Clinical Trial Budget Analyst

A. Introduction to the Organization

The Parker Institute for Cancer Immunotherapy ("PICI" or the "Parker Institute") is a not-for-profit organization whose mission is to accelerate the development of immunological cures for cancer through innovative science, advanced technologies and new modes of research collaboration. The Institute is based in San Francisco, California and officially launched in April 2016.

To achieve its mission, PICI has established significant new cancer immunology research centers at six of the top cancer research and treatment institutions in the country (Memorial Sloan Kettering Cancer Center, Stanford Medicine, the University of California, Los Angeles, the University of California, San Francisco, the University of Pennsylvania and The University of Texas MD Anderson Cancer Center), and will organize and support a portfolio of advanced, collaborative research efforts across this consortium.

B. Overview of the Role

The Clinical Trial Budget Analyst (CTBA) is responsible for partnering closely with the Clinical Trial Study Teams, the PICI legal team, site administrators, member researchers, and industry partners, to create clinical trial budgets for PICI trials and to track milestones that trigger payments from sponsors or payments to sites. Working with the Controller, the CTBA reviews invoices from sites to ensure they meet contractually agreed upon requirements. The CTBA monitors progress in a timely and efficient manner, with minimal administrative burden to the funded investigators and institutions.

C. Reporting Structure and Team

The Clinical Trial Budget Analyst reports to the Controller and is a key member of both the Business Operations and Clinical Development teams.

D. Essential Job Functions

- Partner with the Clinical Development lead to develop budget projections for proposed trials, using existing templates and empirical data.
- Manage tracking associated with roles within the organization and time spend on projects and programs
- Monitor status of protocol of trials under development and facilitate timely coverage analysis and budget proposals with an external vendor.
- Act as liaison between the study team and the vendor to resolve any questions regarding the schedule of events.
- Create site-specific budget templates and provide to the sites, along with the coverage analysis.

- Work with sites to resolve any budget questions and standard of care disputes to ensure that the budget approval process is completed in a timely manner.
- Work with Research Operations to create the mechanistic assay budget.
- Track the costs associated with a dynamic assay plan in collaboration with Research Operations
- Work with the study team to develop the Clinical Operations budget for each trial under development.
- Support the development of the overall study budget with functional inputs.
- Work with potential co-sponsors to provide budgetary information necessary for co-funding.
- Work with the PICI legal and clinical teams to help answer questions from co-sponsors regarding the trial budget.
- Upon initiation of a trial, monitor study progress and flag milestones for the Controller to either send invoices to co-sponsors or to pay invoices to sites.
- In coordination with Clinical Development and Controller Create and maintain tracking systems for all clinical and non-clinical awards (estimated 3-5 new projects annually) and milestone deliverables throughout their lifecycle.
- Work independently and collaboratively on special projects and initiatives as assigned.
- Review study protocols for financial and resource feasibility. Carry out periodic reviews of study files to ensure administrative quality, compliance, and consistency across clinical trials.
- Review protocol amendments for any revisions affecting the budget; update budget as necessary or re-prioritize for additional development by a third party vendor.
- Assist with ongoing review of internal processes to streamline roles and responsibilities; execute process changes or identify resources to accomplish projects and oversee to completion.
- Prepare reports and advise on feasibility and cost effectiveness.
- Participate in the development of new data systems and tools for electronic clinical trials, financing, documentation, and administration.

E. Knowledge, Skills, and Experience

- Bachelor's Degree or equivalent combination of education and experience.
- Five years experience working in research administration, a pharma or biotech industry, a medical or clinical practice arena, or health insurance industry
- Must have working knowledge of clinical trials
- Must be familiar with HCPCS / CPT codes
- Must understand what is standard of care or routine care and what is considered research-related in the context of a clinical trial
- Must be familiar with Medicare regulations, guidelines, policies
- Experience budgeting and estimating clinical trials costs
- Analytical skills to review coverage analyses, budgets, and estimates based on established criteria and PICI guidelines.

- Excellent interpersonal skills to deal with complex, sensitive and confidential material with Principal Investigators, sponsors, and administrative and management personnel.
- Ability to read, identify and extract pertinent information from protocols.
- Knowledge of Good Clinical Practice Guidelines, ICH Guidelines, FDA and HIPAA regulations, Medicare policy on Routine Costs in Clinical Trials is preferred.
- Knowledge of common budgeting practices and general time/effort allotments is preferred.
- Strong attention to detail required.
- Knowledge of Microsoft Office – all programs, required. Knowledge of clinical trial budgeting and payments systems.
- Skill in analyzing information and objectives to define problems, identify relevant issues or concerns, formulating alternatives to affect resolution, and selecting alternative problem resolutions having evaluated all implications for implementation of a given solution.
- Well organized with the ability to set priorities and meet deadlines.
- Ability to provide high quality customer service. Maintain professional communication with investigators, PICI staff, and industry partner representatives by providing regular status updates. Responds to voicemails, emails, and other correspondence in a timely fashion.
- Ability to be a team player. Works with PICI staff in identifying areas for improvement in office procedures and policies, and creating and implementing new methods. Willingness to take on special projects or additional duties as needed.
- Proven ability to handle multiple projects and tasks simultaneously.
- Ability to work independently under pressure and to know when to ask questions.
- Has comfort in ambiguity along with the ability to implement critical thinking skills and strong reasoning.

Apply for this role

To apply, please email your resume and cover letter outlining how you meet the requirements for the position to careers@parkerici.org.