Chapter 7

Summary and Conclusions

The findings and facts observed in the aforementioned chapters/studies emphasized the importance of proper operational and decisional approaches to ensure the targeted timelines, quality and costs. There is a correlation between customer demands and these variables. The relationship between these variables is well described. However, an approach as it relates to activity-based management for a clinical trial study is not generally explored. As described in aforementioned chapters, clinical trial is a part of the drug development value-chain to market new drug entities with urgency for speed, at maximum profits. They operate in an environment where the characteristics of speed and quality in performance determine the competitive edge of the company. These characteristics, however, correlate with costs and price because both can only be attained at a cost to the company and that cost needs to be contained.

The aim of the chapter a rational approach to clinical research: critical path analysis was to describe the time and activity results obtained through the research of the objectives set in this chapter and to make recommendations based on the findings, which was presented as a rational approach finally. The study results were depicted as summarized tables and figures with brief discussions.

The other two investigations in the chapters a rational approach to clinical research: Meta analysis of the research explores the design and analytic approaches in the clinical trial studies so that a clear cut hypothesis and best answer can be summarized in a conclusive information and decision can be easier for the decision maker. The methodology followed in this research to present the results in a descriptive analytical, textural context as well as statistically.

In the chapter rational approach to clinical research: Interim analysis the investigational study was one of the case studies where our research team took the decision for the trial continuation based on specified stopping rules. For the purpose of this thesis, the aim of constructing rational approaches with which the pharmaceutical company intends to profit from its broad array of processes and activities was achieved.

The results indicated that project mutation, i.e. protocol amendments and also other critical activities, had a statistically significant effect on the time factors of a study.
Conversely concepts that seem to be realistic and relevant, e.g. that sample size, number of clinical phases and method development have a significant effect on study execution, were proved to be figments of the imagination. Throughout decades, services have been available for every possible need if the customer is prepared to pay the price. Globally customer needs may have been the same over a period of time, as illustrated by the Business Week citation published three decades ago, management models and strategies of service providers evolve continually over time. Sooner or later tomorrow becomes today, and yesterday’s foresight becomes today’s conventional wisdom. Companies compete for market share via the price and effective throughput of the services they offer.

These rational approaches are therefore an informative tool to dictate how, where and what services should be rendered to generate the operations and decision that fuels the journey to meet the visions and mission of the company, to assess the effect of time on costs that, in the end, erode profitability. A model to calculate the productivity of operations provides the financial intelligence of the profits associated with certain services. Process-related costs driven by resource requirements have bottom-line impacts on profits. The head count from an operational perspective should mirror the profitability, and care needs to be taken that the relationship between operations and resource usage adds value to all stakeholders.

The objectives of this research were successfully realized because not only was the rational approach formulated but, the results presented added value to the knowledge base of CRO/Pharmaceutical Industry operations. It is evident that concepts, theories and traditions used in this business operations need to be tested with an innovative approach because what may be perceived to be profitable may in fact be a system leakage of profits. It can be argued industries are good at discerning subtle patterns that are really there, but equally so at imagining them, when they are altogether absent.

The goal of this research was to develop innovative pivotal approaches that overcome the current trial management, design and analysis limitations. These approaches will better handle schedule constraints, such as project deadline and resource limits; facilitate corrective actions during conduct of clinical trial and produce accurate analysis during study period. This will identify the practical areas of potential improvement that can enhance the representation and formulation of critical path analysis and develop a new critical path analysis model that is based on segmented activity durations and examine the ability of the new critical path segments mechanism to provide a better representation of mid-activity
events, better identify critical path fluctuations, represent the various activity relationships more simply, and enhance the resolution of project constraints.

While we may not recognize it, we all use the skills necessary to conduct and interpret “clinical trials” every single day. Sampling and comparing one restaurant, article of clothing, television show, fitness club, vacation location, date, job candidate, or client to another is effectively conducting a clinical trial. Evidence and results from these mini-trials guide our choices and decisions throughout the day. What job will provide the best experience? Where should we live and what house should we buy? Is it better to hire Job Candidate #1 or Job Candidate #2? Faulty “trial” design, data, or interpretation leads to inaccurate assessments and perhaps poor decisions. For example, using the wrong criteria will result in hiring the wrong person for a job. We all have suffered from that impulse buy, that forehead-slapping wrong decision, or that bad choice of friend, employee, or significant other. Formal and informal clinical trials are a large part of our lives. If we use, produce, study, purchase, invest in, or conduct research in drugs, medical devices, or any type of health care intervention, understanding the science and operations of formal clinical trials can only help.

Today, even understanding many major news items requires at least some knowledge of clinical trials. Whenever a drug or medical device is recalled, a medical intervention is debunked, or a new therapy hits the market, clinical trial design, conduct, or analysis is at the heart of the evidence or the controversy. Health care is such a major business that even seemingly unrelated industries and professions can be dramatically affected by a successful or unsuccessful clinical trial. Flaws in a clinical trial that force a major drug or device to be pulled from the market can alter many lives and rock the economy.

Therefore, during our planning stages for these rational approaches in clinical trials study, confining the research audience was difficult. Should this research approach be geared toward just physicians? Pharmaceutical industry professionals? Statisticians? Academics? Clinical research specialists? Regulatory professionals? Ethicists? Medical students? Nursing students? Medicine residents? Graduate students? Post-doctoral fellows? Epidemiologists? Engineers? Pharmacologists? Pharmacists? Biologists? Pharmaceutical or medical device executives? The more we thought about it, the more we realized that the audience could be quite broad. Both of our career journeys have taken us through a variety of functions and domains in industry, academics, and business. We have seen the investment, research, technical, management, teaching, writing, consulting, and clinical practice realms of the
health care industry. In the end, while each area may have different jargon, cultures, personalities, and perspectives, the guiding principles are the same.

A good clinical trial at an academic institution is a good one in industry and vice-versa. Therefore, we did our research work with a broad audience in mind, trying to minimize the jargon and explain any important terminology in the process. The goal was to focus on rational approaches that could be easily understood regardless of our background, especially since people from so many different backgrounds are involved in clinical trials. In fact, in many professions, understanding the jargon and terminology is half the battle. Moreover, regardless of our interest and function in the clinical research world, knowing the general concepts of all aspects of clinical trials can be very advantageous.

In many ways, the clinical research world has become far too specialized. Many individuals stay ensconced within their areas of knowledge and expertise. But the best clinical researchers or trialists have broad knowledge bases that span statistics, regulatory affairs, ethics, clinical medicine, science, basic probability, data management, and trial personnel management. The ones that stand out, are most marketable, and do the best work cannot afford to say, “I do not need to know that because it is not in my area.” Designing, conducting, and analyzing a clinical trial is like designing, building, and using a house. Recognizing a house’s design and construction helps us to realize its potential use.

For example, a thin-walled house may cause problems during the winter. Very cramped rooms may not facilitate hosting a party. At the same time, anticipating the house’s use aids its design and construction. Our design of a beach house likely will differ significantly from our design of a farm house or a city dwelling.

The contents of clinical research with Part I of the thesis delineating some theory of conduct and management strategy, Part II covering importance of study design and methodology for a particular research problem and the last Part III deals with ethical, scientific and regulatory practicality. The materials in these chapters are analogous to all of the rules and regulations that govern the construction of a house: ranging from general engineering and architectural principles to zoning laws and building codes. Just as we cannot build any kind of house anywhere we choose, we must understand general clinical research theory and comply with legal, ethical, and regulatory principles when designing and conducting a trial.

Similarly, the ultimate end product of a clinical trial is a conclusion that is actionable for the treatment of future patients. So whether we are new to the world of clinical trials or
have been conducting clinical research for many years, we hope that these approaches will serve well. The importance and use of clinical trials will continue to grow in the future.

Concomitantly, trial design and conduct will face increasing scrutiny. In many cases, lives of innumerable patients and significant amount of time and resources will be riding on them. Will we be ready?

These aforementioned chapters focus on the rational approaches for Operational and Decision analysis and offers additional tools that may help in the management planning and analysis of clinical trials.

This thesis presents at least three unique methods to plan, design, analyze and synthesize the modern clinical trials. All these methods namely the CPA, MA and IA are rational unbiased and objective methods which provide tremendous insight into the various stages of the entirety of clinical trials. We have demonstrated in this thesis that CPA provides highly accurate and valuable information about a prospective clinical trial program such that trial is accomplished in a critically time, scope and budget. Similarly the MA gives systematic review information on a drug-efficacy, safety, quality or any other chosen aspects. This information can serve as the foundation of evidence based medicine which perhaps other type of review cannot. Finally, the IA of a portion of large or complex clinical trial gives an opportunity to modify the trial or to continue it without any modification or even to terminate it without any negative ethical or scientific implications.