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White Paper:

Cost Estimation and Modeling for Clinical Research Projects and Longitudinal Studies

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Background

Longitudinal projects for clinical studies are so focused on the research and clinical data collection aspects of the program that they often fall victim to cost overruns, under-budgeting, and inadequate long term cost estimation and forecasting. We have prepared this white paper to summarize our experience working with clinical research programs as well as to highlight our best practices and expertise in project cost estimating and analysis.

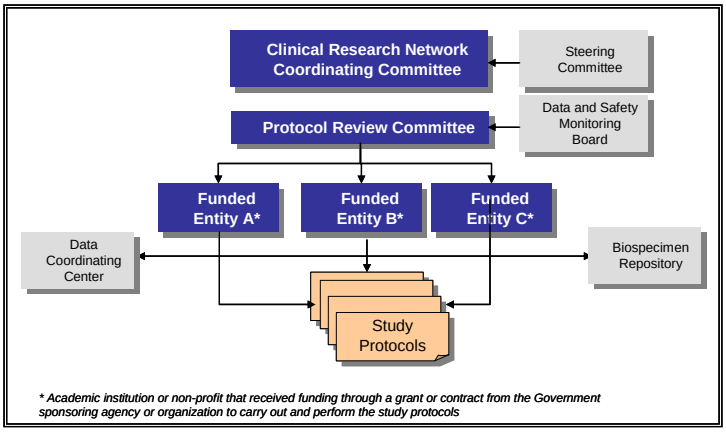
Our Knowledge of the Clinical Research Lifecycle

Booz Allen's experience with research programs such as the National Cancer Institute's (NCI) cancer Bioinformatics Grid (caBIG®), and the Clinical and Translational Science Awards (CTSA), has provided us with significant opportunities to interact with the NIH clinical research community. We have developed a comprehensive understanding of the clinical research lifecycle based on our frequent interactions with NIH staff who are involved in conducting clinical research, managing clinical research portfolios, or collaborating with the research community on improving and enhancing the manner in which research is conducted. This lifecycle encompasses a number of steps, starting with the study concept development and securing the necessary funding, to protocol design and implementation of the study with the necessary mechanisms in place to monitor compliance, and to the interpretation and communication of study results to ensure proper impact and understanding among the research community.

Through our support of projects such as caBIG®, CTSA and the National Children's Study (NCS) at NICHD, our staff has gained valuable knowledge of the roles that must be filled, and of the expertise and resources required, to successfully complete research in accordance with the rules set forth by NIH, HHS, and FDA. We understand the range of regulatory and privacy aspects that arise in clinical research, such as adverse events reporting, tracking conflicts of interest, and ensuring that safeguards are in place for study participant privacy. All of these components must be considered when developing a cost estimate for a research study.

Additionally, clinical research networks often involve several entities which are funded to perform separate activities within the study and protocol regime. Resources for operations such as biospecimen repositories and data coordinating centers, however, may be required by each, making accurate and comprehensive resource (e.g., cost) estimates essential to ensure the on time completion of projects (e.g., see Figure 1). Consequently, these clinical research networks benefit from assessing opportunities for cost recovery and shared services approaches. We recognize that longitudinal research studies that are observational in nature will have different needs than a short-term clinical trial; however, all

Figure 1: Clinical Research Network

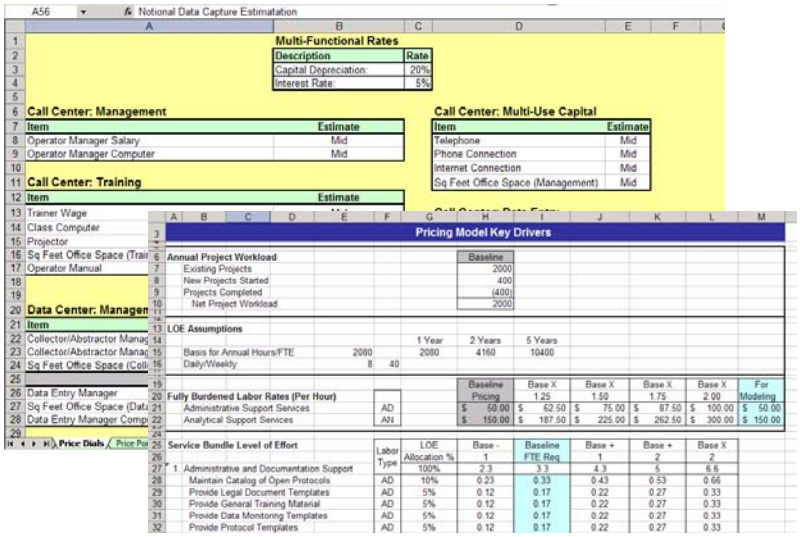


clinical research studies have similarities such as the need to recruit and enroll participants, development of data collection instruments and procedure manuals, training of field staff, analysis and storage of specimens and data, and the dissemination of findings to a scientific community and public stakeholders.

Our Expertise in Project Cost Estimating

One aspect of a longitudinal study that can be particularly challenging is the development of a comprehensive cost model to estimate costs over the complete life cycle of the study. It becomes a challenging undertaking to anticipate the adaptations or unknown factors that could potentially impact a study in the future. Booz Allen has experience in planning for and developing cost models for longitudinal studies. In our work for one clinical research longitudinal study, we helped assess and model the potential costs for implementing various methods and tools that could be used for remote data capture (e.g., see Figure 2). Here, we developed models that the NIH client could manipulate based on criteria such as salary of staff, number of fields sites and participants, and number of health events. Furthermore, we have developed detailed cost models for initial "start-up" projects, as well as for fully-operational programs which were required to restructure and transform in order to satisfy new mission objectives, and to better meet the ongoing capability and capacity needs of program stakeholders and beneficiaries.

Figure 2: Example Cost Model for Clinical Research Project



Based on our involvement in various clinical research projects at NIH and other government organizations, we have developed a strong understanding of the intricacies and challenges that must be considered when planning for and conducting longitudinal research. Given the long time period over which a study may be conducted, it is necessary to consider the infrastructure, tools, and processes that allow for flexibility and scalability. Technology is constantly evolving and may improve throughout the life of a study, creating a more efficient and effective tool or process for researchers to use. Infrastructure for a study must be developed to allow for future adaptations. However, while the option to implement an improved technology or technique is important, it is equally critical to understand that new and innovative tools and processes must be carefully evaluated to ensure they do not impact the quality of the data gathered for a study or compromise the scientific value of the research.

Booz Allen understands that a critical aspect of a longitudinal clinical research project is continuous improvement of the mechanisms used to communicate and share information. In

addition to evolving infrastructure, tools, and processes, a study may experience significant staff turnover which leadership must be prepared to address. Proper training, communications, and consistency of processes must be in place to communicate and transfer the knowledge of departing staff. There is also a critical need to develop and maintain the strength of the community to make sure that a study's goals are consistently communicated throughout its life cycle. It is essential to develop and maintain communication mechanisms to always have a pulse on the issues and needs of a diverse community.

Following is an outline of Booz Allen's approach to project cost estimating which we have tailored for longitudinal clinical studies.

Goals of Project Costing

Sound Project Cost Estimation Depends on Five Key Factors…

- Shared Vision of Project
- Appropriate Cost Estimation Methods
- Data Collection Tools and Techniques
- Clear Documentation of Assumptions
- Thorough Cost Element Structure

The overall goal of project costing is to use a prescribed methodology, process, and tool-set to produce a comprehensive cost estimate that includes essential foreseeable project costs within a confidence level that is acceptable to Project Management principles, the organization's budget office, and ultimately, the funding entity or agency for the program. For new initiatives, the project cost estimate, when finalized, typically becomes the baseline budget for comparing actual project costs.

Successful project cost estimation is predicated on a number of methodological inputs:

1) **Common understanding of project goals –** shared project goals understanding between the project team and the funding authority ensures the accurate alignment of the project's work breakdown structure with specific goals or strategic mandates.

2) **Use of the right cost estimating methods –** selecting the appropriate cost estimation method differs depending on the type of cost being estimated, similarities with other projects, level of detail desired, and the timeframes and level of detail within which the estimates are being requested.

3) **Cost collection techniques –** it is critical to collect costs from project personnel, researchers, contractors, and stakeholders who have a strong sense, or historical perspective, on how specific costs may or should behave. In addition, cost collection tools must be clear, easily understood, and simple to populate.

4) **Careful documentation of cost estimate sources –** establishment of a Basis of Estimate (BOE) data dictionary ensures record of the logic used to develop cost estimates and provides a historical audit trail as more information is learned about research activities, manpower level of effort (LOE) needs, new business processes, or unforeseen cost/resource requirements.

5) **Comprehensive cost element structure –** Cost components must be tailored, relative to the type of project or program, and include a full costing approach (e.g., direct, indirect, shared resource allocations, service fees, and risk contingencies).

Cost Estimation Techniques

Booz Allen utilizes a variety of cost estimating methodologies to develop project cost estimates, which may be applied individually or in combination, depending on the information and resources available for the specific initiative. The estimating methods we use include the following:

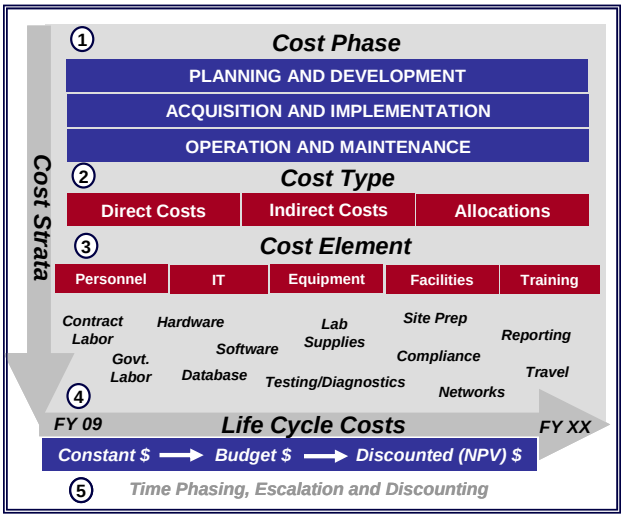
- **Analogous –** an estimate based on the historical cost data of similar (analog) items and utilizing adjustment factors to account for complexity, technical, or physical differences.
- **Engineering Build-up –** an estimate derived by summing the detailed cost estimates of individual work packages and adding appropriate burdens. Usually developed by price analysts and cost accountants.
- **Parametric –** a Cost Estimating Relationship (CER) in which cost is directly proportional to a single independent variable. A brief arithmetic expression wherein cost is determined by the application of a factor, such as a percentage of labor, or a ratio to materials.
- **Expert Opinion –** estimates marked by decisions based solely on individual judgment and similar experience. This method is typically used when cost data is not readily available from comparable sources or projects, and where subject matter experts (SMEs) can shed light on their previous experience or observations.

Booz Allen Project Cost Estimating Framework

Booz Allen's Project Cost Estimating Framework is illustrated in Figure 3 and consists of five key steps:

1) Determine relevant cost phases for the project;
2) Identify cost type;
3) Develop key cost elements;
4) Further define cost sub-elements into detailed cost element structure (CES); and
5) Time phase costs over the life cycle period.

Figure 3: Booz Allen Cost Estimating Framework



In collecting the costs associated with a project, it is important to differentiate between them relative to three phases (step 1), since organizations typically budget or appropriate according to these categories, consistent with the IT capital planning and investment guidance provided by the Office of Management and Budget (OMB). The three cost phases include: (a) Planning and Development Costs; (b) Acquisition and Implementation Costs (e.g., hardware and software, etc.); and (c) Operations and Maintenance Costs. Once we have identified the cost phases have that are relevant to the project (e.g., a new project will require significant up front

planning and development costs, while an ongoing project will require careful examination of costs associated with any new acquisitions, further testing, vendor services costs, etc.), a detailed cost element structure (CES) must be developed that identifies costs by type (step 2, direct, indirect, allocations) and by specific cost element and sub-element (steps 3 and 4) to provide visibility into what resources are truly required to implement and sustain the project.

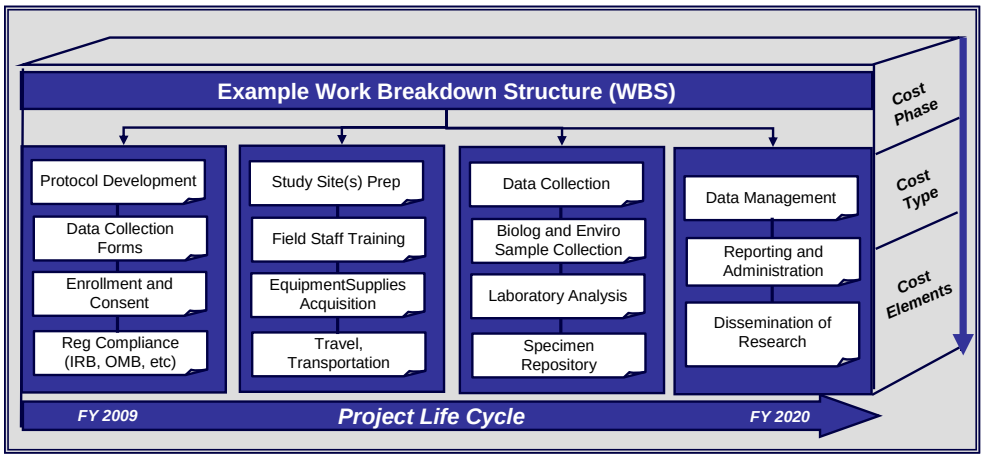
This is perhaps the most important step, as building a complete, comprehensive, and well-structured cost estimate helps to alleviate the risk of missing costs or double counting. Booz Allen will ensure the development of a CES that is tailored to the specific requirements of the project by incorporating the following:

- Examine sample cost reports provided by the organization;
- Examine cost data from vendor invoices or acquisition logs;
- Review existing CES developed for analogous initiatives;
- Apply business best practices and government lessons learned; and
- Incorporate elements as necessary to address costs associated with achieving objectives and mitigating risk for the organization.

Defining the Project Life Cycle

The final step of our cost estimating framework is the estimation of costs over the full life cycle (step 5). For any project, a "life cycle" must be defined over which costs will be projected. Pure IT systems projects may have shorter (e.g., three to five) year life cycles due to the nature of technology's needs for refresh and upgrade to stay abreast and current with end user needs and functional requirements. Research projects requiring longitudinal study periods, multi-phased research and development (R&D) initiatives, and major business process transformation projects, typically require cost estimation over life cycle periods of ten to fifteen years to obtain an accurate picture of costs as they relate to the directed objectives of the project's mission. To develop the cost estimates over the project's life cycle, it is critical to be able to map out the general activities and business processes – or work breakdown structure (WBS) – which will require and consume specific resources and costs. A WBS for a notional example of a longitudinal research study is provided in Figure 4 below.

Figure 4: Notional Longitudinal Study – Project Cost Estimation



In this last step costs must also be time-phased properly, converted from current year dollars, to budget year dollars complete with applicable escalation (e.g., inflation) rates for each cost element, and also illustrated in discounted terms using net present value (NPV) principles. Translating costs into NPV terms is especially critical when looking at various alternatives for a project, or for situations where a program manager would like to compare the time value of project costs, to the discounted time-phased benefits delivered by the project over the life cycle to determine a return on investment.

The Booz Allen Team

The Booz Allen team is distinguished in its ability to provide the highest quality of service for clients by combining functional expertise in cost estimation and modeling, with scientific and technical domain expertise in the areas of clinical research and clinical trials.

Todd Carolin, MBA – Mr. Carolin is a Sr. Associate with Booz Allen's Economic and Business Analysis team and has over 16 years of experience in cost estimating, budget development, and financial planning and analysis. He has led cost estimating and budget analysis tasks for the NCI CBIIT, The Institute for Genomic Research (TIGR), Social Security Administration's Office of Disability (OD), and various Department of Defense organizations (e.g., VA/DoD EHR project, DoD High Performance and Computing Modernization Office, and Department of Navy (DoN CIO). Mr. Carolin is a Gartner Certified Total Cost of Ownership (TCO) expert, as well as a policy expert on OMB guidance and Federal cost accounting standards

Rajni Samavedam, MPH – Ms. Samavedam has over ten years experience in public health, clinical research, and project management. She has conducted research and established public health programs in reproductive and pediatric health both domestically and internationally. She has lead observational and epidemiologic research studies for the National Cancer Institute. She also has provided technical assistance and thought leadership to both state and federal agencies in managing their clinical research portfolio.

Brenda Ecken, BSN, RN, Med – Ms. Ecken serves as the Booz Allen client management project lead for NIH, and has over 20 years experience in managing programs in the clinical and scientific space for commercial and government clients. As the Program Manager for the NICHD IT Supplementary Services Contract and the Clinical and Translational Science Awards Program, Ms. Ecken leads teams to work with the government clients to manage their program current state while planning for their future state.

Contact Information

To learn more about Booz Allen's capabilities and how we can support your organization with clinical research program support and cost estimating expertise, please contact:

- Todd Carolin, Sr. Associate – *Cost Estimating, Modeling, and Analysis* (301) 838-3684.
- Brenda Ecken, Sr. Associate – *Clinical Research Networks*, (301) 838-3649.