (Borner et al., 2015, p. 1857). Visualization literacy has also been defined as “the ability and skill to read and interpret visually represented data in and to extract information from data visualizations” (Lee et al., 2016, p. 552).

Describing and connecting the multiple facets of data literacy to decision-making is included in the body of evidence explored for this project. While patient health literacy may significantly impact treatment effectiveness, the ability for workers in the healthcare industry to analyze, interpret and communicate with health data underscores decision-making related to both health and business outcomes (Stadler, et al., 2016; Caban & Gotz, 2015; Shaw et al., 2015). For example, in the clinical trial domain, the diversity of participants is an important topic. Decision-making related to participating in a clinical trial has been studied in a group with equal gender and racial diversity suggesting a relationship to trust, eHealth literacy, and information-seeking behaviors with a conclusion that focus on the development of information literacy could improve diversity in trials through supporting informed decision-making (Strekalova, 2018).

Numeracy and decision-making are discussed frequently in the literature. In two review articles, conclusions support a relationship between high numeracy and decision-making in health professionals although both review articles expressed methodological challenges and the need for more research to better understand the contributions of patients’ and clinicians’ literacy in making treatment decisions (Malloy-Weir et al., 2016.; Malloy-Weir et al., 2015). In other work, a review article examining 36 publications that included 27,885 participants from 60 countries to connect graph literacy to decision-making and health outcomes, findings were summarized as static visual aids are helpful for those with at least a minimum level of visualization literacy and visual aids that promote risk understanding also improve decision-making (Garcia-Retamero & Cokely, 2017).

Recent research continues to support a strong connection between numeracy and graphical literacy and decision-making among healthcare workers (Lopez et al., 2016). Lopez and colleagues (2016) evaluated 60 practicing nurses using a validated test methodology to determine the level of numeracy and graph literacy in the sample population (Lopez et al., 2016). Results demonstrated a deficiency in both numeracy and graph literacy as well as an association between the two with age having a negative relationship with graph literacy but not numeracy (Lopez et al., 2016). No other significant relationships existed between the other demographics and test results. The implication is that there exists a potential risk in patient treatment and outcomes related to decision-making involving important care decisions such as medication administration which is further supported by research summarized by McMullan and colleagues (McMullen et al., 2009).

Dowding and colleagues (2017) repeated a similar experiment in their research with the same outcomes. Previous work by these same researchers explored dashboard use in healthcare settings and the tool's association with improved care processes and outcomes (Dowding et al., 2015). While the evidence showed that dashboards may increase access to information for decision-making, it was left unclear what aspects were related to outcomes with the subsequent exploration by the researcher of numeracy and graph literacy in the same population (Dowding et al., 2017).

Alternative methods beyond training to address deficiencies in numeracy and graphical literacy would be to consider the creation of displays that facilitate understanding of the information. Research evidence supports that participants largely prefer traditional table displays, however, accuracy in interpretation was most facilitated by icon displays, which none of the participants preferred (Elting et al., 1999). Investigation of the choice of display in understanding information was presented by McCaffery and colleagues (2012) who demonstrated that adults with low literacy best-interpreted pictographs when the numerator was small and bar charts for larger numerators (McCaffery et al., 2012). Further, Okan and colleagues (2016) used eye-tracking software to determine that low graph literacy individuals more often relied on misleading bar graphs and misinterpreted that data while higher graph literacy individuals spent more time viewing the features essential for information (Okan et al., 2016). Implications to the customization of decision support systems are discussed and include theory, methods, and prescriptive design (Okan et al., 2016).

Choosing the right roles within a team or organization to assess decision-making capabilities when supported by data visualizations is important. Tying a tool to an established process is highly dependent on leadership demonstrating their ability to use the information themselves (DeMets, D. and Califf, R., 2011). If it is perceived as a key competency necessary for ascending the ranks of leadership then it could be very motivational in a clinical trial organization. When evaluating competency, expectations around an assessment participant's ability to spend time away from their role are key in selecting the right instrument for evaluation. Appropriate choices for assessing competency related to numeracy and graphical or visualization literacy in a healthcare setting are the Numeracy Understanding in Medicine Instrument (NUMI) (Schapira et al., 2012) and the Visualization Literacy Assessment Test (VLAT) (Lee et al.,2016). An alternative to the NUMI is the Subjective Numeracy Scale (SNS) described in a comparative assessment by Faegerlin and colleagues (Faegerlin et al., 2007). Faegerlin and colleagues compared the NUMI and the SNS and determined that the SNS could address previous significant challenges with the NUMI including low completion rates, receptiveness to taking an aptitude test, and conducting the test remotely where participants could use calculators or ask others to help them solve the problem presented (Faegerlin et al., 2007).

The VLAT is an assessment that includes 12 visualizations covering a multitude of graph types with a total of 61 questions in its original version (Lee et al., 2016). The test was created for non-data experts and is timed out at 25 minutes with the idea that there should be enough time to decide based on the information offered, but not too much time that alternative methods for arriving at the correct answer could be employed. Lee and colleagues (2016) explain that the VLAT provides for a more granular understanding of user abilities and follows previous studies in the field of graph comprehension that assesses visualization literacy at three levels (Bertin, 2010; Carswell, 1992; Wainer, 1992; Curcio, 1987 as cited in Lee et al., 2016). Lee and colleagues (2016) describe the three levels with the first level as the most basic and designed to determine if a graph reader can read a specific value in a graph, and the second level designed to determine if a graph reader can read relationships or trends in a graph and the third level, the most advanced, is intended to determine if a graph reader could read beyond the graph and for example, predict a future trend based on the graph information (p. 552). The

VLAT also provides targeted training interventions by providing the ability to narrow down the specific graphics that are causing the most challenges to users.

In summary, evidence in the scientific body of knowledge demonstrates that there is a multitude of complexity involved in the design, development, and launch of effective visual data displays. While the literature includes ample evidence that a visualization literacy challenge exists, the next question to consider is how important is that challenge in improving outcomes in healthcare and operations? In the information age, visualization literacy has become a more important skill set (Borner, Bueckle, and Ginda, 2019). As technology has enabled the creation of interactive dashboards and information displays designed to assist patients with managing their health needs, the successful use of dashboards as a tool for health decision-making demonstrates results that show a dependency on higher numeracy and graphical literacy skills (Nayak et al, 2016). Having detailed information on user skills and abilities could potentially inform organizations about what type of displays are most effective in the delivery of information for decision-making as well as what type of targeted training solutions could best improve user abilities when incorporating information displays into decision-making.

Clinical Trials and Decision-making. The goal of improved decision-making in clinical trials is related to a reduction in inefficiencies within the trial environment and improvement in outcomes for both clients and patients (Farnum et al, 2019; Sertkaya et al; 2016 & Yang et al., 2018). Having access to the tools and information that support effective decision-making can influence improvements in trial efficiency with better outcomes leading to a reduction in the cost of pharmaceutical development which is currently estimated at a mean cost of $35M for prospective randomized controlled trials (Moore et al., 2018).

The success of clinical trial execution is based on proficiency in activating the right sites promptly, recruiting the right patients in a timely manner, and delivery of clean and error-free results to the regulatory authorities (Fogel, 2018). Assuming that data access is available and engineered appropriately, dashboards could help support decision processes in each of these three areas. Like healthcare in general, clinical trials have been shifting towards increasingly patient-centric designs which means the incorporation of multiple devices designed to capture data remotely at various time points during the study (Bhavnani, Narula, and Sengupta, 2016).

In conjunction with the increased digitization of clinical trials, supporting evidence exists that information technology can be a significant driver of productivity (Barua et al. 1995, Brynjolfsson and Hitt 1996; Bresnahan et al. 2002; see Kohli and Devaraj 2003 for review, Jorgenson and Stiroh 2000; Melville et al., 2007; Oliner and Sichel 2000; Jorgenson and Stiroh, 1999). If organized appropriately and with consideration of user abilities, large amounts of processed data can enhance decision-making and create a competitive advantage for an organization in the clinical trial space.

Current processes in many organizations involve the downloading of multiple reports from relational databases that are then dependent on team members having the time and ability to process them into meaningful information (AlTarawneh and Thorne, 2017). In a recent report from McKinsey and Company (Balz et al., 2021) on anticipated trends for the future of the pharma industry, agile ways of working due to a dramatic acceleration of activities and decisions were listed as the number 1 trend, and digital and analytics capabilities were cited as having the most perceived value in executing on the strategy (Balz et al., 2021). Described in the report is one pharma company that used advanced analytics and data to improve their decision-making related to quality management by more than 65% (Balz et al., 2021).

Previous and current site performance across trials is important in deciding whether to invite a site to participate in a clinical trial. Site performance can be defined as a composite of information that includes turn-around times for contracts and budgets, regulatory approval timelines, speedy patient recruitment, quality of data collection, and timeliness of data entry. Evidence exists showing it is possible to aggregate different performance metrics to assist with site evaluation and selection (Yang et al., 2018). Data visualizations can provide evidence of site performance over time which could support decision-making involving site choice for trial participation including contract and regulatory approval turnaround times broken down through workflow analysis of where information is at any one time and data entry lag times to evaluate site efficiency in entering important trial data on time (Goyal et al., 2021).

While there are multiple cost drivers to clinical trial execution patient recruitment is sometimes the most challenging as it depends on the early identification of patient populations and cooperation from the sites employed to conduct the research. Sertkaya and colleagues (2016) aggregated data from multiple databases and evaluated per-study costs (Sertkaya et al., 2016). Three top costs for clinical trial execution were determined with the top costs being associated with clinical procedures including patient recruitment and enrollment (Sertkaya et al., 2016).

Workflow support and facilitation as evidence for the need for dashboard implementation have been described in a study focusing on visualizing data captured during processes that involve electronic data capture (EDC) in a clinical trial setting (Toddenroth et al., 2016). Although the intent of the implementation described in the study was to support workflow, the technical aspects of collecting, aggregating, and visualizing the data from an EDC system were the focus of the study (Toddenroth et al., 2016). The study was performed at one site with a small number (n=4) of potential users and found that while the data could be captured and transformed into a dashboard visualization, user acceptance may not have been optimal based on the feedback captured (Toddenroth et al., 2016). Concerns raised by the potential users included timeliness of the data, the introduction of an additional application into their workflow, the need to continue accessing other systems to complete the picture, and the potential for un-blinding (Toddenroth et al., 2016). The potential users also included the fact that they often relied on intuition or other knowledge when processing information (Toddenroth et al., 2016). The authors cited the information captured from user feedback as limitations to their study and recommended further research using both a larger sample size and following a scientific methodology to generate additional information about the outcomes and adoption of a dashboard (Toddenroth et al., 2016).

While gaps exist in information specific to clinical trial decision-making in the literature, the body of evidence examining data literacy and decision-making in healthcare is robust and includes assessments of both numeracy and graphical literacy in practitioners and patients (Dowding et al., 2017; Eley et al., 2014; Goodman et al., 2013; Lipkus et al., 2001; Ludewig et al., 2020 and McCaffery et al., 2012). Results consistently illustrate an impact on outcomes related to low numeracy and/or graphical literacy including medication errors, surgical errors, and poor health decision-making (Eley et al., 2014; Lopez et al., 2016; and Okan et al., 2016). In addition, operational dashboards developed to improve quality suggest that while dashboards can improve decision-making related to quality outcomes, a risk still exists around end-user capabilities to interpret the data visualizations (Egan, 2006 and Weiner et al., 2015).

Understanding that visualization literacy could hinder decision-making in a clinical trial setting is an important first step toward determining if such a problem exists. With multiple methods available for assessing visualization literacy, an organization in the health care space needs to choose assessments that lend themselves to the healthcare domain (Faegerlin et al., 2007). It is also important to differentiate between the two closely related concepts of numeracy and visualization literacy to ensure that the problem is well defined, and deficiencies are addressed most appropriately.

Section 3: Methodology (Setting and Project Design)

Setting

The setting for this project is a mid-sized, global, Contract Research Organization (CRO) that is focused on biotech clients seeking assistance with the strategy and conduct of their clinical drug trials. The organization currently has approximately 2000 employees in Clinical Development Services. A subset of that group is project leaders who are responsible for the conduct of the study and the final deliverable.

A CRO exists to provide a service to their pharma and biotech clients. That service is the professional execution and delivery of a clinical drug or device trial. While each phase of clinical drug development grows in size and complexity, the service is performed the same and includes three main components that define a CRO's expertise:

1. The first component is the clinical trial site which consists of the venue for patient visits and procedure completion. Typically, the site is a healthcare provider's office where a research team performs the protocol-specified procedures. A CRO's goal is to engage the most experienced and high-performing sites and have the sites ready and approved by the client and regulatory authorities to conduct the trial as quickly as possible. The management of the site is also important and includes a review of several metrics focused on counts and cycle times as well as process monitoring.
2. The second goal involves the expeditious recruitment of the right patients into the clinical trial. Often the site is relied upon to select and enroll eligible subjects into the trial. The patient data collected by the site or using mobile devices is critical to safety and efficacy monitoring during the trial.

3. The last component is the delivery of high-quality data that supports the client's application to the regulatory authorities demonstrating the safety and efficacy of their product. The data must not only be correct but also verified and of the highest quality to best support a client's successful new drug application.

Each goal involves a complex process that generates both patient and performance data that must be managed and monitored closely following the regulatory requirements that specify the conduct of the trial. The clinical trial team must have frequent and regular insight into all relevant data to complete the project successfully on behalf of their client and deliver the trial within the time, cost, and quality standards defined in the contractual agreement. Unexpected changes to the time, cost, or quality of a project must be identified as quickly as possible and proactively managed by the trial team.

A project team within a CRO consists of several team leaders representing different functions and lead by a Project Manager. The Project Manager along with the Medical Monitor bears a large amount of decision-making responsibility about study progress, patient safety, and the drug monitoring processes.

The data display created as the IT solution for this project was specifically designed to be incorporated into the daily workflow of a clinical trial management team for decision support and includes real-time data displays of critical study points that ideally support decision-making individually and in team meetings. The data display was intended to replace spreadsheet use for data capture and manipulation. In addition, the IT solution replaced conventional Power Point® presentations as the visual display that accompanies the project leader's presentation to senior leadership teams on a regularly scheduled basis. The IT solution was mandated for use in regular workflows including project stage gate reviews and operational leadership reviews. While the use of the IT solution in progress and update meetings has dramatically increased adoption as verified by user metrics, the most effective use of the IT solution still may have challenges due to decision-makers overlooking potentially significant information supplied by the solution. It is important to evaluate whether key decision-makers possess the ability and skill set to exploit the full potential of the information display or may be hindered by misunderstanding or misinterpretation of the data displays.

Project Design

The target participants for the project were all Project Managers and all Medical Monitors within the organization (n = ~250). Participation was voluntary and anonymous and was supported by the organization's senior leadership who support project outcomes being used to assist with the improvement of IT tools and targeted training solutions that follow organizational business objectives. The participants were selected in collaboration with the Senior Vice President of Clinical Development Services who is tasked with oversight of both participant groups within the organization. An initial invitation to participate in the project included detailed information on the project purpose, data collection procedures, assurance of anonymity, and expectations around the use of the information collected for the project.

The project design and instruments included in the project planning were submitted to the University of Texas Health Institutional Review Board (IRB) for approval and were approved as a quality improvement project. The organization where the assessments were planned to occur does not have an IRB. The project was discussed with the organization's Data Protection and Privacy Officer and the Chief Human Resource Officer (CHRO) with no objections raised regarding the project design or execution. After delivery of the project IT solution (project information dashboard) was complete, the question intended to be answered was "Does visualization literacy impact the ability to make decisions when using information visualizations in a clinical trial setting?"

Several frameworks were part of this project. Initially, frameworks such as the Technology Acceptance Model (TAM) (Davis, 1989) and the Socio-Technical Model (Sittig and Singh, 2015) were included during the development and deployment of the IT solution as the importance of considering the various dimensions of the impact of technology on users and organizations as well as the usefulness and usability of a tool being critically important to adoption and success. Specifically for the evaluation phase of the project, several testing frameworks were used. The Subjective Numeracy Scale (SNS) (Faegerlin et al., 2007) is a self-assessment of numerical aptitude and preference for numbers (Appendix E). The test has been compared with objective numeracy tools and validated for that purpose (Faegerlin et al., 2007). The SNS was selected as it offers both an evaluation of numeracy and an additional parameter for consideration which is the user's perception of their abilities.

The second testing framework is the Visualization Literacy Assessment Test (VLAT) (Lee et al., 2016). The Visualization Literacy Assessment Test (VLAT) was developed by a team of researchers interested in testing ordinary users' visualization literacy, especially non-expert users in data visualization (Lee et al., 2016). The authors followed a systematic procedure and described in detail the intended audience, the procedure to construct a test, and the validation of the test. The assessment includes 12 visualizations covering a multitude of graph types with a total of 61 associated questions (Appendix D). For each item in the original research a content validity ratio, item difficulty index, and item discrimination index were calculated. Consideration of the original research parameters around item difficulty could provide a way to gain more granular information on the specifics of the sample being administered the test and translate later into targeted learning solutions.

The second part of the data collection was a decision-making comparison that was planned to employ a common, workflow associated scenario-based assessment supported by the IT solution for this project (Appendix F). As previously noted, the deployed information visualizations were incorporated into the participant's daily workflow and decision responsibilities during the execution of a clinical trial which made both the scenario and the visualizations familiar to participants. The decision-making framework was intended to be utilized to assess participant's decision-making abilities based on data display synthesis as represented in the IT solution and deployed into their regular workflow.

All assessments were programmed using the Qualtrics® application. Qualtrics® is an application in use within the organization mainly for surveys and the collection of data and information from clinical trial partners. The Qualtrics application was selected due to internal familiarity, its ability to be programmed to test specifications and the ability to ensure the anonymity of the participant's responses. The tool also provides information on participant progress which enabled targeted reminders to be sent out at appropriate intervals. Participants were given 6 weeks to complete the assessments which were designed to be completed in less than one hour. The time associated with participation was critical to participant engagement as any significant disruption in work hours would dramatically reduce enthusiasm for participation and support within the organization. Each assessment was timed based on validation specifications from the literature. However, the participants could complete one assessment and assuming they did not start the next, could close the assessment and return later to continue. The timing for the test was set up in this way to further accommodate regular work schedules and to give participants flexibility in the amount of information they wanted to review in one sitting. The assessments were designed so that the participant first arrived at a detailed instruction page which outlined the associated time limit and set expectations for completion. The timing did not start until the first question was launched. The assessments were programmed to be timed following the description in the literature where non-data experts were given enough time to answer a question but not too much time, which equated to approximately 30 seconds per question. The framework fits well into a clinical trial setting where decisions must be both timely and accurate to be most effective.

The decision-making assessment that followed the SNS and VLAT incorporated static visualizations from the IT solution into the Qualtrics tool. The rationale for static visualizations, in place of the actual use of the dynamic information solution during testing, was to remove bias due to functionality concerns or user error during the assessment and to ensure standardization in what was presented to all participants. The decision-making assessment used the same rationale for timing as described in the VLAT.

Metrics

The purpose of the project was to determine if a relationship existed between visualization literacy and decision-making using data displays. All data was intended to be analyzed in aggregate with some parsing by demographic groupings. The data was exported from Qualtrics® and imported into SAS JMP® version 16.2 for analysis. Summary statistics of participant's characteristics were calculated. Means and standard deviations were calculated for continuous numeric data. Frequencies and percentages were used for categorical data. Additional statistical tests included were Chi-square, Fisher's Exact Test, One-way analysis of variance (ANOVA), a general linear model, and a logistic regression model.

A general linear model (GLM) was selected to assess the relationship between the VLAT and the decision-making score. The same approach was selected to assess the relationship between the mean SNS and the decision-making score. Descriptive statistics were used to summarize baseline participant characteristics (frequencies and percentages) and scores (means and standard deviations).

The validated assessment was planned to be scored as the number of correct answers with any questions not answered due to the test timing out scored as incorrect. The SNS was scored by taking the mean of the 8 standard questions where responses ranged from 1-6 where 1 = "not at all" and 6 = "extremely well". The decision-making assessment consisted of a description of a common scenario for the evaluation of passing a specified stage-gate. The criteria for passing the stage gate were clearly outlined and mimicked standard workflow in the organization. The assessment portion was composed of two sections with the first being an objective evaluation of a set of 15 commonly used and familiar information visualizations representing project parameters with multiple choice answers where only one answer was correct. The second section of the decision-making assessment was composed of two subjective questions requesting a decision to be made based on the previously analyzed information displays. The first question was a yes/no question related to deciding if the project passed the specified stage gate. The second question asked the participant to choose all that applied from the suggested next actions/decisions on the project. For the second subjective question, the responses considered best practices received the highest score per answer (5), the responses that might help improve the trial progress but were not considered optimal received a lower score (3), and the answers that would be considered an incorrect decision resulted in subtraction of a portion of the score (-5). The scoring for the decision-making assessment was weighted between the yes/no question and the constellation of choices for the second question where if both were correct 1 point was applied, if either of the two were correct then .6 point was applied, and if neither were answered correctly then -1 point was applied. The decision-making subjective questions were designed to mimic regular workflow and expectations for the role.

Inclusion and Exclusion

The inclusion and exclusion criteria for the project included all project managers and medical monitors employed by the organization during the testing period. The lowest level of project management, the Project Specialists, were excluded due to the expectations of the role not involving the use of data displays. Select members of the project management team were excluded at the request of the Senior Vice President of Clinical Development Services due to workload conflicts. In total, approximately 200 team members were solicited for participation in the project. Participation was voluntary and anonymous. The engagement survey results are not available by project participant exact match and were curated by the Human Resource department of the organization to include a composite of functions represented as the two groups included for participation (Project Management and Medical Management).

Methods Limitations and Shortcomings

Ideally, a more comprehensive and objective assessment of numeracy as well as the subjective model included would benefit the project design. However, due to organizational limitations around participant time involving workload and time availability to complete the assessments a decision was made to substitute the SNS as the primary determinant of numeracy amongst participants.

While the VLAT demonstrated high reliability when administered and as described in their paper (Lee et al, 2016), other papers have described alternative methodologies and frameworks for assessing participants (Boerner et al, 2019; Bueckle et al, 2022). The content of the VLAT was selected by examining three sources to determine which visualizations were most commonly in use and included K-12 curriculums, data visualization authoring tools, and news outlets (Lee et al, 2016). While it is likely that the selected visualizations would be familiar to the participant's group, the context of the questions associated with the graphics were not particular to healthcare which may have generated some anxiety among the participants due to the unfamiliarity of the topics and limited participant ability to answer the questions in the allotted amount of time.

The Qualtrics tool was designed primarily for surveys and not necessarily for timed assessments which added complexity from a programming perspective and required a link to be sent out to the participants which came from the Qualtrics tool. To address participant confusion, additional emails needed to be sent ahead of time so that the Qualtrics email would be recognizable, and participants would be expecting its arrival.

The timing of the assessment was programmed as a whole and not by an individual question which meant that participants would not be able to go back and change answers or review previous data. Programming in this manner, particularly for the decision-making assessment, required participants to remember their assessment of the data displays comprehensively as they progressed through the assessment to answer the decision questions at the end of the assessment. While this method closely resembles current practice in the organization, most of the time the full set of data is available in real-time and can be reviewed more than once.

The timing of the assessment was part of the validation of the instrument for visualization literacy and was intended as a component of participant ability. The intent was that participants would have enough time to answer the question, but not too much time where they could search for answers or get assistance. The same premise was used for the decision-making scenario where participants would be expected during a normal day to make decisions using data promptly to ensure study progress and follow regulations involving monitoring of patient safety. However, it was anticipated that not all participants would complete each assessment before the assessment timed out. The test timing out resulted in participant decreases as the assessment progressed leaving less of a sample size for evaluation of individual concepts offered later in the test. The validation of the test as presented by the authors did not consider offering displays in different orders which meant that all participants would take the test in the same order and potentially skew visualization test results offered later in the assessment. While it is easy to critique the choices of each assessment in a stand-alone format, it is more difficult to determine if the parameters set up for each one would still be correct when they are offered in conjunction with other assessments and as part of an assessment package such as was presented for this project.

The decision to use static data displays rather than the IT solution as the application was designed meant that some quality would be lost in resolution and color as the data display was imported into the Qualtrics tool. It also meant that some of the IT solution features such as zoom and filtering would be lost. While we were able to program in a feature that allowed data display enlargements, the features did not match the ability of the IT solution for the user to explore the data.

The use of the engagement survey as a surrogate for job satisfaction was necessary as asking the participants to complete a similar survey again was perceived to be both time-consuming and frustrating for participants. However, the formal engagement survey results are not available through an aggregate of specifically named individuals. In addition, due to current industry trends and job turnover, it could not be entirely guaranteed that the same participants who were involved in this project were the same employees who completed the engagement survey at the time it was offered. The result is that the engagement survey data does not exactly match the participants invited to participate in the project but is more a reflection of that job role in general within the organization.

Section 4: Results

The assessment was offered to 200 participants across the Project Management and Medical Management teams. A demographic questionnaire was part of the Qualtrics® survey and is included as Appendix H. A total of 129 participants accessed the assessment with 115 completing the assessment. The 115 participants completing the assessment included various levels of Project Managers (n=85) and Medical Management personnel (n=30).

Table 3

Participant Characteristics

Participant Characteristics							
Job Function		**N**	**% of Total**	**Time in Current Role**		**N**	**% of Total**
	Medical Monitoring	30	26.1%		<1 year	69	60.0%
	Project Management	85	73.9%		1-3 years	24	20.9%
	All	115	100.0%		4-6 years	11	9.6%
Job Title					7-10 years	4	3.5%
	APM	30	26.1%		More than 10 years	7	6.1%
	PM-Sr. PM	34	29.6%		All	115	100.0%
	APD-Sr. PD	21	18.3%	**Level of Education**			
	ED and Above	3	2.6%		Did not finish high school	1	0.9%
	CS-CS I	3	2.6%		High school diploma/GED	1	0.9%
	Med Dir I - Sr. Med Dir	16	13.9%		Some college/no degree	2	1.7%
	MMI- Sr. MM	8	7.0%		Associate degree	4	3.5%
	All	115	100.0%		Bachelor degree	33	28.7%
Region					Master degree	38	33.0%
	Asia Pacific	3	2.6%		Doctorate	9	7.8%
	Europe	28	24.3%		Professional degree (MD,DDS, JD)	27	23.5%
	North America	83	72.2%		All	115	100.0%
	Other	1	0.9%	**Post High School Included Data Education**			
	All	115	100.0%		Yes	38	33.0%
Years in Industry					No	69	60.0%
	<1 year	11	9.6%		Not applicable	8	7.0%
	1-5 years	27	23.5%			115	100.0%
	6-10 years	25	21.7%	**My Role Requires Data Interpretation**			
	11-15 years	7	6.1%		Yes	86	74.8%
	16 or more years	45	39.1%		No	18	15.7%
	All	115	100.0%		I'm not sure	11	9.6%
Time in Organization					All	115	100.0%
	<6 months	32	27.8%	**I Use Data Visualizations to Make Decisions**			
	6 months-1 year	20	24.3%		Always	3	2.6%
	1-3 years	23	17.4%		Regularly	44	38.3%
	4-6 years	28	20.0%		Sometimes	57	49.6%
	7-10 years	5	4.3%		Rarely	9	7.8%
	More than 10 years	7	6.1%		Never	2	1.7%
	All	115	100.0%		All	115	100.0%

The typical participant came from the project management team is in North America, has 1-10 years of experience in the drug development industry, has been in the organization for less than 6 months to 1 year, has been in their current role for approximately 1-3 years, and has earned a master's degree or above (see Table 3). The typical participant also did not have data courses included in their degree program. However, they were aware that their role required data interpretation and indicated that they regularly or sometimes used data for decision-making (see Table 3). The summary information from Table 3 is representative of the type of employees in the drug development industry. Most organizations in the drug development industry require a minimum education level of a bachelor's degree in a scientific discipline and advanced education criteria are highly respected similar to an academic or clinical environment in healthcare.

Primary Analysis. The SNS and VLAT scores were summarized by question (SNS) and data visualization (VLAT) and overall. The first section of the SNS focused on cognitive abilities and had a mean score for the section of 4.97 on a scale of 1 (not all at all good) to 6 (extremely good) (see Table 4). The second section of the SNS focused on a preference for display of numeric information and showed a mean score of 4.40 (see Table 4). Overall, the mean for the SNS was 4.60 (see Table 4).

Table 4
Subjective Numeracy Scale (SNS) Summary

	SD	Mean
Cognitive Abilities	0.83	4.97
Preference for Numbers	0.70	4.41
Overall	0.67	4.62

Table 4 demonstrates that most participants were confident in their numeracy abilities based on the mean score close to 5 out of a high of 6 and with little variation as shown by the standard deviation.

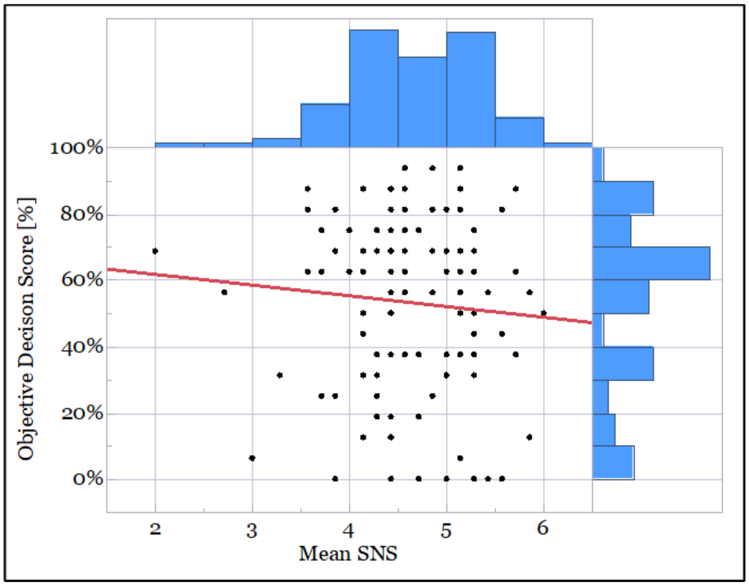
Table 5 summarizes the VLAT overall mean percent correct of 55.48% with a standard deviation of 22.4% showing some variation across the participants. The median was calculated as 59.02% as shown in Table 5.

Table 5
VLAT Score Summary

VLAT Percent Correct			
N	**Mean**	**Median**	**Std Dev**
115	55.48%	59.02%	22.40%

The comparison of the numeracy results (SNS) with the decision-making assessment showed no significance (p=.3766) (see Figure 2).

Figure 2
Subjective Numeracy Scale Compared to Objective Decision Score

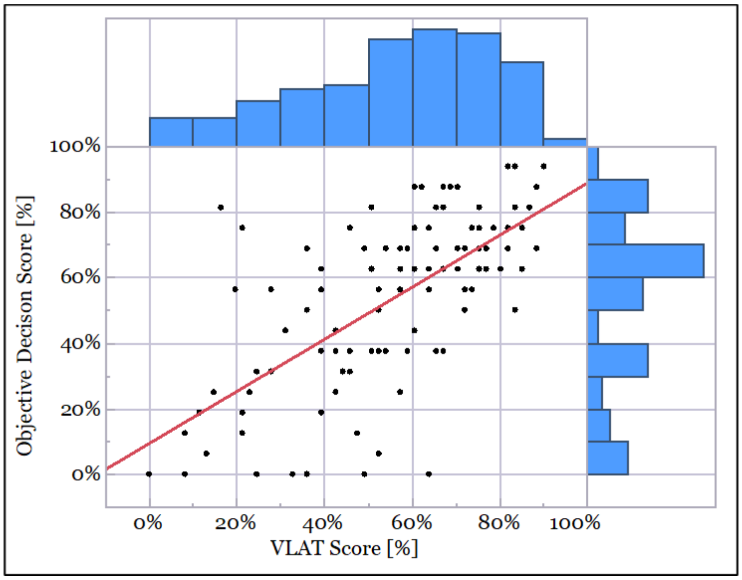


In Figure 2 the y-axis represents the percentage of correct answers on the objective portion of the decision-making assessment. The x-axis represents the mean SNS scores (1=not all – 6= always). The points represent the individual mean SNS and % correct on the decision-making portion. The histogram (blue bars) represents the score distribution and are the frequency of scores in that range by y and x axis (see Figure 2). The red line indicates the statistical slope when testing for the relationship between SNS and objective decision score (see Figure 2). In Figure 2 we see that the self-assessment scores were generally high and there were few if any scores where participants thought they were not good with numeracy. The decision-making scores were much more spread out across the scoring range with almost a flat slope lending to the insignificance of the relationship (see Figure 2).

The VLAT and objective decision-making comparison demonstrated a strong relationship ($p<.0001$) (see Figure 3).

Figure 3

VLAT Compared to Objective Decision Score

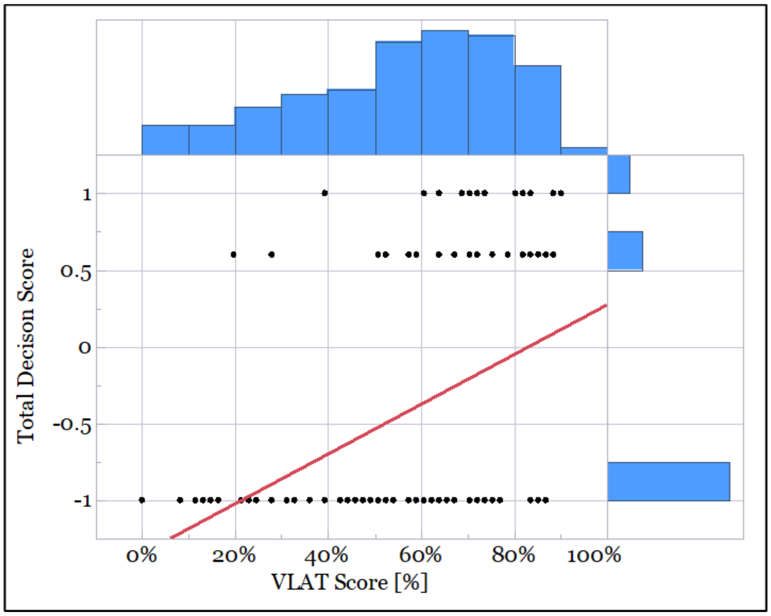


In Figure 3 the y-axis represents the percentage of correct answers on the objective portion of the decision-making assessment. The x-axis represents the VLAT percentage correct scores. The points represent the VLAT % correct and % correct on the decision-making portion. The histogram (blue bars) represents the score distribution and are the frequency of scores in that range by y and x axis. We can see that the VLAT score distribution is representative of a normal distribution although skewed to the right while the objective decision scoring demonstrates more variation (see Figure 3). The red line indicates the statistical slope when testing for the relationship between VLAT and the objective decision score and show that the better the participants did on the VLAT the better they did with their decision-making (see Figure 3).

The VLAT and subjective decision-making comparison also demonstrated a significant relationship (ANOVA, $p<0.0001$, Chi-square R^2=.46) (see Figure 4).

Figure 4

VLAT Compared to Subjective Decision Score

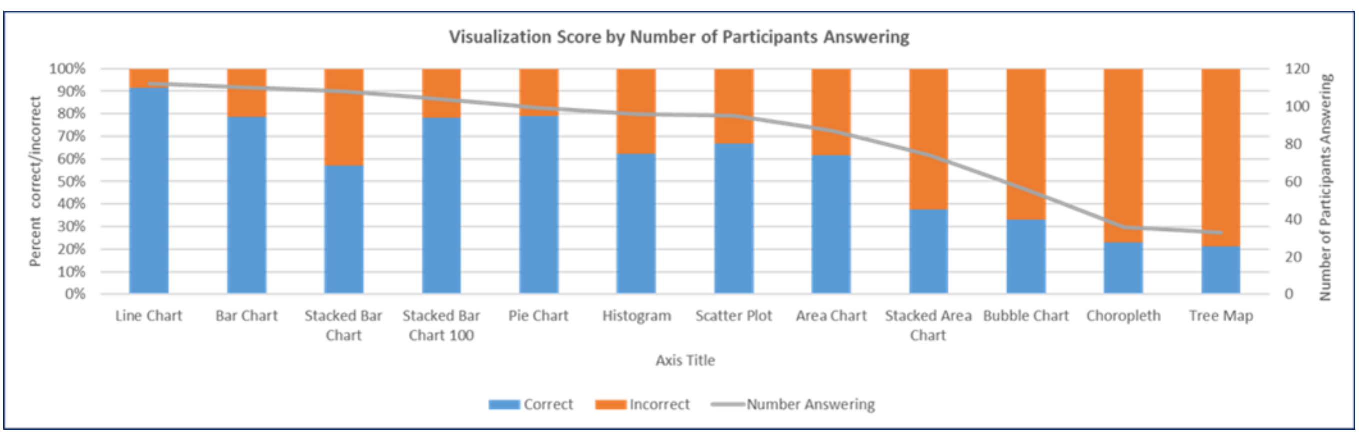


In Figure 4 the y-axis represents the scores on the subjective portion of the decision-making assessment. The x-axis represents the VLAT percentage correct scores. The points represent the individual VLAT % correct and % correct on the decision-making portion using the special scoring algorithm. The histogram (blue bars) represents the score distribution and are the total frequency of scores in that range by y and x axis. In Figure 4 we note the same VLAT result representation as Figure 3, however the subjective decision-making scoring clearly shows a higher percentage of incorrect decisions based on the scenario and scoring (1= both the yes/no and best practice questions were correct, .5 indicates one or the other portion of the decision-making scenario was correct, and -1 indicates none of the decision-making answers were correct) (see Figure 4). The red line indicates the statistical slope when testing for the relationship between VLAT and the total decision score and indicates that the better the participants did on the VLAT the better they did on the decision-making scenario (see Figure 4).

Secondary Analysis. We elected to further explore our data to see if additional information about the participants and their abilities to interpret data visualizations could be of interest in explaining the results. The VLAT was a non-proctored timed assessment and unanswered, skipped, missed, or questions answered as "I don't know" were counted as incorrect. The correct versus incorrect answers in the order that the visualizations were offered on the test are shown in Figure 5. The scores are overlayed by the number of participants answering each section. We noted that by the end of the test 29 participants of the 115 who started the test were able to answer all questions in the time allotted (see Figure 5).

Figure 5

VLAT Scoring by Number of Participants Answering Questions by Visualization Type



The variation in mean scores by individual data visualizations show that participants scored below a pre- determined threshold of 80% on several visualization types (see Figure 5).

When examining percent correct by chart and using the threshold of 80% correct, we see that the stacked bar chart, histogram, scatter plot, area chart, stacked area chart, bubble chart, choropleth, and tree map provided the biggest challenge for participants (see Figure 5).

An analysis of the scores of the subgroup of 29 participants who completed all questions of the VLAT was completed with the VLAT percent correct by mean, median and including the standard deviation (see Table 6). The mean score for the 29 participants completing all questions was 79.32% with a median of 78% and a standard deviation of 12.29%. Table 6 shows that the group of 29 participants scored higher in both the mean and median than the overall analysis and the standard deviation for this group also was smaller than the overall analysis (see Table 5).

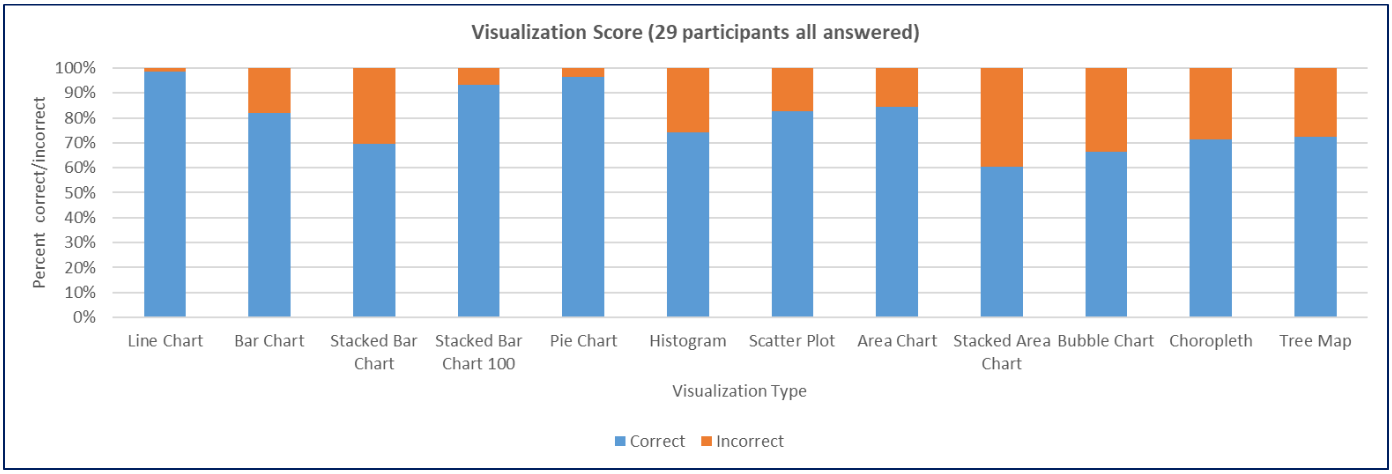
Table 6
VLAT Percent Correct for 29 Completers

VLAT Percent Correct			
N	**Mean**	**Median**	**Std Dev**
115	79.32%	78.00%	12.29%

In figure 6, we see that the visualization types that did not meet the pre-determined threshold of 80% in the group of 29 VLAT completers were the stacked bar chart, histogram, stacked area chart, bubble chart, choropleth and the tree map. All of the visualizations noted as challenging for the smaller group of 29 participants overlapped the all-participant group challenges (see Figure 5).

Figure 6

VLAT Score by Type of Chart for 29 Completers



We compared the all-participant group to the group of 29 participants who completed all VLAT questions to see what similarities and differences might exist using the information gathering questions at the beginning of the assessments (see Table 7). All categories were similar with slight variation in the time in organization metric, the time in current role metric, and the level of academic achievement (see Table 7). In summary, there was little difference that could be derived from the participant characteristics that might lead us to make assumptions about a difference in scoring.

Table 7

All Participant Characteristics Compared to 29 Completers

ALL PARTICIPANTS (n=115)	COMPLETED VLAT (n=29)
Project Management	Project management
APM-Sr. PM	APM-Sr. PM
North America	North America
1-10 Years in industry	1-10 Years in industry
< 6 month-1 year in organization	< 6 month-3 years in organization
< 1 -3 years in current role	< 1 year in role
Master's degree and above	Bachelor/Master's degree
Degree program DID NOT include data ed	Degree program DID NOT include data ed
Roles requires data interpretation	Role requires data interpretation
Regularly or sometimes use data visuals to make decisions	Regularly or sometimes use data visuals to make decisions

Each visualization had several questions of varying difficulty associated with it. The levels of difficulty were level 1 (low), level 2 (medium), level 3 (high). Item difficulty levels of our group of participants were consistent with those provided in the original VLAT validation paper (Lee et al, 2016) (see Figure 6) and were consistent in the group of 29 completers (see Figure 7). What Figure 6 and Figure 7 show are that as the questions become more difficult the percent of correct answers decreases. However, ratios of correct v. incorrect were different between the all-participants group (Chi-square $p<0.0001$) (see Figure 6) and the 29 participants (Chi-square $p<0.0001$) who completed the VLAT assessment (see Figure 7) which indicates that the 29 completers had a higher percent of correct answers across all levels of question difficulty.

Figure 6

Item Difficulty Ratio for All Participants

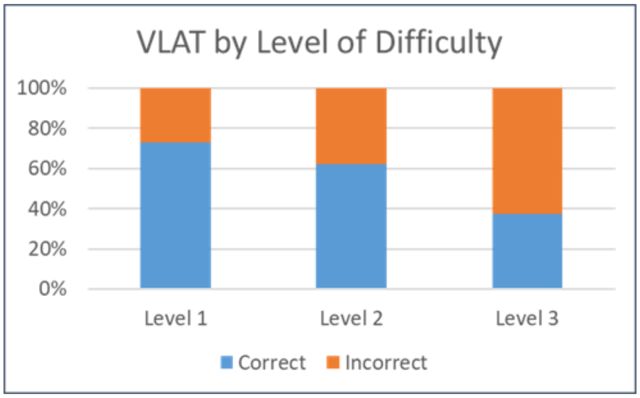
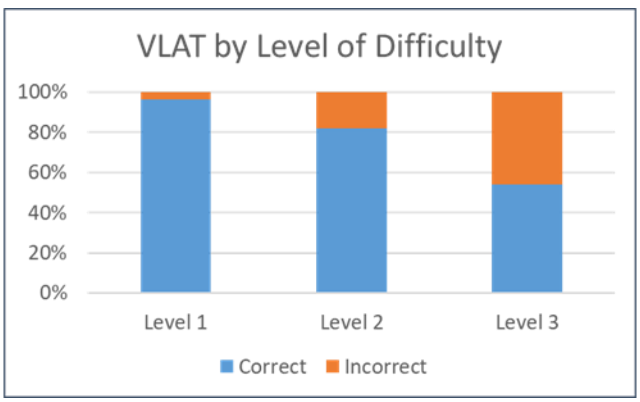


Figure 7

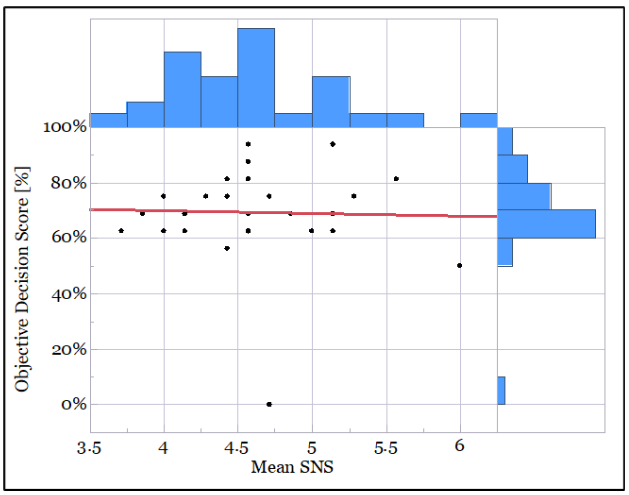
Item Difficulty Ratio for 29 Completers



Comparison of the numeracy results (SNS) with the decision-making assessment showed no significance for the 29 completers (p = .8708) (see Figure 8). The flat red line indicates little to no relationship between the two scores and while there is inconsistency in the scoring there is a tendency in this participant group for the scores to be higher on both the objective decision-making question and the SNS (see Figure 8). It is of note that the participant sample is considerably smaller in this group (n = 29) than the all-participant group (n = 115).

Figure 8

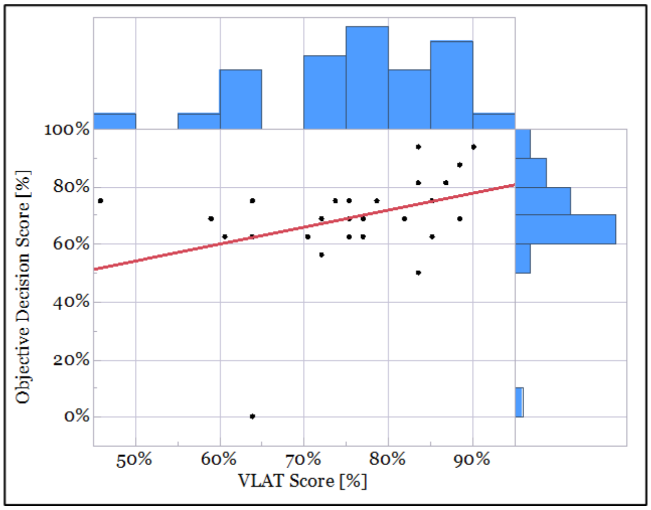
Subjective Numeracy Scale Compared to Objective Decision Score for 29 Completers



The VLAT and objective decision-making comparison showed a relationship for the 29 completers (ANOVA, p<0.0478, Chi-square R^2=.11) (see Figure 9), although the significance was higher for the "all participant" group (see Figure 3). In Figure 9, the slope of the red line shows that as the VLAT scores get higher decision-making ability improves although not as dramatically as in the all-participant group (see Figure 3).

Figure 9

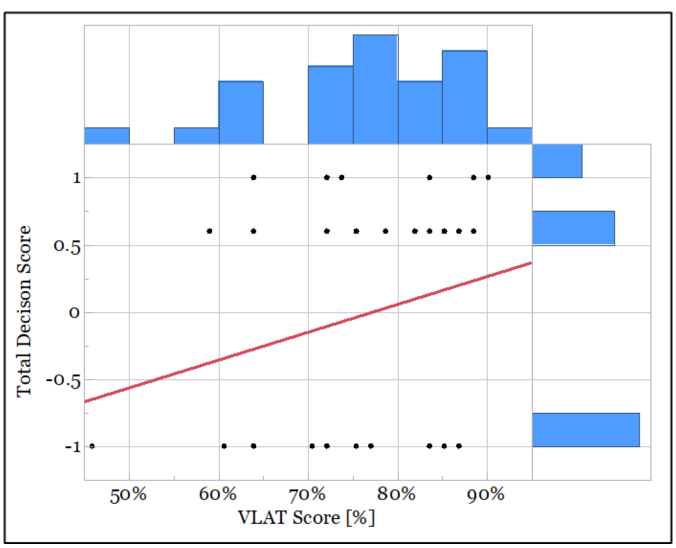
VLAT Score Compared to Objective Decision Score for 29 Participants



The VLAT and subjective decision-making comparison demonstrated an insignificant relationship for the 29 completers (p=0.2054) (see Figure 10). Although the VLAT score, as evidenced by the x-axis histogram was skewed to the right indicating generally higher scoring, the decision score still shows a majority of wrong answers versus correct or partially correct (see Figure 10).

Figure 10

VLAT Score Compared to Subjective Decision Score for 29 Completers



The organization had recently contracted with an outside entity to evaluate engagement through a professionally designed, administered and analyzed survey. The composite scores related to job satisfaction for the Project Management and Medical Management participants were examined as well as individual question scores on the survey to determine if key opportunities surfaced for improving job satisfaction that could be associated with skill sets and abilities related to regular workflow expectations.

The results from the organizational engagement survey completed in Summer of 2021 demonstrated overall favourable scores above 70% that were determined to be in alignment with expectations and generally viewed as positive on the advice of the consulting agency that administered and analyzed the survey (see Figure 11 and Figure 12).

Figure 11
Job Satisfaction Overall Score for Medical Management

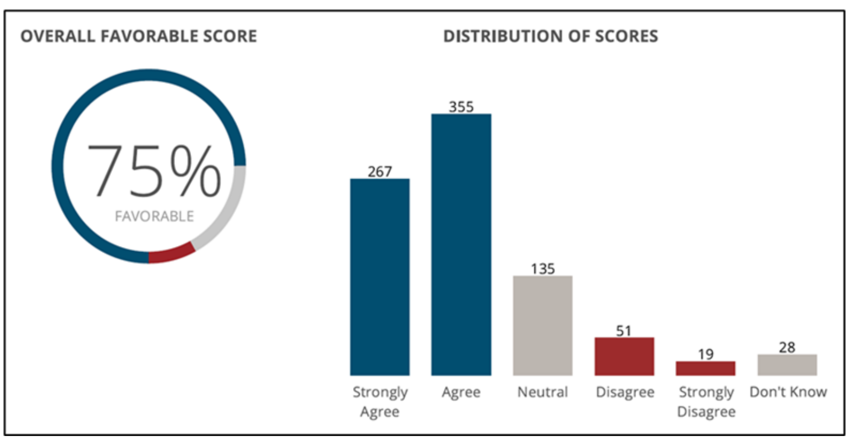
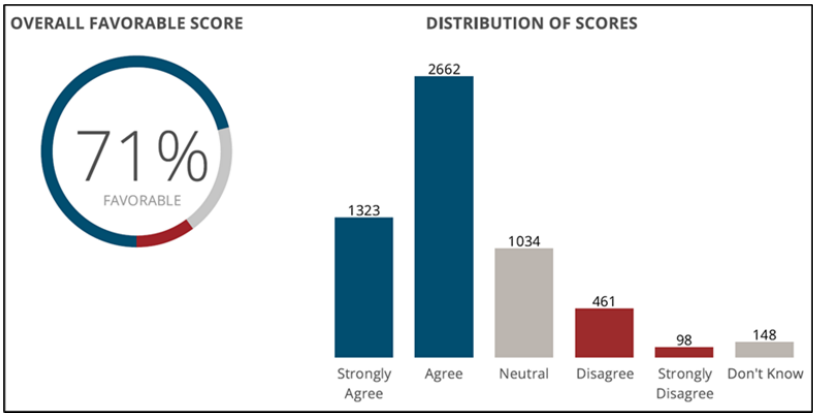


Figure 12

Job Satisfaction Overall Score for Project Management



Opportunities identified from the same engagement survey showed the top items with the highest unfavourable responses for both Project Management (see Table 8) and Medical Management (see Table 9). The items identified represent examples of questions asked within the survey (see Table 8 and Table 9). In general, it would be difficult to put too much emphasis on these results as they are somewhat inconclusive based on the scoring and it is not possible to match the project and engagement survey participants exactly.

Table 8

Opportunities- Project Management

ITEM	FAVORABLE	NEUTRAL	UNFAVORABLE
1. I have the tools and resources I need to do my job well.	61%	16%	23%
2. The amount of work I am expected to do is reasonable.	46%	23%	31%
3. The level of stress in my job is manageable.	49%	27%	24%
17. We work effectively across departments and functions.	53%	24%	23%

Table 9

Opportunities- Medical Management

ITEM	FAVORABLE	NEUTRAL	UNFAVORABLE
2. The amount of work I am expected to do is reasonable.	62%	12%	27%
19. I am satisfied with the opportunities for my own professional growth	52%	28%	20%
17. We work effectively across departments and functions.	68%	20%	12%

Section 5: Discussion

The general conclusions we were able to make based on our primary analysis were that the SNS does not predict decision-making ability in a clinical trial environment, the VLAT accounts for almost half of the decision-making ability in a clinical trial environment (R^2=.46), and using a forward step-wise model we were additionally able to see that time in current role and job title had a very small additive affect (R^2=.526) on decision-making ability. With this project, we have shown that a key decision maker's ability to interpret information necessary to the successful workflow and completion of a clinical trial is related in some part to their decision-making ability. Further, our project demonstrates that the level of education, experience, and functioning in a role where a clear expectation that data interpretation is necessary does not easily predict ability or decision-making success. Our findings are consistent with the body of evidence associated with health care in general where researchers continue to connect the multiple facets of data literacy to decision-making (Egan, 2006; Dowding et al., 2014; Wu et al, 2019).

While the literature includes ample evidence that a visualization literacy challenge may exist in clinicians, the question often asked is how important is that challenge in improving outcomes in healthcare and operations? Evidence shows that data-driven decision-making could impact operational performance (Weiner, Balijepally, Tanniru, 2015) and organizational productivity (Brynjolfsson, Hitt and Kim, 2011). In this project, we associate this evidence with the impact of the results of this project on the successful execution of a clinical trial regarding the ability to use data and information to make an informed decision that impacts study success.

The results of this project are intended to be used to support targeted learning solutions that could enhance decision-making using graphically displayed information. The demographic data we collected did not include age or gender which made it difficult to associate any deficiencies in numeracy or visualization literacy skill sets with a change in school curricula over time. We looked for surrogates in the demographic data such as time in role, time in organization, or years in the clinical research industry but without further information, it would be difficult to cite any one of these items due to industry turnover and rapid advancement in the field based on a current dearth of available talent. Additionally, the "all participants group" and the group that included the 29 participants who completed the entire VLAT had similar demographic characteristics in all categories.

The importance of the skill sets that we looked at in this project is supported by a summary of The National Academies workshop in which skillsets for the 21st century was assessed (National Research Council, 2011). A summary of the workshop concludes that advances in technology support the need for adaptive problem solving, critical thinking, complex decision-making, ethical reasoning, and innovation as the five skills that appear to be increasingly valuable (National Research Council, 2011). Included among the mentioned skills are nonroutine problem-solving and systems thinking (National Research Council, 2011). Summarizing the report, the levels of education related to pay differences have not changed, but the skill sets necessary to work in a computerized and technological-based workforce require specific training related to data and information (National Research Council, 2011).

Another related use case of our project results includes developing better tools for decision-makers including visual displays that incorporate information and present it in formats that are most useful and usable. Goodman and colleagues (Goodman et al., 2013) produced a report for the U.S. Department of Education assessing literacy, numeracy, and problem-solving in technology-rich environments that has been cited as recently as 2020 as evidence of a need to consider these skillsets when implementing tools and technology for decision-making (Millar et al., 2020). In the U.S. Department of Education report, the authors examined 5,000 U.S. adults 16-65 years old along with a similar nationally represented sample in 22 countries to compare data literacy and health status to problem-solving (Goodman et al., 2013). Results demonstrated that the U.S. average score in numeracy is well below the international average and the U.S. average score in problem-solving in a technology-rich environment ranks 3rd from the bottom (Goodman et al., 2013).

For our project, we were curious to know if participant location had an impact on scoring as related to the Department of Education report. We performed a forward stepwise regression model to see if we could predict a "persona" that might perform well in the skill sets we evaluated. We found no significance based on the region that participants designated as their location ($p=0.3504$). While the U.S. Department of Education report may have spurred educational initiatives or supported the importance of Science, Technology, Engineering, and Math (STEM) skill sets, adults already employed in occupations that are rapidly changing as technology advances may not have the same advantages unless they first recognize a deficiency and seek out remediation on their own.

Changing the way a tool is configured to better accommodate existing skill sets may be one way to incorporate technology and information into existing workflows and maximize its use while skill set improvement is simultaneously applied as a solution. As the demand for change in industry parallels technological advances, organizations could potentially find themselves at a disadvantage when competing for business if worker skill sets cannot support the rapid technological change. Although we did not pursue a more granular examination of the item difficulty index, it might be worthwhile to further explore this parameter as it could be that the level of difficulty of the question , or what we might expect the participants to glean from visualizations, could be the real challenge and not necessarily the visualization type itself.

The results for numeracy in our assessment were somewhat puzzling as there appeared to be an inverse relationship between the numeracy assessment and decision-making. While the analysis did not show significance, the literature describes numeracy as a gateway skill to visualization literacy (National Research Council, 2011; Goodman et al., 2013; Borner et al., 2016) indicating that we may have either failed to choose the right numeracy assessment in relation to the visualization literacy assessment, or the decision-making assessment was not as good of a match for the subjective numeracy assessment as it was for the visualization literacy assessment. Optimizing the testing framework may yield different results which could provide additional information on the relationship between numeracy and visualization literacy as well as both skills impact on decision-making.

Examining the recently obtained engagement survey results demonstrated generally favorable scores for overall job satisfaction with opportunities parsed out of the scoring that could be loosely associated with the results of this project. Having the tools and resources to competently complete expectations of the role could be interpreted as a desire for better systems, technologies, and training, but would require further analysis or discussion to definitively associate the response with the IT solution deployed for this project. Both Medical

Management and Project Management indicated a struggle with workload as well as collaboration between departments being sub-optimal, both of which would be expected to benefit from the intended purpose of a tool such as the Project Health Dashboard but also would require additional analysis or information to associate the response directly with the project outcomes.

Section 6: Study Limitations

The focus of this project involved the use of data and information for decision-making which can be broadly defined and explored. The area of interest (clinical trial management) required pinpointing a more specific use case that was closely associated with key decision makers' workflow. The type of strategic decision made during a clinical trial is generally categorized in the time, cost, and quality areas and standardized across the industry. However, narrowing down a specific definition, or description, of data literacy was important for this project but also proved challenging. The various, but related, definitions involve literacy(American Medical Association, 1999), health literacy (Rodriguez et al., 2013), graphical literacy (Aldrich & Sheppard, 2000), numeracy (Goldbeck et al., 2005), visualization literacy(Boy et al., 2014; Borner et al., 2015) and the more collective term data literacy.

In this project, we have accepted these terms as collectively related, interdependent, and relevant to the discussion. While several of the terms such as "numeracy" and "graphical literacy" may be more closely related to an evaluation of the effective use of a data dashboard employing descriptive and predictive analytics, more broadly the terms carry significance in the effective use of decision-making tools in healthcare. However, additional research is likely necessary to further dissect the terminology and pinpoint which of these concepts is more granularly related to the challenges we have illuminated with this project.

This project set out to determine if visualization literacy could have an impact on decision-making when using data visualizations summarizing clinical trial progress. The target participants for this project were project leaders. However, the clinical trial team has other members who specialize in a role that contributes to decision-making or must make decisions about their functional tasks during a clinical trial to support or inform the project leader's strategy. Further, different functions have different associations with data, and as such personnel in those roles may have different backgrounds or educational experiences with data. Further work should be done in this area to examine the impact of visualization literacy on other team members, rather than on the leader in isolation, and within a team from a collaborative decision-making perspective.

Project managers in the clinical trial industry are not always required to be proficient in the skill sets described in classical project management. Therapeutic expertise and the ability to understand the regulatory environment in drug development are perceived as critically important skills. Communication skills are also highly prized in the industry. While we set up a decision-making scenario that was closely related to the established workflow within the organization, arriving at what was considered the correct decision could have been more challenging for participants who were not classically trained in project management or were in a position in the organization that has well-established support from higher-level roles. In this case, answering the questions correctly would not have been of equal difficulty for all participants.

The participant characteristics told us that close to 50% of the participants had been at the organization for 3 years or less and that most of them (>70%) had been in their role for 3 years or less. Recently, turnover across the CRO industry has reached unprecedented levels and in combination with supply and demand issues, there is significant competition for new hires in the roles we have included in this project. While it might be fair to surmise that the challenges illuminated by this project crosses organizations, we did not consider factors such as quality of onboarding and acclimation to the organization's processes nor did we attempt to determine if expectations around the use of data were clearly stated in either an employment contract or standardized across managers. With the current dearth of available candidates, further research should more closely examine the areas of expertise and skillsets of available candidates along with hiring practices to determine if standardization of qualifications could impact participant scores. While there is no reason to believe that compromises were made to employ candidates, the length of time that new hires spend at one organization before moving to the next could impact meeting expectations of the role.

Organizations supporting clinical research compete on their differentiators which means that there could be little standardization across organizations in how data is organized, displayed, or interpreted. Time in the role, time in the organization, and time in the industry percentages were all somewhat low indicating either rapid advancement or movement across organizations. It would be interesting to conduct the same study independent of any one organization with a cross-organization participant group.

An additional limitation was the timing of the assessment. The assessments were offered to participants approximately one week before the traditional holiday period in the industry. Typically, this time-period can be hectic and distracting in relation to workload and expectations for an upcoming break. The time frame for completing the assessment was extended into the first two weeks of January when most participants return after time off and are slowly getting back into their routine. Further research should seek to determine if the pre- or post-holiday period could have an impact on participant attention span and focus on the assessment.

The decision-making assessment laid out the expectations for deciding at the beginning of the assessment. The participants were asked to decide definitively based on the criteria laid out at the beginning between a go or no-go decision for the stage-gate. In current practice within the organization, nearly all projects are allowed to progress regardless of not meeting the metrics expectations as long as an action plan to address deficiencies is presented. The stage-gate meetings serve as more of a checkpoint than a go, no-go bottleneck which is important in keeping study progress moving forward. The assessment set up a scenario that illustrated the project was having significant challenges in the areas related to "passing the gate" and clearly stated that the project leader provided no additional information. However, participants selecting the wrong choice may have defaulted to their daily current practice by habit, leading them to choose the wrong decision. Additionally, while the Medical Monitor is a key decision-maker on the clinical trial management team, the visualizations offered as part of the decision-making assessment are not necessarily part of their daily workflow nor is the process of stage-gate reviews.

A very small number of participants (n=3) had challenges accessing or using the Qualtrics application and reached out for assistance. Although participants were provided with a connection to get help there were very few requests in conjunction with the approximately 17 participants who completed a part or piece of the assessment but did not return to complete the assessment in full after several reminders. It is unknown what caused the 17 participants to abandon the assessment although workload, ease of use of the Qualtrics tool, interest in participation, or other mitigating factors are speculations.

Section 7: Conclusions

As technology continues to evolve and the available data that it generates grows incrementally, the healthcare industry will continue to seek ways to make the best use of that data to develop advanced methodologies that improve the standard of care and quality of life for patients as well as the administrative burden for clinicians. Making the best use of the information that data provides depends on workers in the healthcare industry having the ability to analyze, interpret and communicate with that information. Across the healthcare industry, making timely and accurate decisions is an essential trait that influences both the cost and quality of patient care. Possessing adequate numeracy and visualization literacy skillsets is key to optimizing decision-making related to both health and business outcomes.

Leaders in the industry must strive to design tools and visualizations that support decision-making across a range of data skills. Knowing your user audience and benchmarking where users stand on the spectrum of data skillsets can help to improve the production of tools that are both useful and usable. Understanding the breadth and depth of user skill sets can also support the development of learning opportunities more robust than those centered around the launch of a new system or tool. Much work has been done in frameworks for data visualization literacy (OECD, 2013; OECD, p., 2013; Borner et al, 2019; Bueckle et al 2022) education and could be built upon to develop learning solutions based on the findings in this paper.

In the clinical trial industry information and technology can have a large impact on the productivity of teams and efficient process development. Improving productivity and team efficiencies can effectively reduce delays experienced during the trial process related to ineffective decision-making or interpretation of cycle times that are related to study progress, enrolment, or the retention of study participants. Getting treatment solutions to market in a safe and timely manner results in better options at a lower cost for patients. However, simply making information available to team leaders is often not enough to influence improvements in decision-making. People, process, and technology are three legs on the same stool and bear equal importance in the launch and adoption of tools that are intended to facilitate success in clinical drug development.

This paper explores important aspects of process and technology in clinical drug development and includes a focused assessment of the people aspect of the triumvirate. As variation exists within each of the three points, further research should be done to investigate the intricacies of the relationship between people, process, and technology as well as the complexities of that relationship. Additional aspects that support evolving technologies and processes such as training and leadership support to ensure successful outcomes in drug development can have a strong influence on outcomes and would be interesting to explore as scalable and sustainable options to supporting a changing workforce that is being influenced by the rapid advancements of technology and the democratization of data.

References

AlTarawneh, G., & Thorne, S. (2017). A pilot study exploring spreadsheet risk in scientific research. *arXiv preprint arXiv:1703.09785*.\

American Medical Association, A. H. C. O. T. C. O. S. A. (1999). Health literacy: report of the Council on Scientific Affairs. *Jama*, *281*(6), 552-557.

Balz, M., Burke, A., Montagner, A. & Tarallo, M. (2021). A new operating model for pharma: Howthe pandemic has influenced priorities. McKinsey and Company. Accessed May 2022 at https://www.mckinsey.com/industries/life-sciences/our-insights/a-new-operating-model-for-pharma-how-the-pandemic-has-influenced-priorities.

Barua, A., Kriebel, C. H., & Mukhopadhyay, T. (1995). Information technologies and business value: An analytic and empirical investigation. *Information systems research*, *6*(1), 3-23.

Bennett, K. B., & Flach, J. M. (1992). Graphical displays: Implications for divided attention, focused attention, and problem solving. *Human factors*, *34*(5), 513-533.

Bernstein, M. L., McCreless, T., & Cote, M. J. (2007). Five constants of information technology adoption in healthcare. *Hospital Topics*, *85*(1), 17-25.

Bertin, J. (1983). *Semiology of graphics; diagrams networks maps* (No. 04; QA90, B7.).

Bhavnani, S. P., Narula, J., & Sengupta, P. P. (2016). Mobile technology and the digitization of healthcare. *European heart journal*, *37*(18), 1428-1438.

Börner, K., Bueckle, A., & Ginda, M. (2019). Data visualization literacy: Definitions, conceptual frameworks, exercises, and assessments. *Proceedings of the National Academy of Sciences*, *116*(6), 1857-1864.

Boy, J., Rensink, R. A., Bertini, E., & Fekete, J. D. (2014). A principled way of assessing visualization literacy. *IEEE transactions on visualization and computer graphics*, *20*(12), 1963-1972.

Bresnahan, T., Brynjolfsson, E., and Hitt, L. 2002. "Information Technology, Workplace Organization, and the Demand for Skilled Labor: Firm-Level Evidence*," Quarterly Journal of Economics (117:1), pp. 339-376.

Brynjolfsson, E., Hitt, L. M., & Kim, H. H. (2011). Strength in numbers: How does data-driven decision-making affect firm performance?. *Available at SSRN 1819486*

Brynjolfsson, E., & Hitt, L. (1996). Paradox lost? Firm-level evidence on the returns to information systems spending. *Management science*, *42*(4), 541-558

Bueckle, A., Buehling, K., Shih, P. C., & Börner, K. (2022). Optimizing Performance and Satisfaction in Matching and Movement Tasks in Virtual Reality with Interventions Using the Data Visualization Literacy Framework. *Frontiers in Virtual Reality*, *2*, 727344.

Caban, J. J., & Gotz, D. (2015). Visual analytics in healthcare–opportunities and research challenges.

Card, S., Mackinlay, J.D., Schneiderman, B. Readings in information visualization: Using vision to think. Morgan Kaufmann publishers. 1999

Carpenter, P. A., & Shah, P. (1998). A model of the perceptual and conceptual processes in graph comprehension. Journal of Experimental Psychology: Applied, 4, 75-100.

Carswell, C. M. (1992). Choosing specifiers: An evaluation of the basic tasks model of graphical perception. *Human factors*, *34*(5), 535-554.

Cavanaugh, K., Wallston, K. A., Gebretsadik, T., Shintani, A., Huizinga, M. M., Davis, D., ... & Rothman, R. L. (2009). Addressing literacy and numeracy to improve diabetes care: two randomized controlled trials. *Diabetes care*, *32*(12), 2149-2155.

CenterWatch (2018). Tufts CSDD: Clinical Trial Start-up Process Takes Longer Than 10 Years. Accessed April 2020 at: https://www.centerwatch.com/cwweekly/2018/03/12/tufts-csdd-clinical-trial-startup-process-takes-longer-10-years-ago.

Cleeremans, A., & Elman, J. (1993). *Mechanisms of implicit learning: Connectionist models of sequence processing*. MIT press.

Concannon, D., Herbst, K., & Manley, E. (2019). Developing a data dashboard framework for population health surveillance: widening access to clinical trial findings. *JMIR formative research*, *3*(2), e11342.

Cowan, N. (2001). The magical number 4 in short-term memory: A reconsideration of mental storage capacity. *Behavioral and brain sciences*, *24*(1), 87-114.

Curcio, F. R. (1987). Comprehension of mathematical relationships expressed in graphs. *Journal for research in mathematics education*, *18*(5), 382-393.

DeMets, D. L., & Califf, R. M. (2011). A historical perspective on clinical trials innovation and leadership: where have the academics gone?. *JAMA*, *305*(7), 713-714.

Dowding, D., Randell, R., Gardner, P., Fitzpatrick, G., Dykes, P., Favela, J., ... & Currie, L. (2015). Dashboards for improving patient care: review of the literature. *International journal of medical informatics*, *84*(2), 87-100.

Dowding, D. W., Russell, D., Jonas, K., Onorato, N., Barrón, Y., Merrill, R. J. A., & Rosati, R. J.(2017). Does level of numeracy and graph literacy impact comprehension of quality targets? Findings from a survey of home care nurses. In *AMIA Annual Symposium Proceedings* (Vol. 2017, p. 635). American Medical Informatics Association.

Effken, J. A., Brewer, B. B., Logue, M. D., Gephart, S. M., & Verran, J. A. (2011). Using cognitive work analysis to fit decision support tools to nurse managers' work flow. *International journal of medical informatics*, *80*(10), 698-707

Egan, M. (2006). Clinical dashboards: impact on workflow, care quality, and patient safety. *Critical care nursing quarterly*, *29*(4), 354-361.

Eley, R., Sinnott, M., Steinle, V., Trenning, L., Boyde, M., & Dimeski, G. (2014). The need to address poor numeracy skills in the emergency department environment. *Emergency Medicine Australasia*, *26*(3), 300-302.

Elting, L. S., Martin, C. G., Cantor, S. B., & Rubenstein, E. B. (1999). Influence of data display formats on physician investigators' decisions to stop clinical trials: prospective trial with repeated measures. *Bmj*, *318*(7197), 1527-1531.

Fagerlin, A., Zikmund-Fisher, B. J., Ubel, P. A., Jankovic, A., Derry, H. A., & Smith, D. M. (2007). Measuring numeracy without a math test: development of the Subjective Numeracy Scale. *Medical Decision-making*, *27*(5), 672-680.

Farnum, M., Lobanov, V., Brennan, M., Agrafiotis, D., Kolpak, J., Ciervo, J., & Alquier, L. (2012, October). Clinical case: Enhancing medical monitoring with visualization and analytics. In *2012 IEEE International Conference on Bioinformatics and Biomedicine* (pp. 1-1). IEEE.

Few, S. (2006). *Information dashboard design: The effective visual communication of data* (Vol.2). Sebastopol, CA: O'reilly.

Fogel, D. B. (2018). Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: a review. *Contemporary clinical trials communications*, *11*, 156-164.

Friel, S. N., Curcio, F. R., & Bright, G. W. (2001). Making sense of graphs: Critical factors influencing

comprehension and instructional implications. *Journal for Research in mathematics Education*, *32*(2), 124-158.

Garcia-Retamero, R., & Cokely, E. T. (2017). Designing visual aids that promote risk literacy: a systematic review of health research and evidence-based design heuristics. *Human factors*, *59*(4), 582-627.

Golbeck, A. L., Ahlers-Schmidt, C. R., Paschal, A. M., & Dismuke, S. E. (2005). A definition and operational framework for health numeracy. *American journal of preventive medicine*, *29*(4), 375-376.

Goodman, M., Finnegan, R., Mohadjer, L., Krenzke, T., & Hogan, J. (2013). Literacy, Numeracy, and Problem Solving in Technology-Rich Environments among US Adults: Results from the Program for the International Assessment of Adult Competencies 2012. First Look. NCES 2014-008. *National Center for Education Statistics*.

Goyal, A., Schibler, T., Alhanti, B., Hannan, K. L., Granger, C. B., Blazing, M. A., ... & Jones, W. S. (2021). Assessment of North American clinical research site performance during the start-up of large cardiovascular clinical trials. *JAMA network open*, *4*(7), e2117963-e2117963.

Halford, G. S., Baker, R., McCredden, J. E., & Bain, J. D. (2005). How many variables can humans process?. *Psychological science*, *16*(1), 70-76.

Hedin, A., Patil, S., Esiobu, C. (2020); Drugs in a virtual world: The rise of digital health solutions in clinical trials. Accessed October 18, 2020 at: https://www.bvp.com/atlas/drugs-in-a-virtual-world-the-rise-of-digital-health-solutions-in-clinical-trials

Huber, T. C., Krishnaraj, A., Monaghan, D., & Gaskin, C. M. (2018). Developing an interactive data visualization tool to assess the impact of decision support on clinical operations. *Journal of digital imaging*, *31*(5), 640-645.

Iftikhar, A., Bond, R., McGilligan, V., J Leslie, S., Rjoob, K., Knoery, C., & Peace, A. (2019, September). Role of dashboards in improving decision-making in healthcare: Review of the literature. In *Proceedings of the 31st European Conference on Cognitive Ergonomics* (pp. 215-219).

Jorgenson, D. W., & Stiroh, K. J. (2000). US economic growth at the industry level. *American Economic Review*, *90*(2), 161-167

Jorgenson, D. W., & Stiroh, K. J. (1999). Information technology and growth. *American Economic Review*, *89*(2), 109-115

Kindig, D. A., Panzer, A. M., & Nielsen-Bohlman, L. (Eds.). (2004). Health literacy: a prescription to end confusion.

Kohli, R., and Devaraj, S. 2003. "Measuring Information Technology Payoff: A Meta-Analysis of Structural Variables in Firm-Level Empirical Research," Information Systems Research (14:2), Jun, pp. 127-145

Kosslyn, S. M. (1989). Understanding charts and graphs. Applied Cognitive Psychology, 3, 185-226.

Laurenza, E., Quintano, M., Schiavone, F., & Vrontis, D. (2018). The effect of digital technologies adoption in healthcare industry: a case based analysis. *Business process management journal*.

Lee, S., Kim, S. H., & Kwon, B. C. (2016). Vlat: Development of a visualization literacy assessment test. *IEEE transactions on visualization and computer graphics*, *23*(1), 551-560.

Lee, S., Kwon, B. C., Yang, J., Lee, B. C., & Kim, S. H. (2019). The correlation between users' cognitive characteristics and visualization literacy. *Applied Sciences*, *9*(3), 488.

Lipkus, I. M., Samsa, G., & Rimer, B. K. (2001). General performance on a numeracy scale among highly educated samples. *Medical decision-making*, *21*(1), 37-44.

Lopez, K. D., Wilkie, D. J., Yao, Y., Sousa, V., Febretti, A., Stifter, J., ... & Keenan, G.M. (2016). Nurses' numeracy and graphical literacy: informing studies of clinical decision support interfaces. *Journal of nursing care quality*, *31*(2), 124.

Luck, S. J., & Vogel, E. K. (1997). The capacity of visual working memory for features and conjunctions. *Nature, 390*(6657), 279–281. https://doi.org/10.1038/36846

Ludewig, U., Lambert, K., Dackermann, T., Scheiter, K., & Möller, K. (2020). Influences of basic numerical abilities on graph reading performance. *Psychological research*, *84*(5), 1198-1210

Malloy-Weir, L. J., Schwartz, L., Yost, J., & McKibbon, K. A. (2016). Empirical relationships between numeracy and treatment decision-making: A scoping review of the literature. *Patient education and counseling*, *99*(3), 310-325.

McCaffery, K. J., Dixon, A., Hayen, A., Jansen, J., Smith, S., & Simpson, J. M. (2012). The influence of graphic display format on the interpretations of quantitative risk information among adults with lower education and literacy: a randomized experimental study. *Medical Decision-making*, *32*(4), 532-544.

McMullan, M., Jones, R., & Lea, S. (2010). Patient safety: numerical skills and drug calculation abilities of nursing students and registered nurses. *Journal of advanced nursing*, *66*(4), 891-899.

Melville, N., Gurbaxani, V., and Kraemer, K. 2007. "The Productivity Impact of Information Technology across Competitive Regimes: The Role of Industry Concentration and Dynamism," Decision Support Systems (43:1), Feb, pp. 229-242

Millar, R. J., Sahoo, S., Yamashita, T., & Cummins, P. (2020). Problem solving in technology rich environments and self-rated health among adults in the US: an analysis of the program for the international assessment of adult competencies. *Journal of Applied Gerontology*, *39*(8), 889-897.

Miller, G. A. (1956). The magical number seven, plus or minus two: Some limits on our capacity for processing information. *Psychological review*, *63*(2), 81.

Moore, T. J., Zhang, H., Anderson, G., & Alexander, G. C. (2018). Estimated costs of pivotal trials for novel therapeutic agents approved by the US Food and Drug Administration, 2015-2016. *JAMA internal medicine*, *178*(11), 1451-1457.

Mottes, Theresa A., Stuart L. Goldstein, and Rajit K. Basu. "Process based quality improvement using a continuous renal replacement therapy dashboard." BMC nephrology 20.1 (2019): 17.

National Research Council. (2011). Assessing 21st century skills: Summary of a workshop.

Nayak, J. G., Hartzler, A. L., Macleod, L. C., Izard, J. P., Dalkin, B. M., & Gore, J. L. (2016). Relevance of graph literacy in the development of patient-centered communication tools. *Patient Education and Counseling*, *99*(3), 448-454.

Nuttall, A. (2012). Considerations for improving patient recruitment into clinical trials. *Clinical Leader Newsletter*.

OECD. (2013). PISA 2015 Draft Reading Literacy Framework.

OECD, P. (2013). Draft Mathematics Framework.

Okan, Y., Galesic, M., & Garcia-Retamero, R. (2016). How people with low and high graph literacy process health graphs: Evidence from eye-tracking. *Journal of Behavioral Decision-making*, *29*(2-3), 271-294.

Oliner, S. D., & Sichel, D. E. (2000). The resurgence of growth in the late 1990s: is information technology the story?. *Journal of economic perspectives*, *14*(4), 3-22

OTA. *Computerized Manufacturing Automation: Employment, Education, and the Workplace*. United States Office of technology Assessment, 1984.

Rasmussen, J., & Vicente, K. J. (1989). Coping with human errors through system design: implications for ecological interface design. *International Journal of Man-Machine Studies*, *31*(5), 517-534.

Ratzan, S. C., & Parker, R. M. (2000). Health literacy. *National library of medicine current Bibliographies in medicine. Bethesda: National Institutes of Health, US Department of Health and Human Services*.

Schapira, M. M., Walker, C. M., Cappaert, K. J., Ganschow, P. S., Fletcher, K. E., McGinley, E.L., ... & Jacobs, E. A. (2012). The numeracy understanding in medicine instrument: a measure of health numeracy developed using item response theory. *Medical Decision-making*, *32*(6), 851-865.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., ... & Bindman, A. B. (2002). Association of health literacy with diabetes outcomes. *Jama*, *288*(4), 475-482.

Seow, H. Y., & Sibley, L. M. (2014). Developing a dashboard to help measure and achieve the triple aim: a population-based cohort study. *BMC health services research*, *14*(1), 1-10.

Sertkaya, A., Wong, H. H., Jessup, A., & Beleche, T. (2016). Key cost drivers of pharmaceutical clinical trials in the United States. *Clinical Trials*, *13*(2), 117-126.

Shaw, S. J., Jacobs, B., Stockwell, D. C., Futterman, C., & Spaeder, M. C. (2015). Effect of a real time pediatric ICU safety bundle dashboard on quality improvement measures. *The Joint Commission Journal on Quality and Patient Safety*, *41*(9), 414-420.

Sim, L. L. W., Ban, K. H. K., Tan, T. W., Sethi, S. K., & Loh, T. P. (2017). Development of a clinical decision support system for diabetes care: A pilot study. PloS one, 12(2), e0173021.

Sittig, D. F., & Singh, H. (2015). A new socio-technical model for studying health information technology in complex adaptive healthcare systems. In *Cognitive informatics for biomedicine* (pp. 59-80). Springer, Cham

Stadler, J. G., Donlon, K., Siewert, J. D., Franken, T., & Lewis, N. E. (2016). Improving the efficiency and ease of healthcare analysis through use of data visualization dashboards. *Big Data*, *4*(2), 129-135.

Strekalova, Yulia A. "When trust is not enough: A serial mediation model explaining the effect of race on intention to participate in clinical research." *Health education & behavior: the official publication of the Society for Public Health Education* 45, no. 6 (2018): 1036.

Toddenroth, D., Sivagnanasundaram, J., Prokosch, H. U., & Ganslandt, T. (2016). Concept and implementation of a study dashboard module for a continuous monitoring of trial recruitment and documentation. *Journal of biomedical informatics*, *64*, 222-231.

Tufte, E. R. (2001). *The visual display of quantitative information* (Vol. 2). Cheshire, CT: Graphics press.

Twohig, P. A., Rivington, J. R., Gunzler, D., Daprano, J., & Margolius, D. (2019).

Velcu-Laitinen, O., & Yigitbasioglu, O. M. (2012). The Use of Dashboards in Performance Management: Evidence from Sales Managers. *International Journal of Digital Accounting Research*, *12*.

Vitacca, M., & Vitacca, M. (2019). Proposal of a multidimensional strategic-management dashboard for use in a rehabilitation respiratory unit. *Medicine*, *98*(20).

Wainer, H. (1992). Understanding graphs and tables. *Educational researcher*, *21*(1), 14-23.

Wallace, A. S., Seligman, H. K., Davis, T. C., Schillinger, D., Arnold, C. L., Bryant-Shilliday, B., ... & DeWalt, D. A. (2009). Literacy-appropriate educational materials and brief counseling improve diabetes self-management. *Patient education and counseling*, *75*(3), 328-333.

Waller, R. G., Wright, M. C., Segall, N., Nesbitt, P., Reese, T., Borbolla, D., & Del Fiol, G. (2019). Novel displays of patient information in critical care settings: a systematic review. *Journal of the American Medical Informatics Association*, *26*(5), 479-489.

Weiner, J., Balijepally, V., & Tanniru, M. (2015). Integrating strategic and operational decision making using data-driven dashboards: the case of St. Joseph mercy Oakland hospital. *Journal of Healthcare Management*, *60*(5), 319-330.

Wouters, O. J., McKee, M., & Luyten, J. (2020). Research and Development Costs of New Drugs—Reply. *JAMA*, *324*(5), 518-518.

Wu, D. T., Chen, A. T., Manning, J. D., Levy-Fix, G., Backonja, U., Borland, D., ... & Kandaswamy, S. (2019). Evaluating visual analytics for health informatics applications: a systematic review from the American Medical Informatics Association Visual Analytics Working Group Task Force on Evaluation. *Journal of the American Medical Informatics Association*, *26*(4), 314-323.

Yang, E., O'Donovan, C., Phillips, J., Atkinson, L., Ghosh, K., & Agrafiotis, D. K. (2018). Quantifying and visualizing site performance in clinical trials. *Contemporary clinical trials communications*, *9*, 108-114.

Appendix A: Glossary of Terms

Area Chart A type of graphic display that shows how one or more group values change in relation to time. It is different from a line chart in that the area below the line is shaded in.

Bubble Chart A bubble chart is like a scatter plot but differs in that the points are replaced with bubbles and may vary in size and color as related to one or more measurements

Choropleth A map representing geographical characteristics and uses color or intensity of color to represent a summary of data related to the represented geography.

Clinical Drug Development The process of bringing a new drug to market through a series of steps and processes that verify the drug's safety and efficacy is relation to regulatory requirements.

Contract Research Organization (CRO) An organization that provides support to pharmaceutical and biotech companies in the form of managing the development of their drug assets ranging from full-service development to functional services only.

Data Dashboard A business tool that provides key insights and that organizations use to evaluate, inform and manage their services or products.

Data Democratization A process that allows everyone, whether in an organization or more broadly, to make the best use of their data and the associated insights.

Data Display A representation of data in a graph, table, or other visualization that allows users to explore and communicate information.

Data Visualization The graphic representation of data and information.

Data Literacy The ability to work with, visualize, understand, argue with and communicate with data.

Graphical Literacy The ability to translate or identify important information provided in a data visualization.

Health Data Any data related to the physical or mental condition of an individual including quality of life, wellness, illness and any of the associated conditions.

Histogram A graphical representation typically of continuous data is similar to a bar graph but is represented by grouping the data into ranges or bins and is shown with the bars touching.

Information Age A period starting somewhere in the middle of the 20th century that characterized a shift from industrial production to an economy largely focused on the use of information technology to revolutionize and achieve economic success.

Medical Monitor A physician or other qualified person whose role in a clinical trial includes reviewing medical data to ensure it is accurate and works towards protecting the safety of the trial participants.

Numeracy The ability to work with and understand numbers including basic mathematical skills such as addition, subtraction, multiplication and division.

Organizational Business Objectives Goals outlined by an organization's leadership that specify how the organization will achieve their business purpose and ensure growth and sustainability of the organization.

Project Health Dashboard A data display developed specifically to give project teams the ability to review and monitor key indicators on their project that predict success or failure and that identify opportunities for optimization.

Project Manager A key leadership role on a project that is charged with project oversight and maintaining the time, cost and quality parameters set forth in the project plan.

Scatter Plot A data display that uses dots to represent two different numeric values and is used to observe relationships between those variables.

Stacked Bar Chart A graphic representation of data that is layers two or more categorical data sets on top of each other and is used to visually represent each data sets portion of the whole.

Socio-Technical Model A model for understanding the various factors that have an impact on successful system or technology design and optimizing those factors to ensure design success. The model includes technology as well as various aspects of the user experience that are treated as independent but observed together as a whole.

Subjective Numeracy Scale (SNS) A validated test that is designed to subjectively evaluate an individual's skill and ability to use numbers or numerical data to arrive at a conclusion.

Technology Acceptance Model (TAM) A theoretical model for system design that focuses on both the usability and the usefulness of a technology from the user perspective.

Test Validation A process for determining and ensuring that a test accurately measures what it set out to measure to ensure the validity of the test scores.

Tree Map Displays hierarchical data in a size and color format to visually represent patterns.

Visualization Literacy Often described in various levels of detail, visualization literacy is the ability to use a data display to translate the meaning of the included data into accurate and useful information.

Visualization Literacy Assessment Text (VLAT)	A validated instrument designed to be used with non-data experts to determine their ability to review and translate information as represented in commonly used data displays.
Workflow Analysis	The process of examining processes specifically designed to facilitate the accomplishment of a task or series of tasks leading to an expected outcome.

Appendix B: Project Management Plan

Table of Contents

B. Project Charter
C. Requirements and Characteristics
D. Project Gantt Schedule
E. Work Breakdown Structure
F. Cost Estimation
G. Stakeholder Matrix and SWOT

1.0 PROJECT OVERVIEW

In 1962 the Food, Drug and Cosmetic Act was enacted and set forth the extent to which a new drug or device must be investigated in order to prove it safe and effective for human use (U.S. Food and Drug Administration, 1998). Since that time, clinical trials have grown in operational complexity with that being defined as “the aspects of a clinical trial that may be difficult to implement according to the timeline or procedures outlined in the application” (Smith, Siegel & Kennedy, 2020, para. 6).

Effective management of study initiation, patient recruitment, data capture and safety monitoring are a key role of pharmaceutical and biotech companies and their Contract Research Organization (CRO) partners. Optimal decision-making during a clinical trial requires having real time access to information that provides useful insights into trial progress and that lends itself to collaborative decision-making. The information necessary to support effective management of a clinical trial is often captured from data points that are varied and complex as well as being generated through the use of multiple systems employed during the course of a clinical trial (Farnum et al, 2019).

Clinical trial management teams in a Contract Research Organization are hindered in making strategic decisions due to an inability to quickly access and review data in aggregate across the study lifecycle. Data visualizations in the form of a project summary dashboard have the potential to facilitate clinical trial management as a dashboard facilitates summarizing and presenting data in a way that provides quick and easy analysis of the clinical trial’s status. However, dashboards that have been developed and implemented for healthcare decision-making show varying results in both effectiveness and adoption (Concannon et al, 2019;

Toddenroth et al, 2016). As CROs have been steadily introducing dashboards to measure quality and project outcomes related to the conduct of a clinical trial, the launch of dashboards as an operations management tool has subsequently increased the necessity of users possessing skill sets related to data and informatics. Data or graphical literacy challenges within a project management team could complicate strategic decision-making through an inability to correctly interpret or summarize information presented in the dashboard. The goal of this project is to evaluate visualization literacy in association with decision-making. Numeracy will also be evaluated through a subjective numeracy scale to better define any deficiencies. The instruments used for the project will be the Subjective Numeracy Scale (SNS)(Faegerlin et al, 2007), Visualization Literacy Assessment Test (VLAT)(Lee et al, 2016) and a decision-making scenario using data visualizations from a project health summary dashboard that was developed and implemented within the organization to assist project leaders with decision-making.

2.0 PROBLEM

Problem Statement

Added complexity in clinical trials has resulted in an increase in the cost of an individual trial with a median estimated direct cost of approximately $19 million and ranging somewhere between $12 million and $33 million (Moore et al, 2018). The cost of a clinical trial is directly impacted by the timeline resulting in wide acceptance that 80% of all clinical studies fail to finish on time, and 20% of these are delayed for six months or more (Nuttall, A., 2012). Much of the time these delays are due to inaccurate or ineffective decisions made regarding process cycle times, patient recruitment or other key study metrics that study teams currently monitor to the best of their abilities. Currently, teams are obtaining multiple source system data extracts in the form of Excel® spreadsheets and then reconfiguring that data into a more usable format to understand trial progress. CROs are willing to invest in technology solutions such as data visualization dashboards. A comprehensive, complete, and easy to access information summary tool (the Project Health Dashboard) at the project level is in final development. CROs are less interested in investments such as learning programs that support user effectiveness of technology solutions unless there is demonstrated effect of the learning in relation to an improvement in skill sets necessary to successfully execute important tasks. The goal of this project is to discover if level of visualization literacy is related to an aptitude for learning with the outcome expected to assist with decisions related to developing and implementing data learning strategies within the organization and industry.

Summary of Literature

Improved decision-making on behalf of a clinical trial team could effectively improve management of the costs and accelerate the timeline of drug development. Underscoring the need for improved decision-making, is research in both medicine and clinical trial management where timing is critical. Using disparate information from disparate sources leads to confusion and additional time spent investigating and harmonizing information across a team in order that effective decisions can be made. Data displays, such as a dashboard, can save time and costs related to decision-making as they possess the ability to synthesize a large amount of information produced from various source system data sources in real time. Having the ability to access, analyse, read, work with, and present data to support an argument are important skills that ensure data visualizations fulfil their purpose in clinical trial management. It should not be taken for granted that clinical trial managers possess the skill sets necessary to effectively interpret and use data visualizations.

Review of Evidence

Reference	Year	Description
Borner, K., Bueckle, A. & Ginda, M.	2018	The paper examines the challenges related to the proliferation of large data sets and the resulting need for data visualization literacy (DVL) on a universal basis to support data driven decision making. The paper cites evidence from previous studies examining the topic as well as the various methodologies for assessing DVL. The paper then presents a revised DVL framework that connects DVL core concepts and process steps. Included are A typology, process model and exercises for Defining, teaching, and assessing DVL. The paper is useful as it provides a framework and methodology based on available evidence with which to evaluate and design a DVL program.
Concannon, D., Herbst, K. & Manley, E.	2019	The original research describes a quasi-experimental design investigating the design and deployment of a dashboard for public health surveillance. The research included user feedback on usefulness and usability and, an assessment of user ability to interpret information being displayed. Key outcomes of the research were that dashboards can be utilized

Reference	Year	Description
		to communicate data trends, users must be involved in the dashboard design, and visualization literacy is an important consideration in dashboard implementation.
Dowding et al	2018	Original research examining the association between measures of graph literacy and numeracy with comprehension of quality targets presented in a graphic dashboard format. The users included home care nurses from two agencies. Results suggest that developers of clinical dashboards include target information to evaluate users' ability to understand information displays before the dashboards are released for general use.
Farnum et al	2019	The purpose of this paper was to describe the creation of a dimensional warehouse for inte-grating operational data from clinical trials. The authors primary focus was on addressing the need for timely, consistent, and integrated access to clinical trial data. The warehouse demonstrated the ability to extract, transform and load data using a generalizable metrics engine to enable the computation of operational metrics and key performance, quality, and risk indicators into a graphical user interface to help teams track study conduct and performance. The paper is important as it provides evidence of the usefulness of analytic

Reference	Year	Description
		approaches in enabling clinical trial teams to make better decision around conduct, performance, risk and operational processes during the life of the trial.
Franklin et al	2017	The paper describes a methodological approach to delivery of a dashboard in an emergency department (ED) setting designed to enhance situation awareness leading to improvement in throughput outcomes by improving decision-making. A formative evaluation of the dashboard was created based on work ontologies. Real time throughput measures of various cycle times in the process of ED admit through departure were captured. The authors cited the diversity of users and workflow as challenging to the evaluation. The study did not address all challenges within the socio-technical system. Dashboard access was not uniform across departments. Barriers to user adoption continue to be explored.
Harrison	2016	The paper examines the reasons for clinical trial failure with the objective of decreasing attrition in clinical development. The majority of failures were due to efficacy or safety (52%/24%), but a large amount in combination was also attributable to strategic (15%), commercial (6%), and operational (3%) reasons. This article supports the importance of having

Reference	Year	Description
		data and graphics to monitor study progress and risk to make decisions on trial strategy, even if those decisions involve early study termination in consideration of continuing to invest in a compound that has a questionable efficacy.
Hedin, A., Patil, S. & Esiobu, C.	2020	An industry publication that describes the rise of digital health solutions in clinical trials including what aspects will drive the most value in the near future from a market consultant's perspective. The impact of COVID-19 on the evolving technology ecosystem has been to accelerate solutions that focus on providing insight into the large amounts of health data available with a focus on efficiency and innovation. Key to driving innovation is the increasing complexity and cost of clinical trials along with persistent trial delays. A large focus is on decentralized clinical trials driving the need for technology that can efficiently access, aggregate, and analyze data and deliver insights into trial progress and success.
Iftikhar et al	2019	A systematic review of 8 papers chosen from 62 demonstrated heterogeneity in the process, outcomes analysis and techniques related to dashboards improving decision-making in healthcare. The paper concludes that there is considerable evidence that the use of data visualizations in healthcare can improve the quality of decision

Reference	Year	Description
		making. The paper is important as it reviews a collection of evidence demonstrating the effective-ness of dashboards in improving decision-making in a health data setting.
Mottes, Goldstein & Basu	2019	A case study examining the implementation of a dashboard to capture key metrics related to acute kidney injury (AKI) in critically ill patients. The purpose of the dashboard was to increase quality outcomes and quality improvement strategies related to measuring adherence to institutional standards and the delivery of continuous renal replacement therapy with specific focus on the process of the care. Reducing practice variation to avoid poor patient outcomes were achieved through visualizing process leading to the creation of standards quality of care, and best practice guidelines.
Nayak et al	2015	Original research examining the impact of prostate cancer patient's health literacy, numeracy, and graph literacy in relation to the subject's comprehension of quality of life dashboards. The researchers found that, in general, the subjects had high health literacy with 78% being college educated. There was variation in numeracy and graph literacy when examined in combination with dashboard comprehension leading the authors to

Reference	Year	Description
		conclude that even among higher educated patients, variation in the ability to comprehend graphs exist. Practice implications include the need for awareness around patient communication that employs visual displays of data.
		from three proprietary clinical trial databases
Serkaya et al	2016	The authors of this paper used data aggregated provided by Medidata solutions to explore the increasing cost of clinical research from the perspective of its impact on public health. Factors including therapeutic area, patient recruitment, administrative staff, and clinical procedure expenditures were included. Gaining an understanding of the key cost drivers is important as it demonstrates the value of having real time access to data to make strategic decisions that contain the increasing costs of clinical trials.
Sim et al	2017	A diabetes dashboard was developed to assist with the management of complex chronic disease. A need was identified to assimilate and aggregate data from multiple test results which typically are challenging to interpret and support decision making. The dashboard was developed to graph-ically summarize all relevant laboratory results for quick interpretation and included alerts to inform the user of test that are due for repeat testing. While the dashboard demonstrated that the data

Reference	Year	Description
		displayed could improve the management of diabetes, it did not significantly improve the identification of patients requiring treatment adjustments or the amount of time spent on each case. Limitations of the study included an under powered survey and a focus on a unique cohort of students.
Toddenroth et al	2016	Original research using a quasi-experimental mixed method design that focused on users conducting and coordinating clinical research at a tertiary care facility. A dashboard was created using data from an electronic data capture system to visualize enrollment across multiple clinical trials at one facility. The prototype evaluation was based on user requirements. Comments were collected during the dashboard demonstration along with user interviews assessing the usefulness and usability of the dashboard. Limitations of the research include a small sample size and the use of a single study metric (enrollment). The dash-board may not translate to use with other EDC systems and visualization tools.
Waller et al	2018	The objective of this systematic review was to explore improvement of clinician overload through visualization of key patient information with the potential to increase efficiency and improve quality. The papers included in the review were

Reference	Year	Description
		from critical care and anesthesiology settings. Results of the review were weak evidence in improvement in primary outcomes over usual care in conjunction with the use of comprehensive integrated displays and multi-patient dashboards. Cited as an outcome were important translation gaps from laboratory to actual care settings.
Weiner, J., Balijepally, V., & Tanniru, M.	2015	A case study at St. Joseph Mercy Oakland Hospital developed a dashboard to track key performance Indicators for the purpose of increasing accountability and transparency and to enhance responsibility for the collective vision and action across the enterprise. The paper describes the health system's evolution towards an accountable and responsible culture with a common vision. Shortcomings of the study include lack of scalability to industry, no comparison to other institutions, no clear delineation between the institution's key performance indicators and the dashboard that displayed them as evidence of effect.

3.0 IT SOLUTION

Name of Solution:

1. ePremier Project Health Dashboard supported by Qlik® (Business intelligence tool)

Problem Statement:

Added complexity in clinical trials has resulted in an increase in the cost of an individual trial with a median estimated direct cost of approximately $19 million and ranging somewhere between $12 million and $33 million (Moore et al, 2018). The cost of a clinical trial is directly impacted by the timeline resulting in wide acceptance that 80% of all clinical studies fail to finish on time, and 20% of these are delayed for six months or more (Nuttall, A., 2012). Much of the time these delays are due to inaccurate or ineffective decisions made regarding process cycle times, patient recruitment or other key study metrics that study teams currently monitor to the best of their abilities. CROs are willing to invest in technology solutions such as data visualization dashboards and as such a comprehensive, complete, and easy to access information summary tool (the Project Health Dashboard) at the project level is in final development.

Vendor Name and Website:

Qlik (Business intelligence tool)
https://www.qlik.com
Description of Solution:
The IT solution includes the delivery of a data visualization tool. The Premier Research technical team will deliver a Project Health dashboard to trial management teams. The dashboard will aggregate data from multiple sources systems that capture patient, study management and administrative data points. The data will be displayed through the Qlik® business intelligence tool. The dashboard will consist of 9 views that represent a project overview, timelines and performance cycle times, and the status of the trial from site selection and activation through database lock. Financial measures, metrics and indicators will also be included in a labor and a

revenue view. The summary data will support collaborative decision-making on parameters related to trial progress and delay. Project Managers are expected to be the primary users of the dashboard.

4.0 PROJECT INTEGRATION

4.1 The Organization

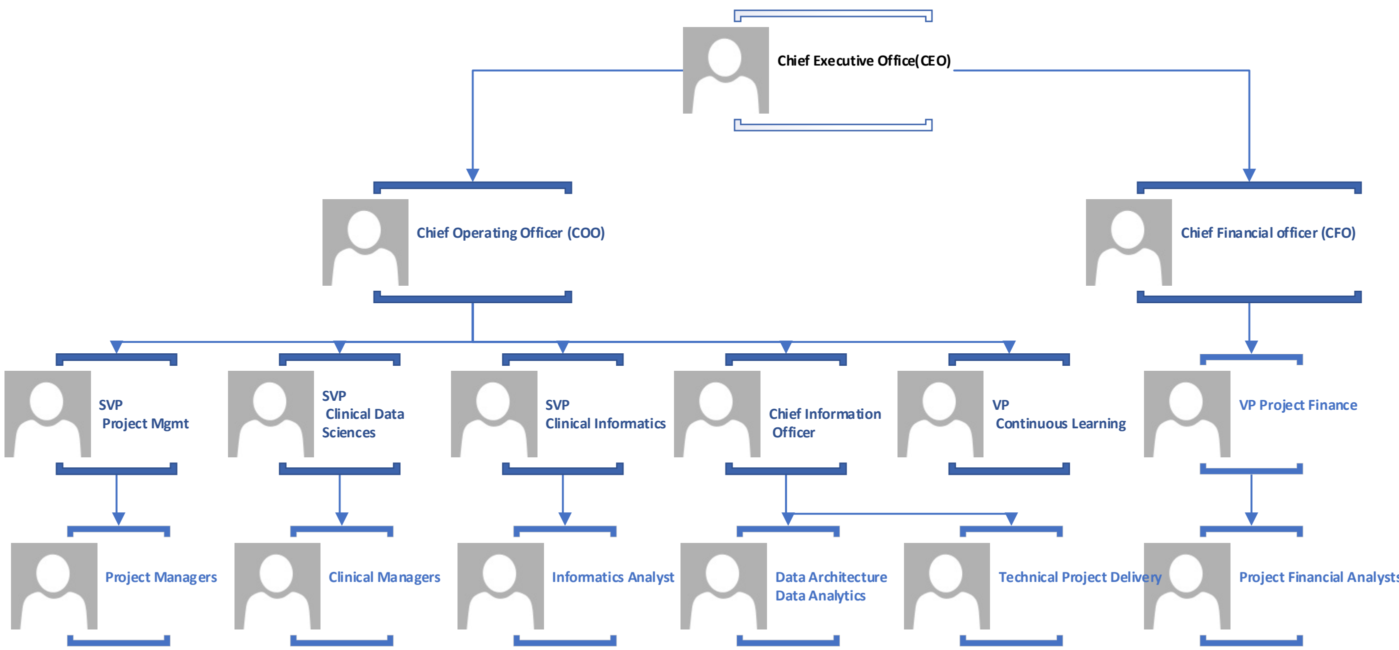


Figure 1.0 Organizational Chart of Stakeholders for Premier Research

4.2 Dr. Alter System Snapshot. (Appendix A, Table 1)

5.0 PROJECT CHARTER AND PROJECT SCOPE

5.1 Scope Statement

Project Purpose and Justification**.** A Contract Research Organization (CRO) exists to provide a service to their pharma and biotech clients. That service is the professional execution and delivery of a clinical drug or device trial. While each phase of clinical drug development grows in size and complexity, the service is performed the same and includes three main components that define a CROs expertise:

1. The first component is the clinical trial site which consists of the venue for patient visits and procedure completion. Typically, the site is a healthcare provider's office where a research team performs the protocol specified procedures. A CRO's goal is to engage the most experienced and high performing sites and have the sites ready and approved by the client and regulatory authorities to conduct the trial as quickly as possible. The management of the site is also important and includes review of several metrics focused on counts and cycle times as well as process monitoring.
2. The second goal involves the expeditious recruitment of the right patients into the clinical trial. Often the site is relied upon to select and enroll eligible subjects into the trial. The patient data collected by the site or with mobile devices is critical to safety and efficacy monitoring during the trial.

3. The last component is the delivery of high-quality data that supports the client's application to the regulatory authorities demonstrating the safety and efficacy of their product. The data must not only be correct but verified and of the highest quality to best support a client's successful new drug application (NDA).

Each goal involves a complex process that generates both patient and performance data that must be managed and monitored closely in accordance with the regulatory requirements that specify the conduct of the trial. The Project Manager and their team must have frequent and regular insight into all relevant data in order to complete the process successfully on behalf of their client and deliver the trial within the time, cost and quality standards defined in the contractual agreement. Unexpected changes to the time, cost or quality of a project must be identified as quickly as possible and proactively managed by Project Manager. Beyond having access to important metrics, measures, and indicators the Project Manager must possess the ability to synthesize data from multiple sources and, through review of that information, come to effective conclusions that support the successful outcome of a clinical trial project.

Scope Description. To facilitate effective decision-making and risk management within a clinical project team, a need exists to ensure project summary data is accessible and available on demand to the Project Manager. The Project Manager must have the ability to interpret and evaluate the information provided to them in a graphical format. This project will provision a Project Health dashboard as the IT solution. The dashboard will summarize in real time project, patient and administrative data related to the conduct of a clinical trial and make that information available on demand to the Project Manager and their team members. Having access to such an information display could reduce the time spent foraging for data, the level of effort spent accessing and analyzing data and in particular, the time spent to communicate information to ensure all team members are aware of the current status and risks to the project.

Although dashboards and data displays have become more common throughout the industry, team skill sets related to data and informatics are hindered by lack of an investment in skill development focused on data literacy, or the ability to access, analyze, read, work with, and present data to support an argument. The assessment will include application of the VLAT and the delivery of a focused data decision-making scenario related to information provided in the dashboard. The aptitude for learning will be based on an interview assessment related to the decision-making scenario content through use of the Project Health dashboard.

The scope of this project is limited to the delivery of a Project Health dashboard and an assessment of the users' visualization literacy in relation to decision-making through use of the dashboard. Having real time access to information that indicates changes in a project time, cost and quality status would be advantageous to the Project Manager if the Project Manager has adequate preparation in the data skill sets necessary to ensure appropriate translation and use of the information displayed.

Boundaries. The IT solution (dashboard) delivery will be preceded by requirements gathering from all relevant departments, conceptualization of the dashboard, production, testing, and deployment of the tool to project teams. The project includes the application of the VLAT and an assessment of decision-making using the dashboard.

Strategies. The dashboard will be assessed with representative sample groups prior to the implementation of the project to identify necessary updates, modifications, and minimize outside risk to the project. The dashboard release schedule is currently expected to be twice yearly with several "hot fixes" immediately following the first release to address unexpected challenges or risks upon release.

Assumptions. The dashboard, VLAT programming, and the decision-making scenario will be ready as planned and vetted thoroughly with adjustments made for quality purposes as necessary. Resources assigned to either the dashboard production or the decision-making scenario will have adequate time and commitment to participate in the project. Project Managers and Medical Affairs personnel who are key decision makers on project teams will be included. Stakeholders will have adequate time available to test the initial dashboard and decision-making scenario.

Constraints. For the organization to take advantage of both the dashboard and decision-making scenario, the project testing period must be completed in the timeframe planned. The data analytics team must be resourced appropriately to address post launch challenges with the dashboard. The organization must be willing to continue the time commitment necessary to implement the VLAT and the decision-making scenario.

5.2 ***Project Charter.*** (Appendix B, Table 1)

5.3 ***Requirements and Characteristics.*** (Appendix C, Table 1)

5.4 **Acceptance Criteria.** The acceptance criteria define the boundaries of the user requirements and will be used to confirm that the Project Health Dashboard is working as intended. The decision-making scenario will be an assessment developed using selected data visualizations from the Project Health Dashboard and will be based on similar assessments in the VLAT in conjunction with regular and expected decisions made on a project team. The dashboard will meet all the following criteria:

- Users are required to follow processes (Premier Research SOP, WPD, and policies/procedures) that define use and data entry into the source systems.
- Data in the source systems will be integrated with and aggregated in the event data warehouse.

- The event data warehouse will update the dashboard data nightly (every 24 hours) US time.
- The dashboard will include data from study management (e.g., clinical trial management system), patient (e.g. electronic data capture) and administrative (e.g. Deltek® financial systems) systems to provide a complete picture of the clinical trial status.
- The dashboard will display data in appropriate formats and provide information that is useful to the study team.

5.5 Project Deliverables. Deliverables produced due to the successful completion of the *Visualization Literacy and Decision-Making* project, and for the project to be considered successful are:

- Deliverable 1: A tested clinical trial management tool (Project Health dashboard) free of errors and that allows users to view study status in real time from a time, cost, and quality perspective.
- Deliverable 2: An evaluation of visualization literacy levels of intended users of the dashboard.
- Deliverable 3: An assessment of decision-making ability using data visualizations in comparison with visualization literacy measures.

6.0 Project Schedule Management

- ***Project Gantt Schedule (***Appendix D)
- ***Work Breakdown Structure (WBS)*** (Appendix E, Table 1)

Project Milestones

The project milestones along with their general sub-tasks include:

- **Background and evidence**
  - PRISMA
  - Synthesis of the literature
  - Proposal to support business case
  - Project Plan
- **Technology/tool selection**
  - Development and delivery of Project Health dashboard
  - Decision-making scenario analysis and optimization
  - Outcomes analysis planning (tools and statistics)
- **Intervention planning and preparation**
  - Sample selection
  - Programming of SNS, VLAT and agreement on decision-making scenario
- **Application of intervention**
  - SNS, VLAT and decision-making scenario
  - Post-intervention assessment and data collection
  - Scoring and preliminary analysis
- **Statistical analysis**
  - Tables, listing, figures delivery
  - Project documentation and summarization

- **Results**
  - Complete and deliver project documentation
  - Presentation of results
  - Project close out

7.0 Cost Management Plan

7.1 **Cost Estimation (A**ppendix F, Figure 1)

7.2 **Cost Excel Sheet** (Appendix F, Figure 2)

Costs for the IT portion of the project have been estimated using an average IT hourly rate. Training and materials have been estimated based on existing projects and the intended sample size. Hardware and software costs are spread across multiple internal initiatives using the same equipment and software for other projects. There will be no travel or per diem costs planned for this project due to environmental factors. All work, meetings, training, and orientation sessions will be conducted virtually using standardized internal equipment procured and managed by the IT department for general work purpose and all internal initiatives and projects.

8.0 Quality Control and Management

8.1 Planning.

Table 8.1

Deliverables and Acceptance Criteria

Deliverables	**Acceptance Criteria / Applicable Standards**
1. Project Health dashboard	Tested, free of errors, allows users to view study status in real time from a time, cost and quality perspective.
2. Data Dictionary	Describes data lineage and algorithms for each measure, metric, or indicator in the dashboard.
3. Standardized IT support process	Supports user in resolving challenges or potential bugs related to the dashboard.
4. Decision-making scenario	Application of a decision-making scenario focused on evaluating user decision-making assisted by specific data visualizations that are commonly used in everyday practice.

8.2 Quality Assurance

Quality Assurance Activities

1. What steps will you take to ensure that Quality is built into the production processes?

   a. The project will include user acceptance testing with subsequent verification of changes. Validation testing will ensure quality and conformance. Quality assurance and control will be built into the IT support process post dashboard launch.

2. Will the test teamwork from a Test Plan? Do they understand their responsibilities?

   a. Yes. The organization supported Delivery Management Office (DMO) policies and procedures will define the project parameters, resourcing, and expectations. The team is accountable to the DMO and all required documents and meetings will occur per standard practice.

3. How will you ensure that requirements are correct, complete, and accurately reflect the needs of the Customer?

   a. User acceptance testing will include a "Think Aloud" protocol that will ensure usefulness and usability on behalf of the end user. Any challenges will be evaluated and addressed in a prioritized and systematic way prior to the final release.

4. How will you verify that specifications are an accurate representation of the requirements?

a. Specifications will be reviewed across the development team and with the business subject matter experts to verify that expectations are being met. Periodic reviews of each view will be scheduled while the dashboard is in development with the associated business leader and any changes to the content or visualizations will be reviewed against the business requirements and adjusted as appropriate.

5. What steps will you take to ensure that the project plan (e.g., Risk Management Plan, Change Management Plan, Procurement Plan) is followed?

   a. Regular project team meetings will review the element and progress of each plan. Quarterly DMO meetings designed to review project progress will also address risk, change management and procurement of materials.

6. Describe how *Requirement – Specification – Test Plan* traceability is managed.

   a. All testing will be documented including formal and informal reviews and resulting action items and will be held within the team files for verification.

7. What audits and reviews are required and when will they be held?

   a. A formal audit and review of the delivered project will occur post project launch and will be documented and signed off on by relevant team members. Any audit documentation will be housed within the DMO per standard processes.

8. What steps will you take to ensure that the vendor is supplying deliverables of adequate quality?

   a. All tools and systems used to create, deliver, and support the Project Health dashboard are broadly used across the organization and connected to formally negotiated and managed contracts through Premier Research Procurement.

9. What will you measure to determine if the project is out of scope?

   a. To determine if the project has met its requirements within the pre-defined margins, we will conduct regularly reviews of the scope and budget and document any additional requests that arise to be considered in future releases. If it is determined that the project is exceeding its scope an ad hoc meeting will be scheduled with the DMO to obtain approval requested activities or scope adjustment.

10. What will you measure to determine if the project is within budget?

   a. We will analyze timesheets against level of effort expectations.

11. What will you measure to determine if the project is within schedule?

   a. The project schedule will be outlined in an initial Gantt chart depiction and will be managed throughout the project using the same tool.

8.3 Quality Control (QC).

Project Monitoring and Control.

1. How will you ensure that adequate testing is done? How do you define “adequate”?

   a. User acceptance testing will be conducted prior to the scheduled release of the dashboard and the beta period prior to the first update/release will be closely monitored to assess usage, IT tickets and requests for dashboard adjustments that come through the business owner as described in the standard process for tool release.

2. How will you report and resolve variances from acceptance criteria?
   a. Any variances from acceptance criteria will be documented and addressed through team meetings and collaborative decision-making with the business users.
3. At what milestones will testing and reviews take place – who and how will they do them?
   a. Informal testing will occur as each view of the dashboard is developed with the associated business owner for that view. UAT will be conducted formally prior to the initial release. Usage will be followed and requests for changes will be document during the beta period prior to the first scheduled update/release.
4. What action by the Sponsor constitutes acceptance of deliverables at each phase?
   a. For informal testing, meeting minutes will document user acceptance. UAT will be formally documented and sign off when complete. Upon formal release transfer of ownership to the appropriate business owner will occur and regularly scheduled meetings for the first six months of the beta period will capture acceptance/rejection of the product.

5. What action by the Sponsor constitutes “full and final acceptance” of final deliverables?
    a. Verification of the final deliverable is documented internally through standard DMO procedures.

9.0 PROJECT RESOURCES MANAGEMENT

Table 9.0 Resource Management

Role	Responsibility	Authority
1. Chief Operating Officer	1. Responsible for all people, process, technology support and success of Clinical Operations staff. DHI committee member.	1. High Authority
2. Sr. Director, Data Analytics	2. Responsible for resourcing and prioritization of data analytics team initiatives and projects. Reports into the CIO and has high influence over corporate IT initiatives.	2. Medium Authority
3. Sr. Director, Continuous Learning	3. Oversees the design, development and implementation of all corporate learning and development initiatives. Is a member of the Operations Leadership Team.	3. High Authority

4. Data Architect	4. Reports to the Sr. Director of Data Analytics. Is responsible for developing and maintaining the organization's data architecture, programming the integration hub data flows and algorithms.	4. Low Authority
5. Qlik Developer	5. Reports to the Sr. Director of Data Analytics. Is responsible for designing and developing the Qlik dashboards and data visualizations.	5. Low Authority
6. Project Manager	6. Reports to the head of the DMO. Is responsible for managing and executing the dashboard development plan. Manages timelines, project costs and resources. Overall responsibility for delivery of the Project Health dashboard.	6. Medium Authority

10.0 PROJECT COMMUNICATION MANAGEMENT

Communication is essential to the success of the project and as such will be managed through a regular cadence and structure with the various stakeholders. The Project Manager will be responsible for maintenance and updates to the Communication Plan.

Table 10.0 *Communication Management*

	Recipient	Message	Assumptions	Timeline	Channel	Recipients Response	Responsible	Contact Information
1	COO	Progress on project/quarterly updates	Summary information only	Quarter-ly	1/2 hour webex meeting/slides	Status of timeline, budget,	Project Manager	Stacy.weil@premier-research.com

						resourcing constraints		
2	SVP, PM	Project progress and plan for deployment	Timeline details. Required meeting time for testing and orientation of staff.	Quarter-ly, monthly during launch	email and presentation at PM Forum	Timing for testing and launch. Staff participa-tion requirement s. Demo of product.	Project Manager	Stacy.weil@pre mier-research.com
3	SVP, Clinical Data Sciences	Progress on CDS view	Timeline details. Required meeting time for testing and orientation of staff.	Quarter-ly	email and presentation at CDS meeting	Provision of staff for consult on developmen t and testing. Timing for launch and source system requirement s for staff.	Project Manager	Stacy.weil@pre mier-research.com
4	Sr. Dir., Continuous Learning	Development of training and change mgmt for DB.	Project summary and details around communicatio n, training and change mgmt plan.	Monthly and weekly during launch	email, team meetings	Plan for training and developmen t of training materials for orientation. Change mgmt and adoption plan. Timing for launch.	Project Manager	Stacy.weil@pre mier-research.com
5	Sr. Dir, Data Analytics	Resourcing and planning for design and development. Review of DB views as they are mocked up. Test plan and deployment strategy.	Frequent discussion and collaboration on DB design and developmen.	Weekly and ad hoc	email, weekly webex, adhoc webex meetings with analytics team	Confirmatio n of requirement s and changes during developmen t. Resourcing of team for developmen t including timeline. Escalation of risks and constraints.	Project Manager	Stacy.weil@pre mier-research.com
6	Delivery Mgmt Oversight Committee	Project review and update	Summary information with details on time, cost, and resourcing. Risk review.	Quarterly	Webex meeting/slide presentation/summ ary document	Feedback and support for removal of roadblocks and needs around resources and budget.	Project Manager	Stacy.weil@pre mier-research.com

7	Project Team	Project overview, all details around project plan, highlight risks and mitigation strategy.	Detailed information during each phase of the project including confirmation of resources, budget status, and review of deliverables.	Minimum weekly, daily during testing and deployment	email and webex meetings.	Risks and issues must be resolved or escalated. Regular verification of resourcing and costs.	Project Manager	Stacy.weil@premier-research.com

11.0 RISK MANAGEMENT

11.1 Risk Plan Overview.

The risk plan encompasses the monitoring and tracking of all identified elements of risk throughout the project lifecycle that could affect the project outcome. Initially, risks identified are noted along with their potential impact in the risk register. Throughout the life of the project as risks are identified they will be added to the register along with discussion on potential mitigation.

Table 11.0 *Risk Register*

Risk	Possible impacts on the project
Data from source systems is not accessible	Each of the many source systems requires permissions and programming to extract data and bring it into the integration hub for aggregating and visualizing. If permissions are not granted or data is not accessible for another reason the visualizations will be incomplete and rendered useless.
Data visualizations are not useful	The nature of clinical trials is that each one is unique and each therapeutic employs a different protocol and plan. Flexibility is important but standardization creates efficiencies and reduces errors. It is possible that some teams will find the dashboards not as useful as they anticipated due to unique circumstances of their protocol/plan. Such an occurrence could reduce adoption.
Resources are not available	Depending on the business climate, new and more important priorities could distract the team from either completing the project on time or reducing the effectiveness of the outcome through compromise.
Turnover	Currently the industry is experiencing close to a 25% turnover rate. Increased turnover could slow dashboard completion and DHI project completion if team members depart the organization mid-stream or if a critical team member departs and there is a lag in a replacement position. Departures during the testing phase of the project could mean starting over or adding additional test cases causing re-work.
Poor quality data	Poor data quality at the source (user entry into source system) will result in erroneous visualizations and foster distrust among dashboard users.

11.2 Risk Identification. The expectation is that all team members will be responsible for risk identification along with risk escalation to the project manager. While the Project Manager is responsible for the updating and maintenance of the risk register, the action to update and maintain the register may be delegated to another team member.

11.3 Risk Management Schedule. As risk management is an ongoing activity, the register will be reviewed in each regularly scheduled team meeting for new additions, retirement of risks that have expired, and discussion of existing risk status and mitigation efforts.

Inputs	Tools and Techniques	Outputs
Scope management plan	Expert judgment, Bidder conferences	Agreements (starting p. 11 summarized as attachment A)
Requirements management plan	Data analysis- proposal evaluation	Requirements management plan in PM plan
Cost baseline	Negotiation	Cost baseline (Section B- Supplies or Services, Prices)
Requirements documentation	Expert judgment, Bidder conferences	Requirements traceability matrix (Performance work statement starts p. 10)
Enterprise environmental factors	Expert judgment	PM plan (Risk, Quality- example is section 4.0.11 Subtask 11 Instructor KSAs)
Seller proposals	Advertising, Bidder conferences	Agreements
Organizational process assets	Data analysis, bidder conferences	Agreements

11.4 Risk Analysis. Risk analysis will be completed using a risk matrix where each risk is evaluated for likelihood and impact. The risk matrix will support the prioritization of risk discussions during team meetings and for escalation and presentation at quarterly DMO meetings.

11.5 Risk Response and Mitigation. Communication and metrics are both important for risk response and mitigation and go hand in hand towards resolution. Risks that have an objective measure associated with them will be monitored and reviewed as part of a proactive mitigation strategy. Communication across project team members, with stakeholders, and with points of escalation are critical to mitigation of impending risks.

11.6 Risk Monitoring and Control. Employing the previously described methods, risks will be controlled as effectively as possible through a combination of identification, analysis, measurements, and communication.

12.0 PROJECT PROCUREMENT MANAGEMENT

The project will utilize currently deployed Premier Research technologies, platforms and programs and will not engage with additional outside vendors to provide additional technology, resources, or tools for the project completion.

13.0 PROJECT STAKEHOLDER MANAGEMENT

13.1 Stakeholder Matrix, Appendix G, Table 1

13.2 SWOT Analysis, Appendix G, Table 2

14.0 IMPLEMENTATION AND DEPLOYMENT STRATEGY

The implementation of the Project Health Dashboard will be for the entire organization at the same time but will be focused on the Clinical Development Services (Project Management) as the primary user. This project focuses on the leader of the project team, namely the Project Manager. The entire development process is built on close collaboration between the business users and the data analytics team within IT. The process is being driven by the business users with primary ownership of the product and process being Project Management. While the selected approach is a “big bang” methodology for roll out of the product, the development process will be scheduled, frequently reviewed, and the approach will be organized around effective communication to minimize frustration or unexpected surprises. The deployment strategy and implementation for the tool (Project Health Dashboard) will be done in the following sequence of events:

1. Capture business user requirements.
2. Build prototype in collaboration with the business users.
3. Perform user acceptance testing using a “think aloud” protocol.

4. Adjust dashboard based on testing.
5. Orient and train users over a pre-defined period.
6. Production rollout (go-live) for Beta testing.
7. Establish release and update schedule while performing hot fixes for items noted during Beta.
8. Engage users through project stage gate reviews and operational leadership reviews with the dashboard as the reporting tool during reviews.

The deployment strategy and implementation for the project evaluation will be done in the following sequence of events:

1. Identify test group from Project Management.
2. Administer the SNS and Visualization Literacy Assessment Test (VLAT).
3. Administer the decision-making scenario.
4. Interview assessment using the dashboard.
5. Comparative analysis of visualization literacy levels to decision-making ability

Table 14.0

Go Live Schedule and Intervention Schedule

Event	**Planned Start**	**Planned End**	**Contact**
Capture Business User Requirements	Sep-19	Mar-20	Sr. Director Data Analytics
Build prototype in collaboration with the business users	Mar-20	Nov-20	Sr. Director Data Analytics
Perform user acceptance testing (UAT) using a "think aloud" protocol	7-Dec-20	16-Dec-20	SVP, Clinical Informatics
Adjust dashboard based on UAT	17-Dec-20	15-Jan-21	Sr. Director Data Analytics

Orient and train users	18-Jan	22-Jan-21	SVP, Clinical Informatics
Production roll out Beta testing	29-Jan-21	29-Jan-21	Sr. Director Data Analytics
Establish release/update schedule, hot fix performed.	1-Mar-21	1-Mar-21	Sr. Director Data Analytics
Engage users- project reviews	Apr-21	Dec-21	Project Management
Final release for 2021	1-Oct-21	1-Oct-21	Sr. Director Data Analytics
Identify test group from Project Management	Sep-21	30-Sep-21	SVP Clinical Informatics
Administer SNS and VLAT	Nov-21	Nov-21	SVP Clinical Informatics
Administer decision-making scenario	Nov-21	Nov-21	SVP Clinical Informatics
Evaluate scoring on assessments	6-Dec-21	21-Jan-22	Biostatistician, SVP Clinical Informatics
Comparative analysis	24-Jan-22	Apr-22	Biostatistician, SVP Clinical Informatics
Presentation of results	Fall-22	Fall-22	SVP Clinical Informatics

Table 14.1 *Dashboard Production Verification Participants*

Name	Function
SVP Clinical Informatics	Project Executive Leader, Final sign off
Sr. Director Data Analytics	Verification of validation
Data Architect	Run scrips for validation
System Business Owner	Verifies data matches source system

Data Validation and Source System Verification. Final verification that data from source system matches dashboard visualization and that data dictionary is complete and accurate.

General Guidelines.

1. Data architect will build and launch test scripts.
2. System Business Owners will verify data is accurate and matches source system data.

3. All issues will be prioritized and discussed for adjustments.
4. Approve the dashboard and the associated data dictionary are valid and functional.

Final Actions.

- 28 January 2021 email notification to Project Management that the dashboards are live in Beta testing.
- 1 February 2021 email notification to full organization that dashboards have been successfully deployed.
- Summer 2021 first release post dashboard deployment.

References

Börner, K., Bueckle, A., & Ginda, M. (2019). Data visualization literacy: Definitions, conceptual frameworks, exercises, and assessments. Proceedings of the National Academy of Sciences, 116(6), 1857-1864.

Concannon, D., Herbst, K., & Manley, E. (2019). Developing a data dashboard framework for population health surveillance: widening access to clinical trial findings. JMIR formative research, 3(2), e11342.

Dowding, D. W., Russell, D., Jonas, K., Onorato, N., Barrón, Y., Merrill, R. J. A., & Rosati, R. J. (2017). Does level of numeracy and graph literacy impact comprehension of quality targets? Findings from a survey of home care nurses. In AMIA Annual Symposium Proceedings (Vol. 2017, p. 635). American Medical Informatics Association.

Fagerlin, A., Zikmund-Fisher, B. J., Ubel, P. A., Jankovic, A., Derry, H. A., & Smith, D. M. (2007). Measuring numeracy without a math test: development of the Subjective Numeracy Scale. *Medical Decision-making*, *27*(5), 672-680.

Farnum, M. A., Mohanty, L., Ashok, M., Konstant, P., Ciervo, J., Lobanov, V. S., & Agrafiotis, D. K. (2019). A dimensional warehouse for integrating operational data from clinical trials. Database, 2019.

Franklin, A., Gantela, S., Shifarraw, S., Johnson, T. R., Robinson, D. J., King, B. R., ... &

Rubio, A. (2017). Dashboard visualizations: Supporting real-time throughput decision-making. Journal of biomedical informatics, 71, 211-221.medical training-a literature search. BMC medical education, 17(1), 262.

Harrison, R. K. (2016). Phase II and phase III failures: 2013–2015. Nature reviews Drug discovery, 15(12), 817.

Hedin, A., Patil, S., Esiobu, C. (2020); Drugs in a virtual world: The rise of digital health solutions in clinical trials. Accessed October 18, 2020 at: https://www.bvp.com/atlas/drugs-in-a-virtual-world-the-rise-of-digital-health-solutions-in-clinical-trials

Iftikhar, A., Bond, R., McGilligan, V., J Leslie, S., Rjoob, K., Knoery, C., & Peace, A. (2019, September). Role of dashboards in improving decision-making in healthcare: Review of the literature. In Proceedings of the 31st European Conference on Cognitive Ergonomics (pp. 215-219).

Mottes, Theresa A., Stuart L. Goldstein, and Rajit K. Basu. "Process based quality improvement using a continuous renal replacement therapy dashboard." BMC nephrology 20.1 (2019): 17.

Nayak, J. G., Hartzler, A. L., Macleod, L. C., Izard, J. P., Dalkin, B. M., & Gore, J. L. (2016). Relevance of graph literacy in the development of patient-centered communication tools. Patient Education and Counseling, 99(3), 448-454.

Sertkaya, A., Wong, H. H., Jessup, A., & Beleche, T. (2016). Key cost drivers of pharmaceutical clinical trials in the United States. Clinical Trials, 13(2), 117-126.

Sim, L. L. W., Ban, K. H. K., Tan, T. W., Sethi, S. K., & Loh, T. P. (2017). Development of a clinical decision support system for diabetes care: A pilot study. PloS one, 12(2), e0173021.

Toddenroth, D., Sivagnanasundaram, J., Prokosch, H. U., & Ganslandt, T. (2016). Concept and implementation of a study dashboard module for a continuous monitoring of trial recruitment and documentation. Journal of Biomedical Informatics, 64, 222-231.

Waller, R. G., Wright, M. C., Segall, N., Nesbitt, P., Reese, T., Borbolla, D., & Del Fiol, G. (2019). Novel displays of patient information in critical care settings: a systematic review. Journal of the American Medical Informatics Association, 26(5), 479-489.

Weiner, J., Balijepally, V., & Tanniru, M. (2015). Integrating strategic and operational decision-making using data-driven dashboards: the case of St. Joseph mercy Oakland hospital. Journal of Healthcare Management, 60(5), 319-330.

Appendix A, Table 1

Dr Alter System Snapshot

<table>
<tr><td colspan="6"></td></tr>
<tr><th colspan="3">Customers</th><th colspan="3">Products & Services</th></tr>
<tr><td colspan="3">• Project Managers
• Clinical Managers
• Project Specialists
• Project Oversight Directors
• Operational leadership</td><td colspan="3">• Data architecture that allows capture of data points from multiple source systems into an integration hub.
• Business intelligence tool (Qlik®) that visualizes data from the integration hub.
• Data dictionary that summarizes for users all data points, where the data came from, specified metrics and algorithms included in each view of the dashboard.
• ePremier Project Health dashboard.
• Support services in place with clearly defined pathway for requesting assistance.</td></tr>
<tr><th colspan="6">Major Activities or Process</th></tr>
<tr><td colspan="6">1. Technology project team visualizes data using business intelligence tool (Qlik®) for clinical trial team leads.
2. Project managers view graphical representations of project data to view progress and make strategic decisions.
3. There is no visibility into team members skills or proficiency with using data visualizations to make decisions.
4. The VLAT and a decision-making scenario using the IT solution will be used to measure a relationship between visualization literacy and decision-making.</td></tr>
<tr><th colspan="2">Participants</th><th colspan="2">Information</th><th colspan="2">Technologies</th></tr>
<tr><td colspan="2">• SVP Clinical Informatics
• Sr. Director, Data Analytics
• Director, Data Architecture
• Qlik Developer
• Sr. Director, Continuous Learning and Development
• Sr Analyst, Strategic Business Optimization</td><td colspan="2">Dashboard products:
• Project overview details including project summary, team list, financial summary, and key milestones
• Project timeline details including comparisons to contract and cycle time metrics related to key milestones.
• Site status details such regulatory submissions and site contract cycle times.</td><td colspan="2">• Software: Microsoft Power Point®, Adobe Captivate®, Articulate®
• Cornerstone® Learning Management System
• Webex® training platform
• Qlik® business intelligence tool
• Source systems: Clinical Trial Management System (CTMS) including study start up module, Electronic Data Capture system (EDC),</td></tr>
</table>

	• Enrollment details such as subjects screened, screen failed, enrolled, early termed, and completed. • Clinical quality details such as case report form status, query status, protocol deviations and open action items • Financial details such as work package progress, estimate to complete hours, revenue and project margin status.	Deltek® financial platform, SalesForce® • Data architecture and integration hub: WSO2® (Enterprise integration and message broker) • Okta® authorization and authentication technology (identity management)

Source :Steven Alter, *The Work System Method: Connecting People, Processes, and IT for Business Results*, Work system Press, 2006

Appendix B, Table 1

Project Charter

<table>
<tr><th colspan="2">Project Charter</th></tr>
<tr><td colspan="2">Enabling Effective Decision-making in the Complex Domain of Clinical Trial Management</td></tr>
<tr><th>Problem Statement</th><th>Benefit/Impact</th></tr>
<tr><td>The cost of a clinical trial is directly impacted by timeline resulting in wide acceptance that 80% of all clinical studies fail to finish on time, and 20% of these are delayed for six months or more (Nuttall, A., 2012).
delays are due to inaccurate or ineffective decisions made regarding process cycle times, patient recruitment or other key study metrics that study teams currently monitor to the best of their abilities.
A comprehensive, complete, and easy to access information summary tool at the project level does not exist.
Uncertainty regarding team competency in the synthesis and effective analysis of graphical health data visualizations could impact the effective of an information summary tool.</td><td>Data standards promoted
Collaborative decision-making across functions
Transparency into data processes
Transparency into data lineage: Improved data quality
Improved decision-making
Improvement in organization data literacy</td></tr>
<tr><th>Current Pain Points/Defects</th><th>Scope</th></tr>
<tr><td>Data quality is impaired due to lack of understanding of data lineage and point of entry systems
Clinical trial management team data literacy skills are inconsistent
Organization’s data structure is not well known by clinical trial management teams
Data quality is inconsistent across project teams</td><td>In Scope:
Develop and deploy a Project Health Dashboard including a data dictionary
Train/orient teams on use of the dashboard
Conduct assessments on data literacy and decision-making
Evaluate outcomes/make recommendations
Out of Scope:
Revision of existing training materials
Customization of dashboard by project
Change to existing organizational tools and equipment</td></tr>
</table>

Constraints and Boundaries	Risks
• Resource and time allocation of project team members • Cooperation from internal project teams • Revision of existing training materials	• Ongoing systems and data projects (ensuring harmonization across data ecosystem) • Organizational support for data literacy initiatives • Previously developed/implemented

Project Milestones		Core Team Members	
Milestone	Completion Date	Role	Name
Project Start	1 Sep 2019	Executive Sponsor/DHI Committee Member	COO
Internal Data Literacy Pilot Program	7 Jul-18 Dec 2020	Project Lead	SVP Clinical Informatics
Dashboard UAT	10-17 Dec 2020	Team Member A	Sr. Dir, Data Analytics
Dashboard in Production	25 January 2021	Team Member B	Sr. Dir, Continuous Learning
Evaluation and Update Dashboard, Create training	1 Feb-15 July 2021	Team Member C	SVP Biometrics
Dashboard Release	1 Aug 2021	Team Member D	Adaptive Clinical Partner
Study team selection	1 Aug-1 Sept 2021	Team Member E	Senior Specialist, Strategic Business Optimization
Administer assessments	Oct/Nov 2021		
Compile results	January-April 2022		
Report outcomes	Fall 2022		

Appendix C, Table 1

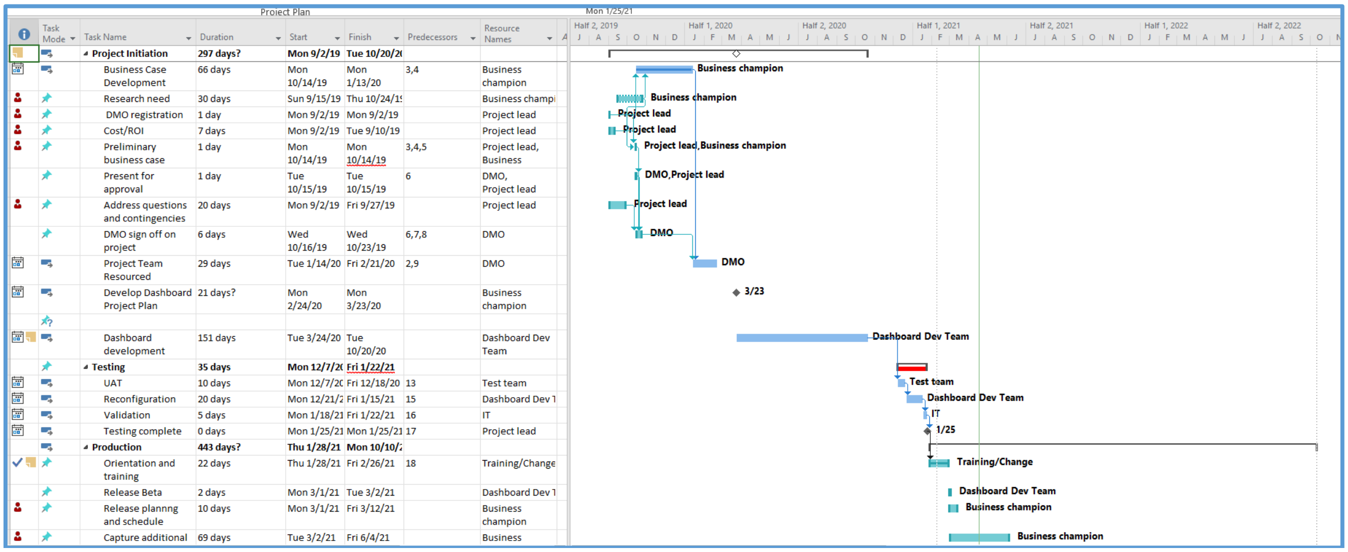
Requirements and Characteristics

Requirements and Characteristics

Number	Desired Functionality	Existing Functionality	Change New	Justification for the Desired Functionality	Stakeholders, Business Impacted	Priority
1	Data aggregation across multiple source systems	Manual aggregation using Excel® spreadsheets.	Change	Currently teams extract data from multiple source systems and transcribe that data into spreadsheets. The practice results in transcription errors, inefficiency, and non-standardized representation of the data.	Project Teams	High
2	Real time access to data for analysis	Although project teams can access individual data sets from multiple source systems, real time data displays require the continual manual extraction of data sets in order to refresh displays.	Change	Continuous manual extraction of the data and compilation of any data displays requires project hours that are not part of the project budget resulting in inefficiencies, budget overspends and team frustration/dissatisfaction with their role.	Project Teams	High

3	Consistent, standardized, visual representation of data sets	Currently each team creates their own graphic display of time, cost and quality data based on each team's expertise with creating displays in Excel®.	New	Teams are dependent on someone on the team having the ability to create charts and graphs within a spreadsheet. There is no standardization or verification that the displays are appropriate or include the correct data. Budget hours do not support these tasks.	Project Team, Clients	Medium
4	Transparency across the organization and with clients of project status	There is no common access for internal teams and leaders, or clients to a common, standardized display of project status.	New	Teams keep individual project information on separate drives accessible to only specific team members.	Project Teams, Organization Leaders, Clients	Medium
5	Support for a comprehensive training and orientation to the data and information displayed in the dashboards.	Team's abilities to access, analyze, interpret, argue and communication with data are largely unknown.	New	Clinical trial project team members do not receive standard data and informatics education and their experience with the use of data is inconsistent. There is a perception that data displays could expose team challenges.	Project Teams, Organization Leaders	High

Appendix D
Schedule Gantt Chart

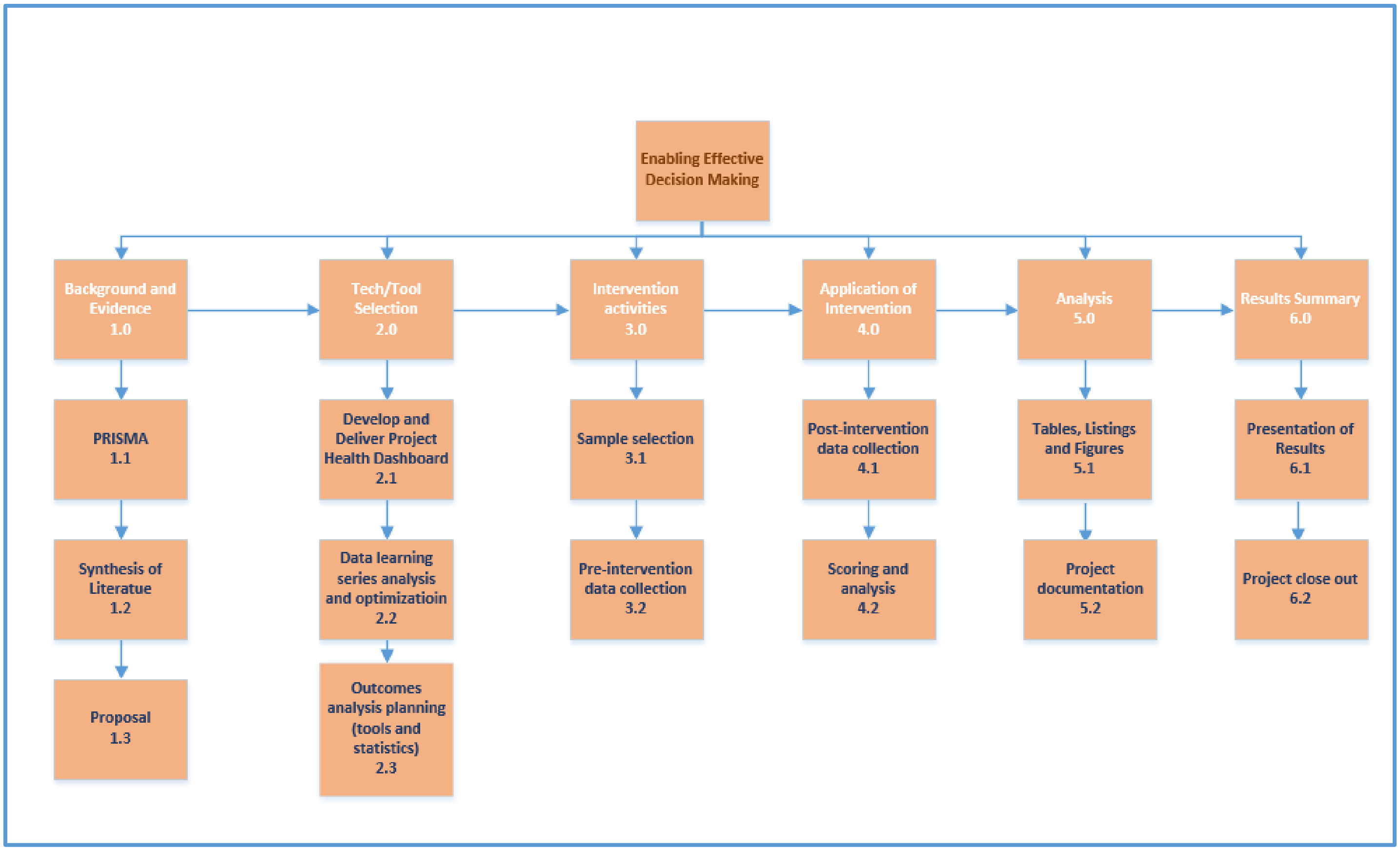


Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
	Project Initiation	**297 days?**	**Mon 9/2/19**	**Tue 10/20/2(**		
	Business Case Development	66 days	Mon 10/14/19	Mon 1/13/20	3,4	Business champion
	Research need	30 days	Sun 9/15/19	Thu 10/24/1!		Business champi
	DMO registration	1 day	Mon 9/2/19	Mon 9/2/19		Project lead
	Cost/ROI	7 days	Mon 9/2/19	Tue 9/10/19		Project lead
	Preliminary business case	1 day	Mon 10/14/19	Mon 10/14/19	3,4,5	Project lead, Business
	Present for approval	1 day	Tue 10/15/19	Tue 10/15/19	6	DMO, Project lead
	Address questions and contingencies	20 days	Mon 9/2/19	Fri 9/27/19		Project lead
	DMO sign off on project	6 days	Wed 10/16/19	Wed 10/23/19	6,7,8	DMO
	Project Team Resourced	29 days	Tue 1/14/20	Fri 2/21/20	2,9	DMO
	Develop Dashboard Project Plan	21 days?	Mon 2/24/20	Mon 3/23/20		Business champion
	Dashboard development	151 days	Tue 3/24/20	Tue 10/20/20		Dashboard Dev Team
	Testing	**35 days**	**Mon 12/7/2(**	**Fri 1/22/21**		
	UAT	10 days	Mon 12/7/2(	Fri 12/18/20	13	Test team
	Reconfiguration	20 days	Mon 12/21/2	Fri 1/15/21	15	Dashboard Dev 1
	Validation	5 days	Mon 1/18/21	Fri 1/22/21	16	IT
	Testing complete	0 days	Mon 1/25/21	Mon 1/25/21	17	Project lead
	Production	**443 days?**	**Thu 1/28/21**	**Mon 10/10/2**		
	Orientation and training	22 days	Thu 1/28/21	Fri 2/26/21	18	Training/Change
	Release Beta	2 days	Mon 3/1/21	Tue 3/2/21		Dashboard Dev 1
	Release plannng and schedule	10 days	Mon 3/1/21	Fri 3/12/21		Business champion
	Capture additional	69 days	Tue 3/2/21	Fri 6/4/21		Business

Note that the full and complete project Gantt chart is available outside this document in MS Project for the Project Manager and project team use.

Appendix E, Table 1

Table 4, Work Breakdown Structure: Enabling Effective Decision-making in the Complex Environment of Clinical Trial Management



Appendix F, Figure 1

Proposed Total Cost of Ownership

Premier Research
Enabling Effective Decision Making
Proposed 5 Year Total Cost of Ownership (TCO)
2021-2025

Vendor Cost	One-time Fees	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Licensed Software	$ 1.00	$ 1.00	$ 1.05	$ 1.10	$ 1.16	$ 1.22	$ 6.53
Sublicensed Software	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Subscriptions	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Professional Fees	$ 1.00	$ 1.00	$ 1.05	$ 1.10	$ 1.16	$ 1.22	$ 6.53
Remote Hosting Fees	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Installation Fees	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Support/Maintenance Fees	$ 1.00	$ 1.00	$ 1.05	$ 1.10	$ 1.16	$ 1.22	$ 6.53
Go-live Support Fees	$ 1.00	$ 1.00	$ 1.05	$ 1.10	$ 1.16	$ 1.22	$ 6.53
Travel/Hotel to Client Site	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Other Fees	$ 1.00	$ 1.00	$ 1.05	$ 1.10	$ 1.16	$ 1.22	$ 6.53
Organizational Cost	**One-time Fees**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Hardware	$ -	$ 50,353.00					$ 50,353.00
Build/Backfill Team	$ -	$ 97,250.00					$ 97,250.00
Go-live Support Team	$ -	$ 9,500.00					$ 9,500.00
Training Materials	$ -	$ 7,900.00					$ 7,900.00
Travel/Hotel to Vendor Site	$ -	$ -					$ -
Other	$ -	$ 1.00					$ 1.00
Vendor Total	$ 5.00	$ 5.00	$ 5.25	$ 5.51	$ 5.79	$ 6.08	$ 32.63
Organizational Total	$ -	$ 165,004.00	$ -	$ -	$ -	$ -	$ 165,004.00
Taxes	$ 0.41	$ 13,613.24	$ 0.43	$ 0.45	$ 0.48	$ 0.50	$ 13,615.52
Grand Total	$ 5.41	$ 178,622.24	$ 5.68	$ 5.97	$ 6.27	$ 6.58	$ 178,652.15

Figure 1. Proposed 5-year total cost of ownership for the Visualization Literacy and Decision-making project.

Appendix F, Figure 2

Cost Sheet

Estimated Cost Breakdown			
Hardware/Software	**Quantity**	**Unit Cost**	**Total**
Computer	1200	$ 0.01	**$ 12.00**
Qlik®(BI software)	1	$ 50,341.00	**$ 50,341.00**
Sub Total	**1200**	**$ 0.01**	**$ 50,353.00**
Dashboard build team	**No. of Required Build Hrs**	**Rate per hr**	**Total**
Sr. Director, data analytics	150	$ 50.00	**$ 7,500.00**
Data architect	250	$ 50.00	**$ 12,500.00**
Qlik developer 1	575	$ 30.00	**$ 17,250.00**
Qlik developer 2	350	$ 30.00	**$ 10,500.00**
Database programmer	100	$ 50.00	**$ 5,000.00**
Project Mgr	800	$ 50.00	**$ 40,000.00**
Business support	150	$ 30.00	**$ 4,500.00**
Sub Total	**2375**	**$ 290.00**	**$ 97,250.00**
Go-live Support	**No. of Support Hrs**	**Rate per hr**	**Total**
Project Manager	50	$ 30.00	**$ 1,500.00**
IT	100	$ 50.00	**$ 5,000.00**
Sr. Dir Data Analytics	10	$ 50.00	**$ 500.00**
Data Architect	50	$ 50.00	**$ 2,500.00**
Sub Total	**210**	**$ 180.00**	**$ 9,500.00**
Training/Materials	**No. of Materials**	**Rate per hr**	**Total**
Powerpoint live orientation	5	$ 30.00	**$ 150.00**
Training guide/video instruction	50	$ 30.00	**$ 1,500.00**
Assessments and analysis	75	$ 250.00	**$ 18,750.00**
Sub Total	**130**	**$ 310.00**	**$ 20,400.00**
Travel/Hotel	**No. of Persons/Items**	**Unit Cost**	**Total**
Airfare	0	$ 400.00	**$ -**
Hotel Nights (5 days, 2 per room)	0	$ 150.00	**$ -**
Meals per day (5 days x no of per	0	$ 65.00	**$ -**
Other	0	$ 30.00	**$ -**
Sub Total	**0**	**$ 645.00**	**$ -**

Figure 2. Estimated cost breakdown for the *Visualization Literacy and Decision-Making* project.

Appendix G, Table 1

Stakeholder Matrix

Tier 1 Stakeholders Senior Leaders and Key Decision Makers		
Ensuring project feasibility	**Name of person/group**	**Why exactly is this person/group important?**
<u>Funding Support</u> Project Management Clinical Management Continuous Learning and Development Operational Leadership Team	• Senior Vice President, Project Management, • Project Oversight Directors • Senior Vice President Clinical Data Sciences • Clinical Managers • Chief Operating Officer • Senior Vice President Biometrics • Vice President Study Start Up • Senior Director Continuous Learning	• Has direction and oversight of the primary users of the technology and tool. Team is frustrated with workload and manual tasks involving data. • Have oversight of primary users of the technology/tool. • Has direction and oversight of secondary users of the technology/tool. Has recently reorganized her team and is seeking data education for users. • In the same boat as project managers. • Concerned about performance across operations and client perception of skills, abilities and progress with data and technology. Is on DHI committee. Is supervisor of DHI student. • Part of EOC for several clients and is concerned about numeracy and data literacy skills and abilities of team members. • Team is responsible for primary data entry in source

	• Chief Information Officer	systems included in the data ecosystem of the dashboard. • Leads recruitment and retention initiatives and is focused on data learning and development as part of the plan. • Responsible for the data analytics team including the data architect and Qlik developer as well as the DMO. Would like to see his team deliver services to the organization that make company more competitive and the preferred vendor for clients.
<u>Provision Resources</u> Chief Information Officer SVP, Project Management Chief Operating Officer Delivery Management Organization	• CIO • SVP PM • COO • Sr. Director DMO	• Has authority to provide/approve internal resources to project • Has authority to provide/approve internal resources to project • Has authority to provide/approve internal resources to project • Has the authority to assign internal resources to the project
<u>Go/No-go Decision</u> Chief Operation Officer Delivery Management Organization	• COO • DMO oversight committee	• Has decision-making authority regarding project status • Has oversight of project and program portfolio. Makes recommendations based on

		budget, priority ranking, and overall project progress.
<u>Remove Obstacles and Barriers</u> Chief Operating Officer Chief Information Officer Executive Project Champion	• COO • CIO • SVP PM	• Has the formal authority to make go/no-go project decisions. Has influence over other stakeholders. • Has authority of project team members prioritization of tasks and resourcing. • Has informal authority over project team and initiative. Has influence with COO.
<u>Approve/sign-off on deliverables</u> • SVP, Clinical Informatics	• SVP Clinical Informatics	• Has authority to approve/sign-off on deliverables
<u>Build additional senior level political support</u> SVP, PM Chief Operating Officer SVP, Clinical Data Sciences SVP, Biometrics Sr. Director, Continuous Learning	• SVP PM • COO • SVP Clinical Data Sciences • SVP Biometrics • Sr. Director, Continuous Learning	• Has a strong relationship with other senior leaders. Oversees second largest group driving corporate revenue. Has strong relationship with CEO. • Is member of the executive leadership team. Has influence with CEO, CMO and CHRO. • Has a good reputation and strong relationship with other senior leaders. Oversee the largest group driving corporate revenue. • Has a good reputation for client management, team management, statistical knowledge, and continuous learning support. Has influence over other senior leaders. • Drives the organizations continuous learning plan. Is responsible for engagement and retention initiatives. Has a

		strong relationship with CEO and COO.
Other senior leaders and key decision makers who can have an influence on the project Chief Commercial Officer	• Chief Commercial Officer	• Is continuously pushing the organization to be more competitive in the industry. Wants dashboard and data analytics that are the same or better as competitors. Wants to be able to use dashboards with clients. Wants transparency into work progress and management for clients.
Tier 2 Stakeholders **Project Contributors**		
Ensuring the quality of deliverables and activity execution:	**Name of person/group**	**Why exactly is this person/group important?**
Project Resource Location Delivery Management Organization Project Management Operational Leadership Team	• DMO • SVP PM • SVP Clinical Informatics • Sr. Director Continuous Learning	• Has the authority to assign and reassign certain employees based on performance and need. • Has the authority to assign and reassign the business owner and staff for business requirements collection. • Has the authority to request project changes, project resources, and assign team for training and change management. • Has the authority to assign staff for training development and management of assessments, LMS processes, and training delivery.

<u>SME location</u> Delivery Management Organization Data Analytics Project Management Clinical Informatics	• Sr. Director, DMO • Sr. Director, Data Analytics • SVP PM • SVP, Clinical Informatics	• Oversees the resources needed for the project management. • Oversees resources that have skills in data architecture and dashboard development. • Has resources that are critical to development of business user requirements. • Has skills in data strategy and understands connections with project and other data analytics initiatives. Has experience and skills in intended end user groups.
<u>Training Support and Competency Development</u> Continuous Learning	• Sr. Director, Continuous Learning	• Manages the corporate training department. Collaborates with HR on competency development and position profiles.
<u>Project Communications</u> Continuous Learning DMO Clinical Informatics	• Sr. Director Continuous Learning • Sr. Director DMO, SVP Clinical Informatics	• Has authority over company wide notifications involving training and development. • Has authorization to distribute messaging from IT to organization. • Has team members who can support development of communications, sharepoint site, training development and messaging around project progress.
<u>Post Deployment Support</u> Information Technology Project Management	• Information Technology, Technical Assistance Team • Sr. Director PM	• Controls help desk. Has triage plan for source system trouble shooting. • Will be business owner post deployment. Will work with data analytics team to manage future releases and bug fixes.

Tier 3 Stakeholders Recipients		
Areas where people/groups may be impacted:	**Name of person/group**	**Why exactly is this person/group important?**
<u>Intended Audience</u> Project Management Clinical Data Science	• Project managers, Project oversight directors and project specialists • Clinical team leads • Clinical data leads	• The initiative will require a change to how all these people/groups work. • Process changes in how data is accessed, aggregated, and presented will occur for each of these groups. • New or enhanced data skills will be necessary to maximize the effectiveness of the tool.
<u>Secondary Effects</u> Biotech clients Finance Commercial Development	• Biotech Clients (multiple) • Project financial analysts • Business Development Directors	• Biotech clients will ultimately have access to their study dashboard creating transparency into project processes. • Financial displays in the dashboard will provide information to project teams with the intent of improving project financial management. • Business Dev Directors will have the opportunity to present improvements in data and data displays as a selling point to new and existing clients.

Appendix G, Table 2 SWOT Analysis

Problem Statement
Added complexity in clinical trials has resulted in an increase in the cost of an individual trial. Improved decision-making on behalf of a clinical trial team could effectively improve management of the costs and accelerate the timeline of drug development. A comprehensive, complete, and easy to access information summary tool could support collaborative decision-making. Team competency in the synthesis and effective analysis of data visualizations could impact the effectiveness and intended use for decision support of the information summary tool.

INTERNAL FACTORS	
STRENGTHS (+)	WEAKNESSES (-)
• Internal expertise in data architecture, data analytics, and production of data visualizations. • Hardware and software necessary for the project is available internally. • Continuous learning department has a vested interest in improving employee data visualization skill sets. • Commercial development is eager for the launch of a tool that will improve competitive advantage. • Executive leadership support for the project. • Data learning is viewed as an opportunity for staff that may result in retention gains. • Marketing department is eager to provide support for data initiatives due to fierce competition across the industry for expertise in health data management. • Project lead has experience and expertise in both the end user roles and the tech team processes.	• Resources are extremely stretched with the volume of projects and deliverables for the next year. • Modifications to processes due to COVID has resulted in competition across internal teams for project resources as well as SMEs. • Restrictions over which systems can support the dashboard are in place due to API access and permissions resulting in data gaps for the dashboard. • Data numeracy, graphical, and visualization skill sets are not uniform across the board in intended end users. • Specific data competencies do not yet exist as part of position profiles. • Internal competition for attention can result in misplaced intentions around competing initiatives. • Competing project launches could result in overload of change expectations for project teams.

EXTERNAL FACTORS	
OPPORTUNITIES (+)	THREATS (-)
• Clients are interested in transparency around project processes. • Clients are interested in acceleration of project timelines and cost control. • COVID has accelerated the desire for remote data capture and analysis with transparency across teams. • Interest across the industry results in opportunity for socializing the project through publications and presentations.	• Competitors have launched various versions of dashboards over the last few years. • Large competitors have advanced data organizations allowing them to accelerate improvements in their data capabilities. • Competition for resources is fierce across the industry. • COVID has resulted in the loss of resources necessary to support trial success across the industry. • Clients have the same gaps in data literacy as internal teams. • Competitors will hire away our staff who develop advanced competency with data.

Appendix H: Return on Investment (ROI) / Cost-Benefit Analysis

The original cost of the project as estimated in the Project Management Plan (see plan for greater detail) was approximately $177,000 with break down in costs as follows:

Cost Breakdown	
Hardware/software	50,353.00
Dashboard build team	97,250.00
Go-live support	9,500.00
Analysis/training/materials	20,400.00
Travel/Hotel	0.00
Total	**177,503.00**

The costs for the project were closely managed and accurately represented except for the addition of statistical services to support the assessment analysis which added an additional $5,000.00 to the project costs.

Opportunity costs such as loss of new opportunities, clinical trial project overspends, and system and data integration for clinical trial projects was estimated as a missed opportunity total value of $130M. These costs are an example of what might be incurred by mid-size global organization of the type represented in this project but are not exact due to the organization's status as a private entity that does not publicly disseminate exact cost and revenue estimates. Additional costs to not doing the project included tangible assets such as training and onboarding staff due to turnover and intangible assets such as moral, motivation, frustration, job dissatisfaction, and brand damage. The tangible and intangible asset costs were estimated to add an additional $350,000/yr.

The benefits of doing the project were projected to include an increase in sales and repeat business, increased employee morale, development of a competitive advantage, improved decision-making and continuous improvement, process inefficiencies and a reduction in development time. These benefits are challenging to measure but can be conservatively estimated at $51M.

Comparing the two categories of costs along with the benefits assessment results in an extremely large and likely erroneous return on investment (return /costX100). A challenge is that both the costs and benefits noted in this plan would be difficult to associate solely with the project and are most likely a combination of both controllable and uncontrollable factors leading to either a positive or negative outcome.

Project Return on Investment (ROI)	
Opportunity costs	$130M
Benefits	$350K/yr
Estimated project cost	$177.503.00

Appendix I: Visualization Literacy Assessment Test

The Visualization Literacy Assessment Test was used by permission from the study authors and can be accessed in its entirety by using the links embedded in the permission.

From: Sung-Hee Kim
To: Stacy Weil
Subject: Re: Visual Literacy Assessment Test
Date: Saturday, March 6, 2021 10:35:25 PM

EXTERNAL: This email originated from outside of our organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Stacy,

Thank you for contacting us. I am sending this email on behalf of Sukwon, the first author. We would be happy to share our research with you.

Here is a link to VLAT webpage (https://www.bckwon.com/publication/vlat/), that was developed by one of the co-authors, Bum Chul Kwon. You can download "problem sets" and "answer sets" separately. There, you'll be able to read the questionnaire we used for the paper.

The online version hosted on Heroku was developed to make the test more visible for other researchers and practitioners, and it has some adaptation from the original one we used for evaluation. For instance, the online version has 60 questions, but the original has 53.

There has been a modified version of VLAT being used for other studies, including our follow-up study (https://www.bckwon.com/publication/cogvislit/).

We are happy to share our work with you. Please refer to our publication when used in manuscripts or other presentations.
Feel free to contact us if you have further questions.

Regards,
Sung-Hee Kim

Appendix J: Subjective Numeracy Scale

Cognitive abilities (1=not at all good, 6=extremely good)

1. How good are you at working with fractions?

2. How good are you at working with percentages?

3. How good are you at calculating a 15% tip?

4. How good are you at figuring out how much a shirt will cost if it is 25% off?

Preference for display of numeric information

5. When reading the newspaper, how helpful do you find tables and graphs that are parts of a story? (1=not at all, 6=extremely)

6. When people tell you the chance of something happening, do you prefer that they use words (‘‘it rarely happens’’) or numbers (‘‘there’s a 1%chance’’) (1=always prefer words, 6=always prefer numbers)

7. When you hear a weather forecast, do you prefer predictions using percentages (e.g., ‘‘there will be a 20% chance of rain today’’) or predictions using only words (e.g., ‘‘there is a small chance of rain today’’)? (1=always prefer percentages, 6=always prefer words)

8. How often do you find numerical information to be useful? (1=never, 6=very often)

(Faegerlin et al, 2007)

Appendix K: Decision-making Assessment

The clinical trial oversight process requires that you attend pre-defined Stage Gate reviews where decisions are made about proceeding to the next gate and/or solutioning project challenges.

You are reviewing a trial that is scheduled for Stage Gate III (25% Subjects Enrolled Scheduled). The decision for passing this stage gate is defined as "On track for LPI (Last Patient In)". In addition, some of the key events reviewed to support the decision include:

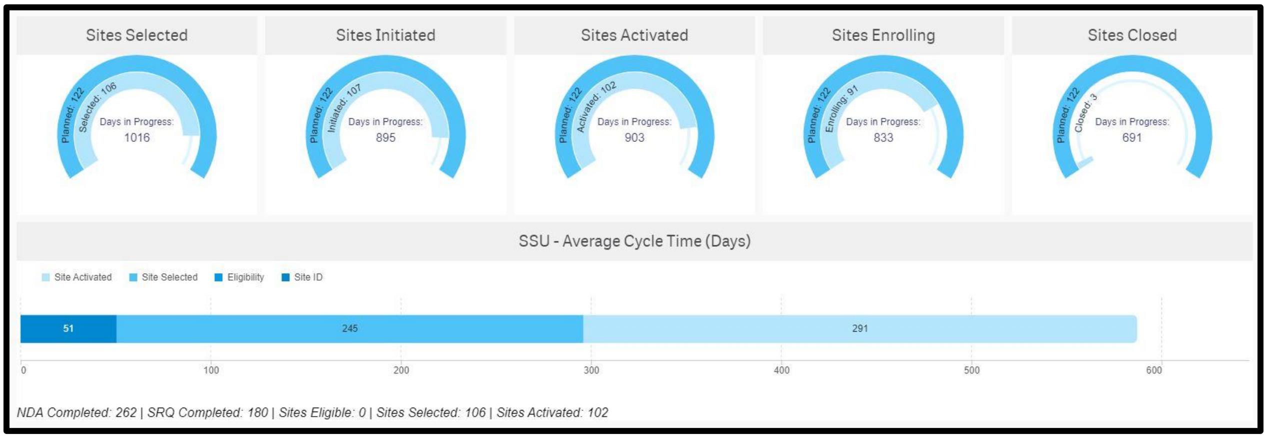
- Assess site ID, selection and activation to ensure that it supports enrollment targets.
- Assess enrollment trends.
- Quality assessment including protocol deviations and open action items.
- Financial health of the project

The process for passing Stage Gate III specifies that if the exit criteria is not met, the PM must provide a strategy to get the project back on track.

Your decision will be based on the following data.

The project timeline trend represented shows that the first missed milestone occurred at:

A. First site activated
B. All sites activated
C. 75% of sites activated
D. 25% of subjects enrolled
E. All the above
F. None of the above



The site activation graphic shows that the cycle time for site activated is:

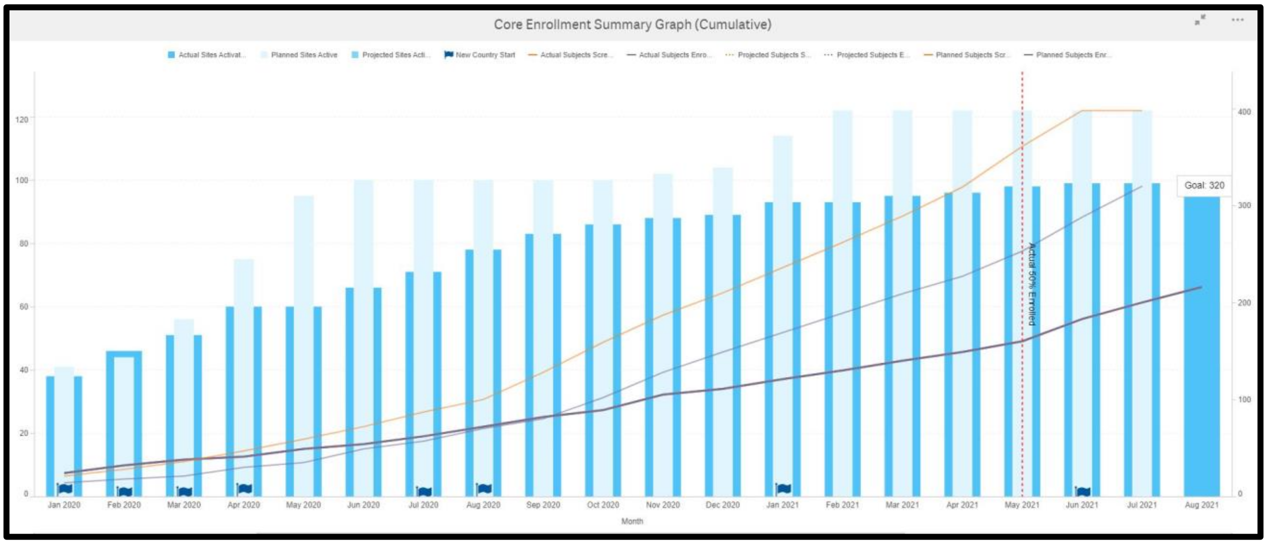
A. The longest part of the cycle
B. The shortest part of the cycle
C. The same as site ID
D. The same as site selected
E. All the above
F. None of the above

Approximately what percentage of sites selected have been activated:

A. 26%
B. 97%
C. 52%
D. 76%

According to this graphic all sites have enrolled a subject:

A. True
B. False



Comparing the planned to actual enrollment dates, at the time when 50% of the subjects were "actually" enrolled was the timeline on target?

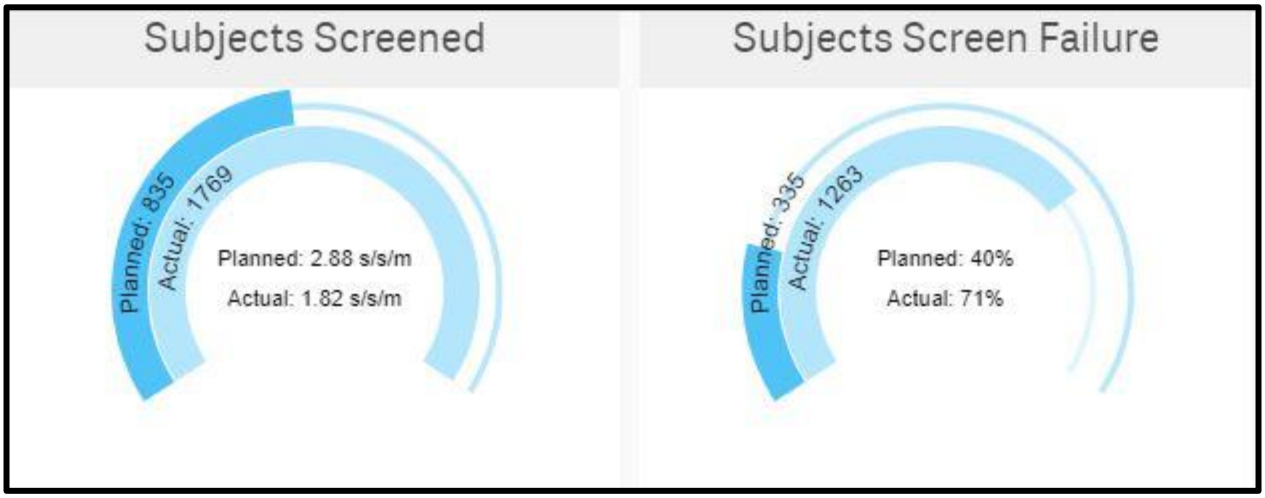
A. Yes
B. No

When 50% of the subjects were actually enrolled, how far above or below the 50% enrolled target (planned) were the enrolled subject numbers?.

A. The total enrolled is 90 subjects above the actual planned
B. The total enrolled is 90 subjects below the actual planned
C. The total is 270 above the actual subjects planned
D. The total is 270 below the actual subjects planned
E. It is not possible to tell from this graph

According to the graph the last patient in will be achieved by July 2021:

A. True
B. False

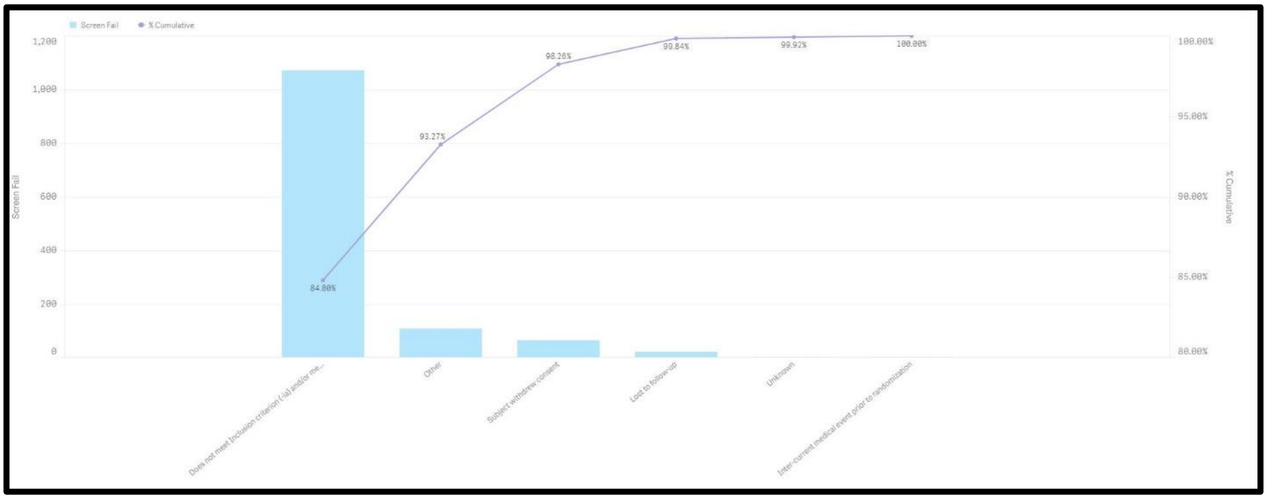


According to the screening information shown here:

A. Less subjects have been screened than planned.
B. Almost twice as many subjects have been screened as planned.
C. Almost four times as many subjects have been screened as planned.
D. It's not possible to tell from this graph how many subjects have been screened.

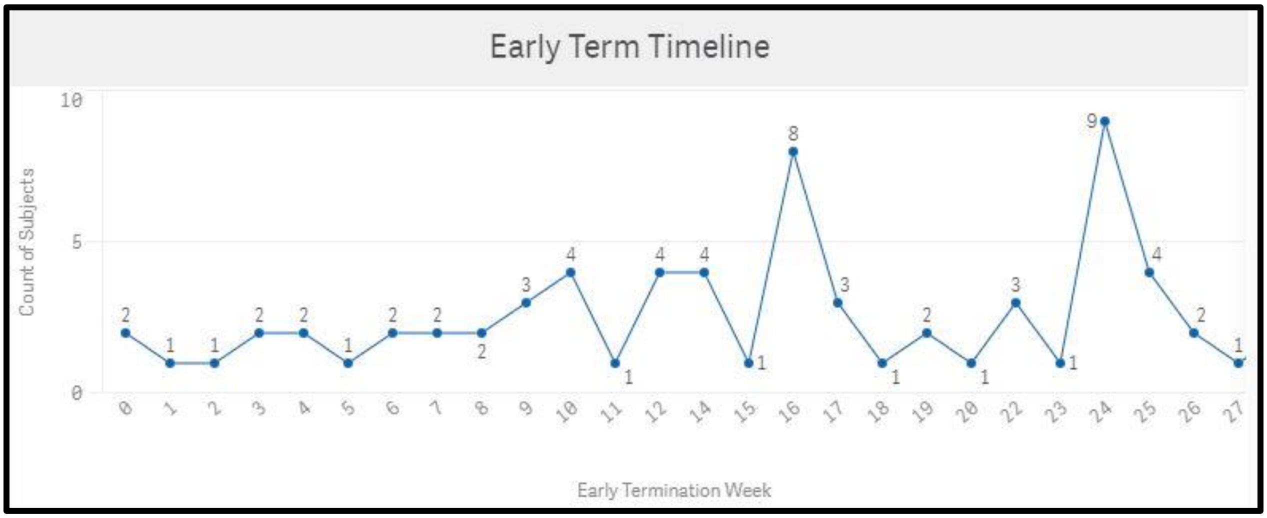
According to the screening information show here:

A. Less subjects have screen failed than were planned.
B. Almost twice as many subjects have screen failed as were planned.
C. Almost four times as many subjects have screen failed as planned.
D. It is not possible to tell from this graph how many subjects have screen failed.



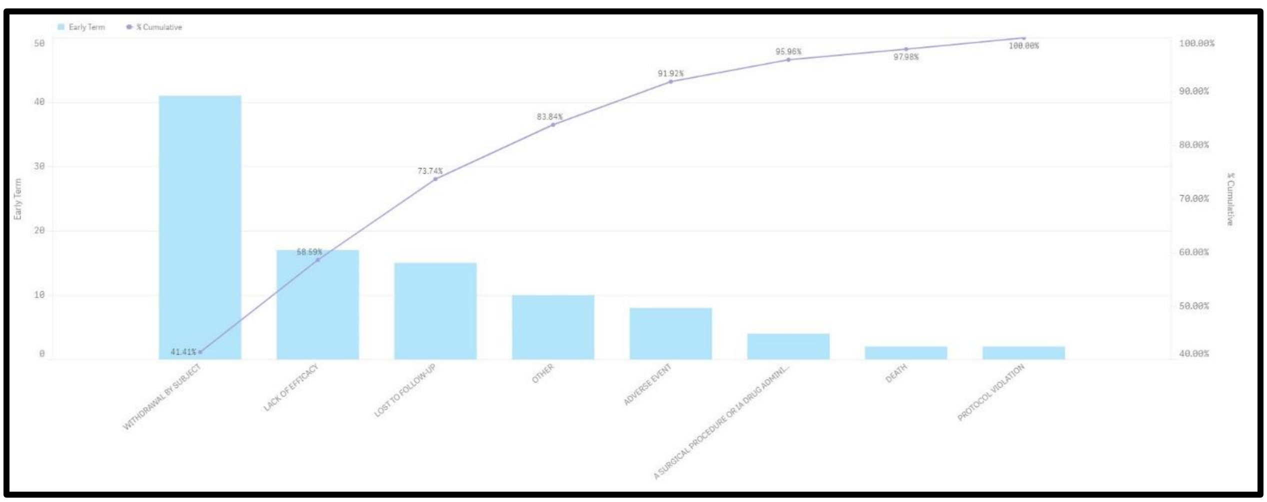
According to the above graphic, the most effective way to address screen failures at this point is:

A. Recommend putting the study on hold
B. Recommend adding more sites
C. Recommend advertising for more subjects
D. Recommend modifying one or more of the protocol inclusion/exclusion criteria
E. All of the above
F. None of the above



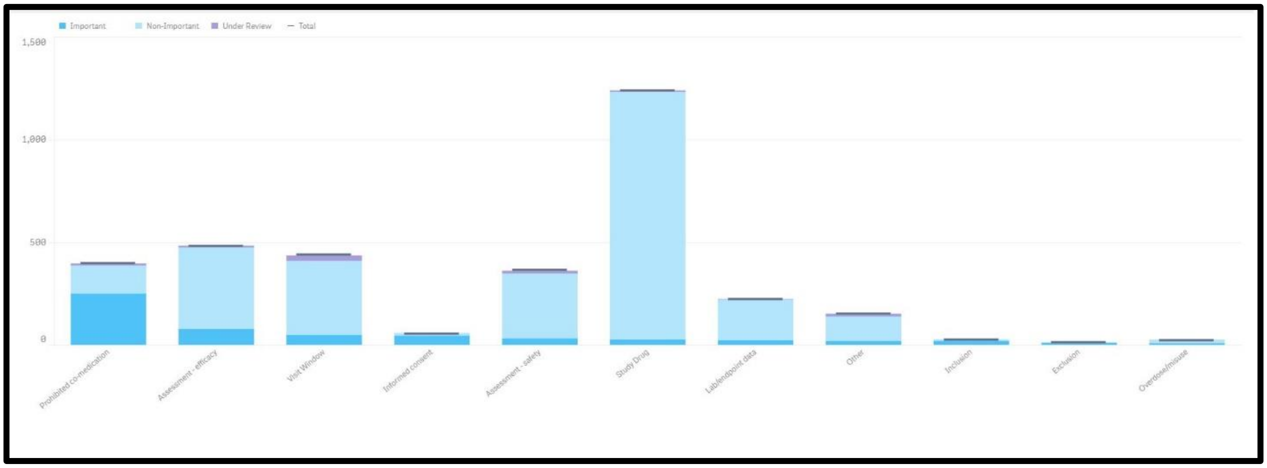
According to the early term timeline:

A. Most subjects leave the study within the first two weeks.
B. Early terminations have increased at weeks 16 and 24
C. Increases in early terminations have occurred between weeks 17 and 18.
D. All of the above
E. None of the above



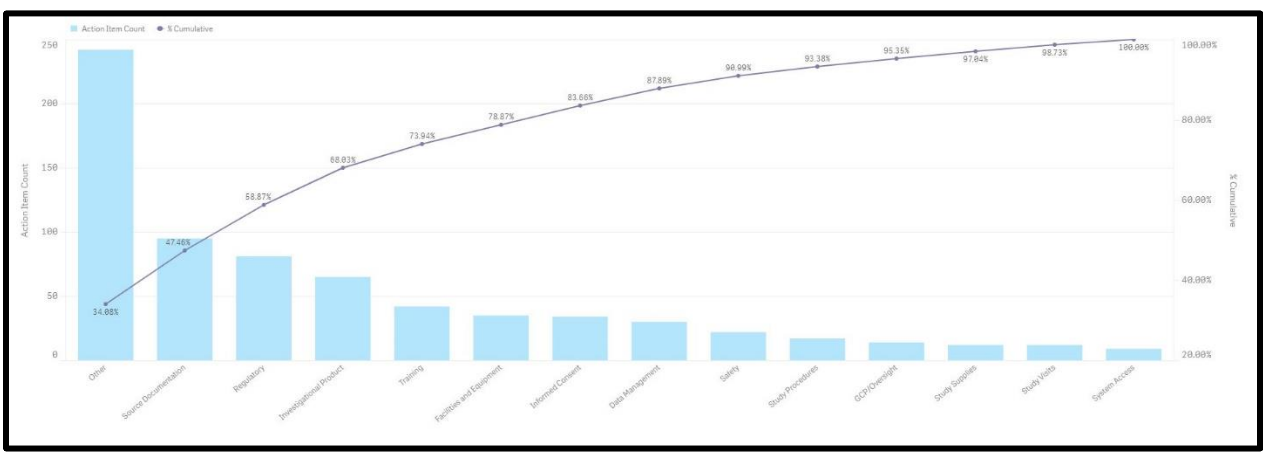
The reasons for early termination that make up ~80% of the total are:

A. Adverse event, death, lost to follow up, protocol violation
B. Withdrawal by subject, lost to follow up, other, protocol violation
C. Withdrawal by subject, lack of efficacy, adverse event, protocol violation
D. Withdrawal by subject, lack of efficacy, lost to follow up, other



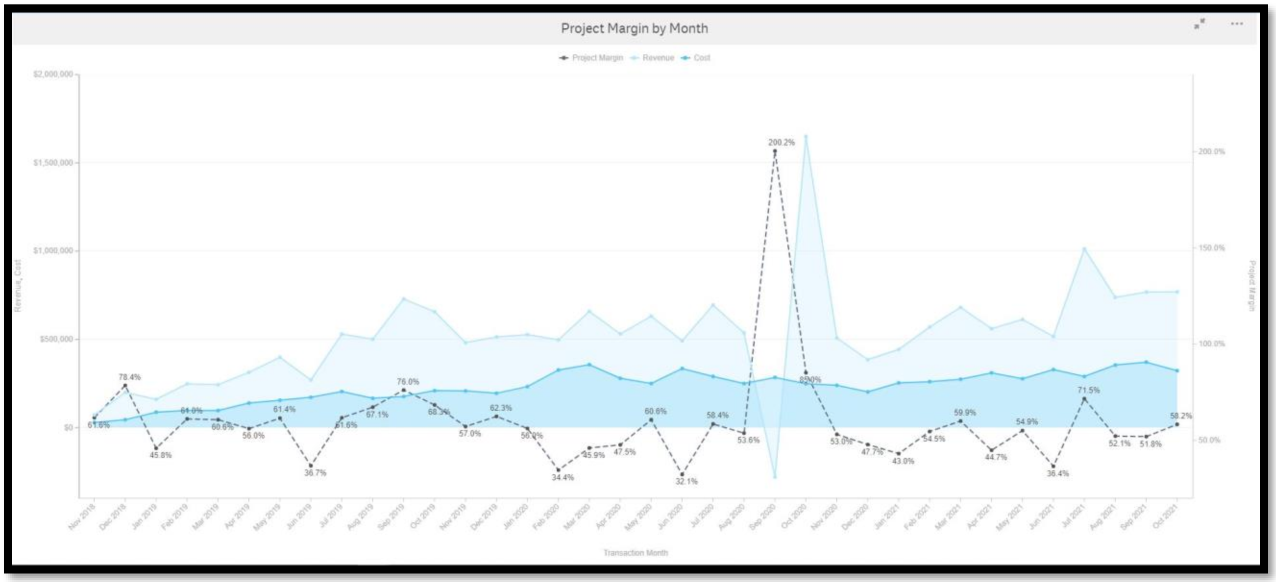
In descending order, the three most common important protocol deviations are:

A. Study drug, assessment-efficacy, visit window
B. Prohibited con med, visit window, assessment-efficacy
C. Study drug, assessment-efficacy, assessment-safety
D. Prohibited con med, assessment-efficacy, visit window



The first three action item categories account for approximately what number of items total?:

A. 250
B. 100
C. 400
D. 20



What is the longest number of consecutive months that the project margin drops below 50%?

A. 3
B. 16
C. 10
D. 2
E. It is not possible to determine

Realization % by Department / WP – Details

Role Department	Actual Hrs	Budget Hrs	EAC Hrs	Realization %
Totals	130,013.0	179,143.0	214,742.7	
RMQ	165.0	0.0	1,133.1	0.00%
CAD	42.0	0.0	42.0	0.00%
PCV	4,965.8	3,703.2	10,229.6	36.20%
MSD	4,158.5	4,029.4	5,872.3	68.62%
CMS	36,358.8	60,492.7	74,799.7	80.87%
CMG	19,878.0	28,593.8	34,429.7	83.05%
DMD	11,482.8	14,708.5	17,640.8	83.38%
STA	10,344.8	10,094.2	12,009.9	84.05%
SSU	24,110.0	23,195.8	25,587.1	90.65%
PMD	15,001.8	21,688.2	22,585.6	96.03%
IFM	1,274.5	3,563.5	3,568.2	99.87%
MWD	216.8	784.2	747.6	104.90%
DOC	1,571.5	5,586.8	5,251.2	106.39%
QAR	431.3	764.2	632.5	120.83%
FIN	3.3	552.3	183.0	301.81%
IRT	8.5	320.1	28.1	1139.10%
INF	0.0	551.4	0.0	-
REG	0.0	514.6	2.2	-

Considering estimate to complete hours, how many functions that had hours planned in the budget are expected to exceed their budgeted hours by more than 50%?

A. 13
B. 5
C. 1
D. 10
E. It is not possible to determine that from this graph

The PM has presented no additional information beyond the graphics you have reviewed.

Based on the information you have reviewed you decide that the study would:

A. Pass Stage Gate III
B. Not pass Stage Gate III

The conclusion (s) that you come to based upon a review of the information included is/are (select all that apply):

A. The study is under resourced.

B. The study is on track and meets expectations for time, cost and quality.

C. The study has enrollment challenges that should be investigated further.

D. A meeting with the client should be scheduled to discuss the high screen failure rate in relation to subjects withdrawing consent.

E. The study should immediately be put on hold until further information is gathered.

F. The early termination trends along with reasons for early termination should be brought to the attention of the team for discussion.

G. More advertising support should be added to ensure that enough subjects get enrolled in the study.

H. The number and type of protocol deviations and action items are routine and standard for a clinical trial and therefore are not of concern currently.

I. Verification of a change order for additional investigator grant funds should be obtained.

Appendix L: Instructions to Participants

Participant Instructions

Introduction

As part of a Doctoral Program in Health Informatics through the University of Texas Health School of Biomedical Informatics I am conducting a project examining the value of data visualizations in support of the decision-making process in healthcare. More specifically, I am interested in whether an ability to interpret data visualized in commonly used informatics tools can impact the decision-making process.

Data Anonymization

If you choose to participate, your participation on this project will be pseudonymous. You will be assigned a number to use during the process, rather than your name, each time you access the project assessments. All access to the project including data collection will be electronic and will use validated technology to capture and aggregate project data. To verify the integrity of the data and that a complete data set is obtained, it is important to be able to demonstrate that each person is assigned a number and each person uses that number to complete the project. Therefore, one project team member will have access to the master key. That person is the project Statistician. The project is being performed in a pseudonymous way to prevent the use of your answers on the assessments from being used for an evaluation of your work performance. Your information and responses will not be shared with your supervisor, work colleagues, or others in an identifiable manner.

Description of assessment

If you choose to participate you will be asked to complete a series of assessments related to health data visualizations. The assessments involve showing you a graphic depiction of a set of health data and then asking a series of questions related to what you see. Parts of the assessment will involve numbers and other parts of the assessment will include your visual impression of a graph. Part of the assessment will appear novel to you while other parts will include familiar data graphics that you use on a regular basis during your work at Premier Research.

There will be a time limit for completing the assessments and your access will be terminated when the time limit is reached. The assessments employed during this project have been previously validated for the purpose used during this project. The assessments will be available to you 24 hours a day for a period not to exceed two weeks. You can expect your participation in this process not to exceed 2 hours total. It is not required that you take all the assessments at the same time or day. There will be a total of 4 assessments that you will take during this project.

(Cont.)

Expected outcomes

The results of this project are expected to support the following outcomes that relate to Premier Research and the clinical trial industry's business objectives:

- The continuous improvement and development of useful and usable data visualizations.
- Targeted training solutions focused on addressing the use of technology and data in the clinical trial industry.
- The development of role specific competencies related to the interpretation and use of clinical trial data.

By participating in this project your consent to the use of your pseudonymized data to determine project outcomes is implied.

Appendix M: Participant Information

Participant Information

Please select your function and job title/role

Function: Project Management

Medical Monitoring

Job title/role: Associate Project Manager

Project Manager-Senior Project Manager

Associate Project Director-Senior Project Director

Vice President and above

Clinical Scientist I- Clinical Scientist II

Medical Monitor I- Sr. Medical Monitor

Medical Director I- Sr. Medical Director

Executive Director and above

In what region do you live?

Asia Pacific

Europe

North America

Other (Please specify)

How many years have worked in the industry?

< 1

1-5

6-10

11-15

15 or more

How long have you worked at Premier Research?

< 6 months

6 months- 1 year

1-3 years

4-6 years

7-10 years

10 years or more

How long have you worked in your current role?

< 1 year

1-3 years

4-6 years

7-10 years

More than 10 years

What is your highest level of education?

Did not finish high school

High school diploma/GED

Some college/no degree

Associate degree

Bachelor's degree

Master's degree

Doctorate

Professional degree (ex. MD, DDS, JD)

Your post high school degree included data, analytics, informatics or technology education

Yes

No

Not applicable

Is the interpretation of data an expectation for your role?

Yes

No

I don't know

I use data visualizations to make decisions

Never

Rarely

Sometimes

Regularly

Always