A START UP GUIDE

Research 101
"So you plan to do some research?"

Pre start

- Great - we are here to help you!
- It takes a while to set up a clinical research study.
- Involve a statistician at an early point.
- Ethics/Governance submission to approval is around 3 months.
- Having someone with some research experience involved is really helpful.
- Undertake a Good Clinical Practice (GCP) course - covers international standards of clinical research.

Considerations

- Reduce procedures / activities that create additional work for sites & patients.
- Eliminate items not participant safety-related and keep those directly relevant to answering main research question.
- Determine correct randomisation & stratification methods.
- Only collect data necessary to maintain participant safety and address main study objectives (endpoints).

Start

- Keep it simple.
- Aim to answer 1 question and/or formulate 1 hypothesis.
- Limit protocol complexity.
- Start with the big picture and move to the details.
- Things will get complicated, consider speaking to someone who has done research before to get advice.

Write the Protocol

- Reasons for doing the trial (participant safety is key).
- Numbers of participants needed in the study?
- Who can be in the trial (eligibility criteria)?
- What treatment is to be given?
- What medical tests needed.
- How, when and what information will be collected?
- How and when results will be released or provided to participants?

Funding

- See the budget template.
- Consider applying for funding
- Set a budget.
- Create milestones and a way to keep costs on track.
- Find the best way to measure the performance, remember:

NEXT STEP

- Go to, **'What is the submission process?'**.