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HRB Clinical Research Facility Cork

"KNOWING WHAT IS FEASIBLE" IN CLINICAL TRIALS

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CHALLENGE

Many clinical studies fail to recruit sufficient numbers of participants

- Wastes valuable resources and time
- Potentially delays treatments becoming available to patients.
- Incomplete recruitment to studies leads to significant opportunity costs.

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WHAT IS FEASIBILITY?

- Conducting clinical trial feasibility is one of the first steps in clinical trial conduct.
- A robust feasibility ensures a realistic assessment of capability to conduct the clinical trial.
- Overall objective is delivering a project to completion:
  - On time
  - To target
  - And within budget

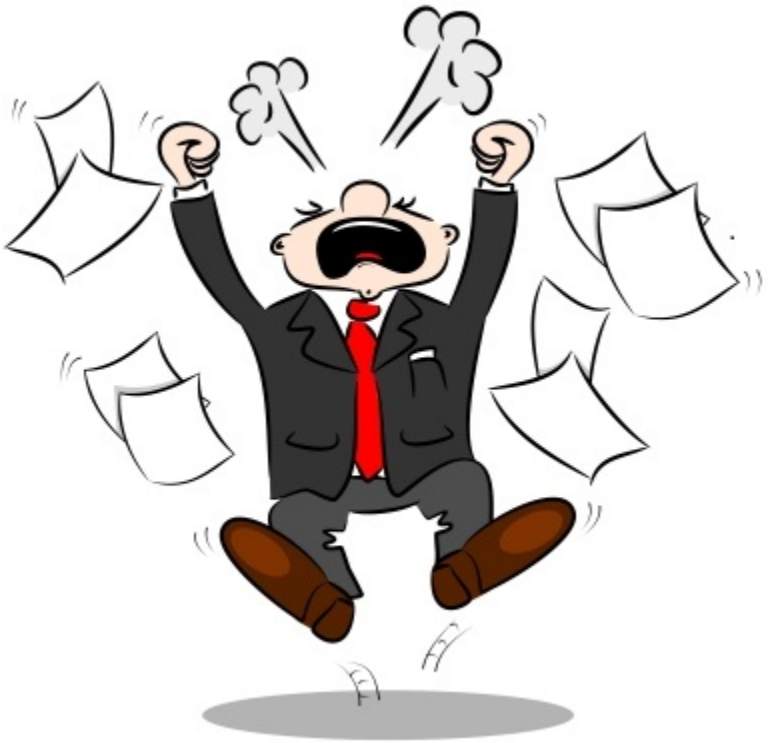
KEY QUESTIONS

- **Not just about numbers!**
- Relevance and intensity of the study for participants and the study team.
- We need to think about whether the study is:
  - Compatible with current practice?
  - Consistency in practice e.g. is the control treatment schedule appropriate?
  - Inclusion/exclusion criteria restrictions

CLINICAL RELEVANCE – PATIENT PERSPECTIVE

- Consider the patient's perspective
- Suggest – consult with patient support groups/charities at the beginning
- **Patient and Public Involvement (PPI)** can improve trial feasibility and recruitment by addressing questions such as:
  - Will the recruitment plan work?
  - Can we make it **easier** to **encourage** patients to participate?
  - Are patients going to **accept** the **study schedule** and requirements?
  - How could it be made easier to **retain** the patient?

RECRUITMENT CAN BE FRUSTRATING!



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Trends in Clinical Trial Site Selection & Patient Recruitment

http://2q7s5i3mswlx752dnuj8u9px.wpengine.netdna-cdn.com/wp-content/uploads/2014/12/final_sitepatienttrends_infographic.pdf

from CliniPace

INVESTIGATOR/SITE SELECTION

- **The sponsor is responsible** for selecting the investigators and sites.
- Careful selection and evaluation of investigator sites is critical:
  - for the successful completion of a trial within budget
  - timelines
  - to ensure high quality data
- How will Investigator site be selected?
- Previous experience working with the sponsor

INVESTIGATOR/SITE SELECTION – EVIDENCE

- Interest in the research question.
- Availability of suitable patient population
- Audit figures
- Conflicting studies

SPONSOR CONSIDERATIONS

- **Site demographics**
  - Clinical trial experience
  - Availability of study coordinators, research nurses, pharmacists
  - Experience conducting studies involving EDC and interactive Web response system (IWRS)
- **Quality management**
  - Standard operating procedures
  - Experience and results of audits and inspections. Were any concerns raised.
- **Local processes**
  - approvals, agreements etc
  - Ethics committee requirements

INVESIGATOR SITE SELECTION - RESOURCES

- **Adequate facilities:**
  - Availability of any specialised diagnostic or therapeutic equipment
  - Adequate space and storage conditions (including archive)
  - Equipment
    - e.g. fridges, freezers, non standard equipment?
  - Pharmacy support - Drug storage, etc
  - Laboratory support - processing of biological samples
  - Radiology support

INVESTIGATOR RESPONSIBILITIES - RESEARCH STAFF

- The Investigator should have sufficient time to properly conduct and complete the trial **(ICH GCP 4.2.2)**
  - i.e. Be available for patient assessment , consenting, etc.

- The investigator should have available an adequate number of qualified staff and adequate facilities **(ICH GCP 4.2.3)**

- The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the IP and their trial-related duties and functions **(ICH GCP 4.2.4)**

  - **Investigator – not sponsor – responsibility!**

HOW IS FEASIBILITY ASSESSED?

- Initial contact - Protocol summary provided for review
- Site Assessment Form completed by PI
- Confidentiality agreement signed ➡ Full protocol or synopsis of protocol provided
- **Site assessment visit**
  - Sponsor makes decision about site selection
  - Investigator makes decision about whether to proceed

SITE ASSESSMENT VISIT

- Attended by Sponsor or CRO representative/s, Investigator, Study Coordinator/Research Nurse/ Ancillary staff
  - Discussion of logistics of trial
  - Tour of facilities
  - Opportunity to identify local issues/requirements e.g. Processes to gain necessary approvals at site
  - Opportunity to discuss budget issues e.g. set-up costs, archiving costs

ITEMS THAT MAY BE UNDERESTIMATED WHEN CONSIDERING A STUDY!

- Unscheduled patient visits or follow-up activities
- Time spent with CRA/auditors, resolving queries, following up AEs etc
- Payment for recruitment activities, screen failures, patients that withdraw from study
- Patient expenses – e.g. parking, transport, meals
- Training Costs
- Archiving costs

CONCLUSION

- Feasibility assessment is **an investment** to ensure a good study outcome for all parties - sponsor - investigators - patients
- Unmet recruitment targets are costly for both the sponsor and the investigator/site
- Unrealistic projections can impact on a sites selection for future studies

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Thank you