Dreaming Toward the Future

Pre-Award Process Mapping - Clinical Research Feasibility

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Abstract

Many factors determine financial and logistical feasibility of clinical trials. This poster provides an overview of standard operating procedure and tools necessary to make this determination, citing the collaborative process across multiple entities. Tips on reviewing initial documents such as the proposed contract, sponsor budget, protocol and schedule of events and informed consent in the development of accurate internal cost assessments and cost benefit analysis & their relative collaborative process flow are outlined.

Introduction

Clinical Research Feasibility: "A process of evaluating the possibility of conducting a particular clinical program/trial in a particular geographical region with the overall objective of optimum project completion in terms of timelines, targets and cost."

Dr. Viraj Rajadhyaksha

Key Terms and Definitions

Clinical trial: research study that *prospectively* assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes and may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. This definition includes Phase I - IV trials. *World Health Organization Glossary.*

Percentage of Registered Studies by Location (as of October 2022)
Total N = 432,490 studies https://clinicaltrials.gov
Legend for Registered Study location
Non-U.S. only (51%); U.S. only (33%); Not provided (12%)
Both U.S. and non-U.S. (4%)

Methods
Financial Feasibility Assessment

Mitigating Factors

- Centralized or decentralized management
- Lack of consistency in budget development
- Consistency in SOPs and associated tools
- Best practice guidelines for cost recovery priorities

Operational Impacts: Pre Award

- "Bottom up" Budget development
- It takes how long? Engagement of clinical personnel in effort assessment; Process mapping and time studies
- Research Pricing estimates
- Focused contract management

Operational Impacts: Post Award

- Award set-up, Maintenance and Close-
-NOGAs – often incomplete
not flagging clinical trials, capturing nuances
-Referencing contracts and attachments
- Clinical trial project end dates
- Study close-out best practice

Process Mapping Tools

Tools of the Trade – Financial Feasibility Assessment

- Internal Cost Assessment: Counting the cost
-Realistic assessment and capability, Fixed and Variable Costs
-Site Fees and cost structure
- Elements of Review
-Clinical Trial Agreement; Internal Budget; Protocol and Schedule of events
-Informed consent form; Initial sponsor budget; Grant Pricing estimates

Preliminary Results
Feasibility Factors

Factors Determining Feasibility

- Patient Population: Number one sponsor concern will be quick enrollment of eligible patients. Before accepting a trial, carefully review the enrollment criteria to ensure that you have the appropriate patient population. Have a viable recruitment plan. Don't make assumptions. Use data.
- Financial Viability: Cost benefit analysis performed to ensure adequate reimbursement for study expenses. Compare contract value with projected expenses. Ascertain sponsor financial stability. Beware of mergers.
- Space: Dedicated space for research. Consider use of the Clinical Research Unit.
- Staffing considerations: Studies vary considerably in amount of time required to conduct them. Review schedule of events and case report forms for best idea of time required. A research coordinator is essential.
- Training and Certification: GCP, Licensure, Certification
- Access to Investigational Products and Cutting Edge Technologies: Might represent an otherwise unavailable opportunity to provide treatment for patients.

Collaborative Process Flow

Collaborative clinical research cross-functional process flow diagrams for process re-engineering and continuous improvement.
""Hub Team Model
- VPR, Dean, Chair, Clinical Research Units – Therapeutic Units
- Central offices; Research Admin, Sponsored Programs, Contracts and Collaborations, Clinical Research Office, Central IRB
- PI, study team, division leaders, Grant Manager, financial analysts
- Departmental Business Unit, Human Resources
- Associated facilities and service centers, Policies, SOPs

Conclusion

The global research enterprise offers the Research Administrator a full array of opportunities to significantly impact the successful conduct of clinical research. Financial feasibility assessments are critical in identifying and highlighting potential challenges. Mitigating study delays and recruitment and variability issues, these assessments provide a scorecard for performance at the site, investigator and program level. Anticipated areas of impact for research administrators include:

- General timelines for study approval and site start-up
- Assessing study performance and revenue positions
- Forecasting of factors and trends in the research industry
- Networking to establish relationships with sponsor and future collaborations
- Facilitating research administration transformational leadership

In conclusion, performance of the financial feasibility review process map is both an art and science and ensures the proposed study has an improved likelihood to be successfully completed. This will result in good clinical practice and enhanced financial opportunities.

Literature Review

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2022 Annual Meeting SRA International
October 31-November 4, Las Vegas, NV

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Pre-Award Industry Clinical Research Process