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Clinical Research Feasibility
Tools of the Trade
SRA International
"Educating Research Administrators for the Future"
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Course Description:

Many factors determine financial and logistical feasibility of clinical research studies. This session provides an overview of standard operating procedure and tools necessary to make this determination, developed from study examples and case studies. 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 will be demonstrated. Vetting and ranking of study trials will be discussed.
Objectives:

1. Review the factors impacting financial feasibility of a clinical research.

2. Manage the development of internal cost assessments and cost benefit analysis
Clinical Research

NIH defines human clinical research as:
Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:
Clinical Research

(a) mechanisms of human disease,
(b) therapeutic interventions,
(c) clinical trials, or
(d) development of new technologies.
(2) Epidemiologic and behavioral studies.
(3) Outcomes research and health services research
Clinical Trial

A clinical trial is any 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. Clinical trials 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, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

World Health Organization Glossary
What is 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.”

Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study

Dr. Virai Rajadhyaksha
Significance of Clinical Trial Feasibility

Explore 256,763 research studies in all 50 states and in 201 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine
Significance of Clinical Trial Feasibility

Percentage of Registered Studies by Location (as of October 16, 2017)
Total N = 256,763 studies

Legend for Registered Study location pie chart image

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Significance of Clinical Trial Feasibility

Percentage of Recruiting Studies by Location (as of October 16, 2017)
Total N = 44,933 studies

Legend for Recruiting Study location pie chart image

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https://clinicaltrials.gov
Factors Determining Feasibility

• Patient Population:
  – The number one concern of the sponsor will be quick enrollment of eligible patients. It is important before accepting a trial that you 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
Factors Determining Feasibility

• Financial Viability:
- Is the company providing adequate reimbursement for the expenses of the study? Study procedures may not be billable to private or government insurers, and it is imperative that you be able to cover all third party study expenses.

- Use a financial tool to provide a cost benefit analysis
Factors Determining Feasibility

- Compare contract value with projected expenses for both full and partial enrollment of patients.

-Ascertain financial stability of the potential sponsor, making note of potential mergers or signs of instability.
Factors Determining Feasibility

• Space:
  - Do you have dedicated space for research? You will need space to see patients and also to keep patient files in locked cabinets in a secure location.
  
  - Consider utilizing a Clinical Research Unit if available at your location.
Factors Determining Feasibility

• Staffing:
- Studies vary considerably in the amount of time required to conduct them. Even something as simple as a physical and history could vary between 5 minutes and an hour and a half in different studies.

- The case report forms will offer you the best idea of the time required, so request to see them.
Factors Determining Feasibility

• Staffing considerations:
  - It is essential to hire a research coordinator rather than rely entirely on physician time and effort.

  - If physician time will still be extensive, review whether the loss to other revenue streams such as private clinical practice is acceptable.

  - Other Staffing options may be available.
Factors Determining Feasibility

• Training and Certification:
  - At a minimum, all staff doing human subjects research need to be certified by the Institutional Review Board (IRB).
  
  - All staff should also be trained in Good Clinical Practices.
  
  - National Licensure and Certifications should also be considered.
Factors Determining Feasibility

• Access to Investigational Products and Cutting Edge Technologies:
  - Industry sponsored clinical trials generally offer access to medications or devices not yet on the market. These studies might represent an otherwise unavailable opportunity to provide treatment for your patients.
  - Many studies offer compassionate use extensions, wherein all patients, even the placebo control group, receive free medication after the study is over.
Factors Determining Feasibility

• Networking:
  - Performing an industry sponsored clinical trial will establish a professional relationship with a drug/device sponsors, often leading to future studies and collaborations.
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-out
  – NOGAs – often incomplete, not always flagging clinical trials, capturing nuances
  – Referencing contracts and attachments

• Clinical trial project end dates

• Study close-out best practices

Duke Medicine
Research Administrator’s Tool Box

• Internal Cost Assessment
  – Counting the cost
  – Realistic assessment and capability
  – Fixed, Variable and Hidden 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
Fixed Cost Case#1

Scenario: Upon review of the Clinical Trial Agreement for financial feasibility, the budget negotiator overlooked the standard “study records” clause. The CTA required record retention of 15 years. The sponsor budget omitted this line item. The final study budget projected costs for standard institutional requirement of six years archival fee based on a rate from three years ago. However current costs for record retention have increased by $104 per month.

What steps should be taken to resolve this issue?
Research Administrator’s Toolbox cont’d

• Financial Feasibility Checklist
  – What we need to know

• The Basics
  – Study team demographics
  – Contact information
  – Study Title
  – Projected enrollment and recruitment
  – Projected effort

• Sites receiving clinical services
Research Administrator’s Toolbox Cont’d

• Possible cost sharing requirements
• Project Duration
  – Focus of the study
• Study procedures
  – Specialized equipment requirements
• Funding Agency
  – Sponsor contact for CTA negotiation
  – Study type
  – Visit type
• Milestones and invoicing requirements
• Etc., etc., etc.
Research Administrator’s Tool Box cont’d

• Who’s on the Team for Development
• A “hub” model
  – Clinical Research Units – Therapeutic Units
  – Central offices and Research Units
    • Sponsored Programs
    • Research Integrity/Risk Management
    • Legal teams – Contract negotiation
    • Central IRB, IACUC, Biosafety Committee
  – PI and study team
  – Grant managers and financial analysts
Research Administrator’s Tool Box cont’d

– Departmental Business Unit
– Human Resources
– Associated facilities and service centers

• Resources
  – Policy
  – Standard Operating Procedures
Research Administrator’s Tool Box cont’d

• Putting it all together- Scientific and Financial review
  – Standard Operating Procedures
  – Competition with other projects
  – Publication
  – Benefit
  – Data Safety and Complexity
  – Statistical Analysis

• Vetting and Ranking
  – The common good, high impact research
  – A future Nobel Laureate
  – External sponsor vs Internally supported
Research Considerations

• 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.
Research Administrator Impacts

• 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
Conclusion

Performance of the financial feasibility review and assessment 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.
Concurrent Session Handouts Online

Go to the meeting app or go to the presentation link to view concurrent session presentations:
https://srainternational.org/2017-sra-international-annual-meeting-presentations

The web site will be updated as speakers send in their presentations.
Conclusion:
Performing Clinical Research financial feasibility, a vital function in research administration, is both art and science.

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