



SOCIETY OF
RESEARCH
ADMINISTRATORS
INTERNATIONAL



Ensuring Success

CLINICAL RESEARCH FEASIBILITY

THE RIGHT FIT



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Course Description

Many factors determine financial and logistical feasibility of clinical research studies for your site. This session provides an overview of standard operating process and tools necessary to make this determination; developed from study examples and case studies. Tips on reviewing initial documents such as site feasibility questionnaires, proposed contract, sponsor budget, protocol with schedule of events and informed consent in the development of accurate internal cost projections and budgets will be reviewed.

Objectives

Analyze the factors impacting logistical and financial feasibility determinations for your site.

Cite case study scenarios and mechanisms to determine merit: and financial review of timelines, targets and costs.



Overview

Determining study feasibility is applicable for all studies (i.e., investigator initiated, industry funded, foundation funded or federally funded). The goal is to ensure sufficient interest in the study design and research questions. The next steps are to ensure that there are proper resources (i.e., study staffing including coordinators, investigators, research assistants; IRB and contract review teams, statisticians, etc.) to conduct the study; proper facilities (access to investigational pharmacy; inpatient or ambulatory facilities, etc.) and equipment (centrifuge, freezers, access to MRI or CT equipment); as well as sufficient and proper patient populations. Determining the proper mechanism for scientific review will ensure validity of the research questions. Proper financial review of direct and indirect costs by the grants and finance teams; and access to legal review through the contracts team are essential. The “right fit” ensures success in choosing high impact studies for your site.

What's Your Role?

Poll Question #1

What is your role in Research Administration?

1. Study Team member (PI, CRC, Research Assistants, Research Nurse, and Statistician)
2. Clinical Research Units - Therapeutic Units
3. Sponsored Programs
4. Institutional Review Board
5. Grants and Contracts Manager
6. Research agreement Manager

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, behavioral treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

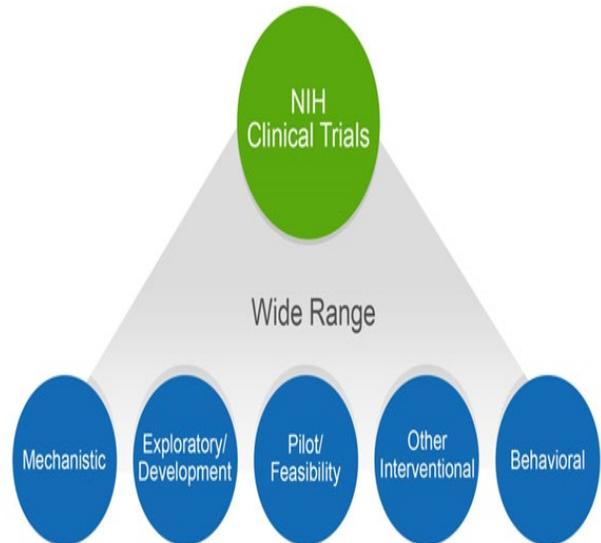
NIH Clinical Trials

Does the study involve human participants?

Are the participants prospectively assigned to an intervention?

Is the study designed to evaluate the effect of the intervention on the participants?

Is the effect that will be evaluated a health-related biomedical or behavioral outcome



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.”

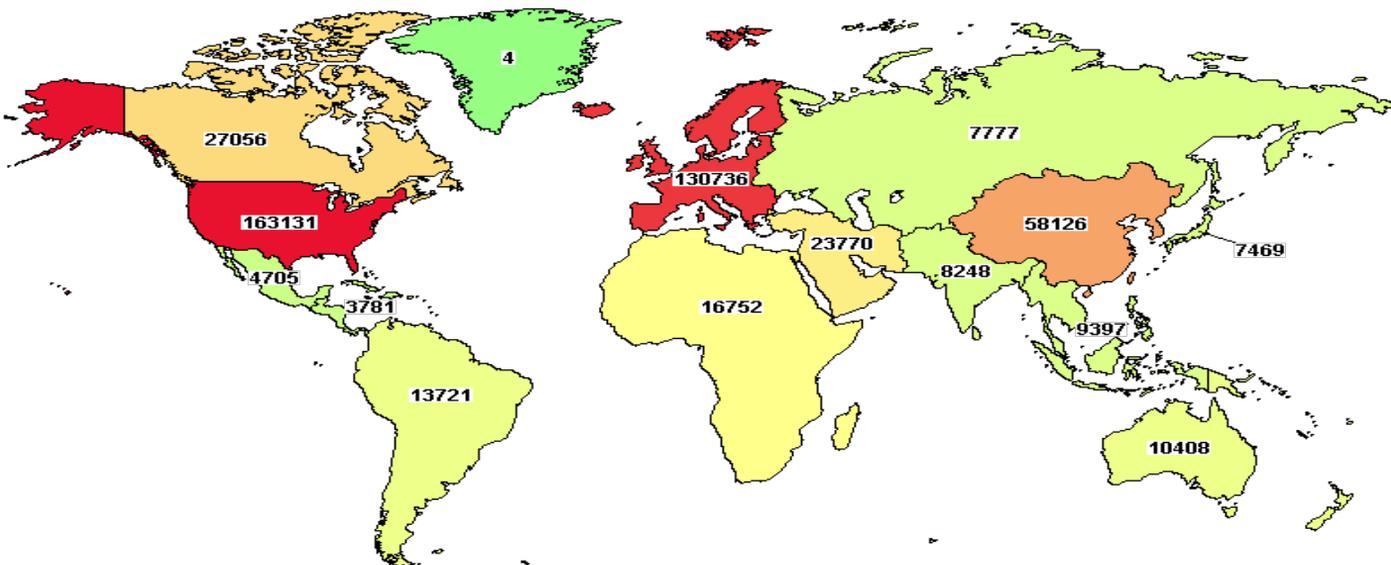
Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study

Dr. Virai Rajadhyaksha

Why do we assess Feasibility?

Significance of Clinical Trial Feasibility

Explore 513,469 research studies in all 50 states and in 223 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 24, 2024)

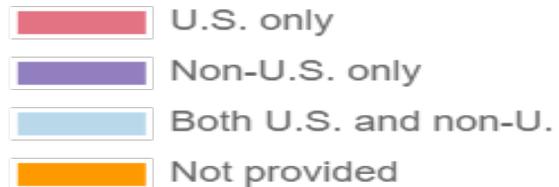
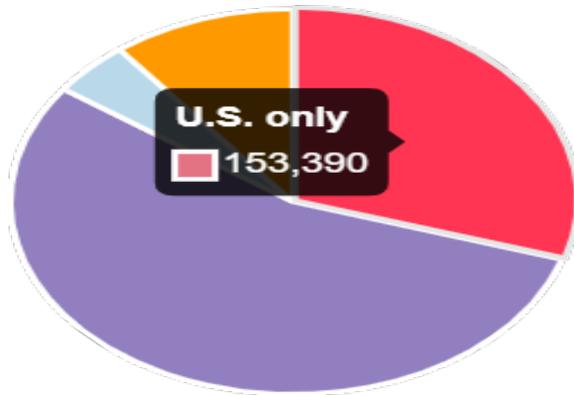
Total N = **513,469** studies

<https://clinicaltrials.gov>

Legend for Registered Study location pie chart image

Pie Color

Location

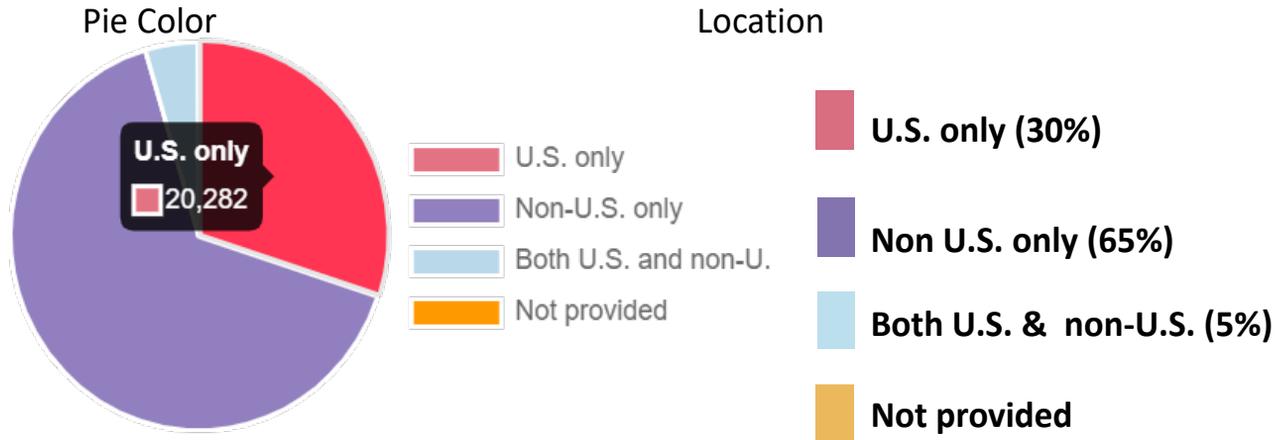


Non US only 282,721 (55%)
Both US and non US 23,426 (5%)
Not Provided 53,932 (11%)

Significance of Clinical Trial Feasibility

Percentage of Recruiting Studies by Location (as of October 24, 2024)
Total N = 67,586 studies <https://clinicaltrials.gov>

Legend for Recruiting Study location pie chart image



What Can Go Wrong? Recruitment & Retention

>90% of all clinical trials are delayed due to over-ambitious timelines and difficulty with patient enrollment.

Roughly 70% of all trials are delayed from one to six months due to patient enrollment problems.

30% of PIs under-enroll in a given trial.

Estimated 20% of PIs fail to enroll a single patient.

Delays in the drug development process cost pharmaceutical companies billions of dollars per year.

IF A CLINICAL TRIAL IS NOT WELL PLANNED – IT WILL FAIL!

Feasibility Factors

Feasibility Checklists

- Site Feasibility Questionnaires
- Protocol Considerations
- Budget Considerations

CLINICAL TRIAL FEASIBILITY CHECKLIST FORM

PI and Study Team: YOUR RESPONSES TO THIS SURVEY CONSTITUTE A BEST ESTIMATE OF RESOURCES AND YOUR DESIRE AND CAPABILITY TO PARTICIPATE IN COMPLIANCE WITH PROTOCOL REQUIREMENTS. Tool for budget preparation. Study team should complete the form after reviewing the synopsis, protocol, and other sponsor materials. Information from the checklist will be reviewed by the Scientific Review and is a tool for budget preparation.

Protocol Title:
Principal Investigator:
Clinical Research Coordinator(s):

Item	Yes	No	NA	UNK	Comment
I. Protocol (Section completed by PI and Clinical team)					
1. Are there any competing trials ongoing at this site?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If no, will there be a sufficient number of eligible patients for this trial?					
3. Is this study similar to previous studies conducted at your site?					
4. If so, were the previous studies successfully completed?					
5. Are the protocol and procedures understandable and readable to all staff?					
6. Are the standards of care?					
7. Is specialized equipment required? If yes, comment on availability, use.					
8. Are there any special requirements for patient care areas?					
9. Is there any special equipment or supplies required for the research protocol? If yes, specify (should be addressed in Primary Care Managers (PCM) support letter). Contact Christine Stewart, Assoc. Chief Nurse Researcher, at Christine.Stewart@duke.edu and with any questions.					
10. Indicate if Clinical Research Services (CRS) nursing services are required to conduct special procedures or interventions. <i>Specify treatment, site, sub-specialist physician.</i>					
11. Will special procedures require vaccinations or testing outside of routine clinic hours?					
12. Are there specific facility requirements?					
13. Are there any special AEC requirements? If yes, comment on clinical implications and how resources affect trial.					
II. Enrollment (Section completed by Clinical team)					
1. Are the inclusion/exclusion criteria reasonable to meet enrollment?	<input type="checkbox"/>				
2. Will the following factors impede enrollment? Comment on whether factors will be managed. Comment from protocol or trial sponsor.					
3. Age?					
4. Duration of participation?					
5. Frequency of visits?					
6. Frequency of dosing?					
7. Medication complexity?					
8. Other medical conditions?					
9. Procedural discomfort?					
10. Other medical conditions?					
11. Visit schedule?					
12. Based on participant knowledge, how many can be enrolled based on education and review?					
13. Total number of subjects?					
14. No. of subjects/visit?					
15. Ratio of success to failure?					
16. What is the source of patients? E.g. clinic, preadmission testing, referrals?					
17. Will the sponsor provide resources and/or a plan of action for enrollment? If yes, comment.					
Item	Yes	NO	NA	UNK	Comment

Factors Determining Feasibility

Study Protocol

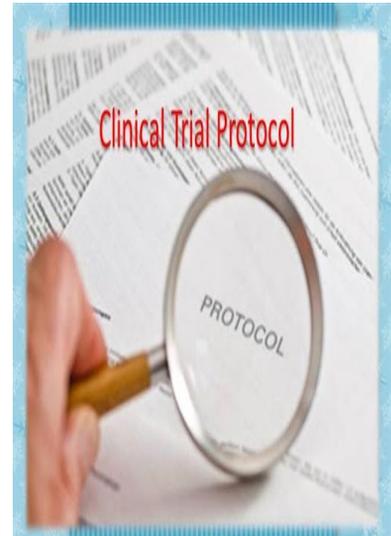
- Scientific merit
- Specific clinical need

Fit and alignment

- Institutional mission and goals

Enhance Research Portfolio

- No competitive studies



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
- Past accrual

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
- Consider study start-up timelines

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 participants and also to keep participant 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.



Operational Impacts

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



The Right Fit

Relevant research questions
Operational
and Financial feasibility

ON TIME, ON TARGET, ON BUDGET

Research Considerations

The global research enterprise offers the Research Administrator a full array of opportunities to significantly impact successful site selection and 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: Putting it all Together

Performance of the site 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.



References and Resources

Rajadhyaksha, Viraj (2010). *Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study. Perspect Clin Res. Jul-Sep; 1(3): 106–109.*

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Clinical Leader. (2018). Clinical Trial Feasibility. <https://www.clinicalleader.com/doc/clinical-trial-feasibility-0001>.

Kirsh, Danielle. (2019). *Understanding budgets, extra costs and feasibility in clinical research.* <https://www.massdevice.com/understanding-budgets-extra-costs-and-feasibility-in-clinical-research/>.

Feasibility Templates.

<https://globalhealthtrials.tghn.org/resources/templates/>

Questions or Comments

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