Clinical research: before you start

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1 Before you start : the research process – designing your study

There are a number of well-established steps to undertaking a research study in the pre-clinical or clinical sciences. Successful research requires a systematic research process.

- Plan your study before you start
- Planning now will save time and tears later

Steps to undertaking a research study:

1. Formulate your research question
2. Select the best study design
3. Plan your data collection
4. Plan your data analysis
5. Estimate the sample size needed
6. Consider the ethical implications
7. Write a detailed study protocol including your statistical analysis plan
8. Conduct your study
9. Analyse and report your results
10. Submit your manuscript
11. Address the reviewer's comments
12. Congratulations, your study is published!

A note on the side - authorship. Authors of the paper and their order of appearance should be decided before the study starts.

- Invite colleagues and co-researchers to work with your project team early in the process

- Decide on a policy for authorship - who will be first author, middle and last author - saves misunderstandings later on
- In general, the person who actually conducts the study and writes the bulk of the manuscript is first author
- The most senior colleague is the last author (head of research team, clinic director, senior mentor)
- Everyone else goes in the middle
- Authors have to have made a substantial, justifiable intellectual contribution
- Technical staff doing their normal 'day job' receive an acknowledgement at the end of the paper

2 Formulate your research question or series of questions

This is possibly the most important part of your study. Using the PICO (Population, Intervention, Comparison and Outcome) format will help you formulate an answerable research question.

3 Select the best study design to answer your question

The most common study designs are randomised controlled trials or observational studies, which encompass cohort, case-control or cross sectional (survey) studies. Each of these has particular strengths and weaknesses. See the SPIRIT and CONSORT statements for randomised controlled trials; STROBE statement for observational studies. For a comprehensive list see the Equator Network. If you are not confident in this area, talk to an epidemiologist or biostatistician BEFORE you select a design for your project. Download a pdf guide to types of study here: Design: types of study.

4 Plan your data collection

You need to plan in advance how you will collect and store your data. Download a guide to data collection here: Data collection and spreadsheet management. For a cheat sheet on statistical methods, see: Statistics cheat sheet.

5 Plan your data analysis

Plan your data analysis to answer your research question/s. For formal studies, you may be obliged to write a 'Statistical Analysis Plan' (SAP). Even for smaller more informal studies an analysis plan is strongly recommended. Tabulate the outcome variable, predictor variables and the method of analysis for each research question.

6 Estimate the sample size needed

Estimate the sample size you will need to have a pre-determined chance of accepting or rejecting your hypothesis. For example, it is conventional to set the power of a study at 80%, or an 80% chance of detecting a difference between groups, if there is one. You also want to have a low chance of making a 'false discovery', conventionally set at 5%. These concepts are known as 'Type II' and 'Type I' errors. Estimate your sample size based on the primary outcome for your study. See Sampling and sample size calculation Sampling and sample size.

7 Ethical implications

Consider the ethical implications of your study. What is the potential for benefit or harm to your study participants and the wider community?

8 Write a detailed study protocol

This will be the 'Bible' which details all aspects of your study. The protocol will need to be submitted to your institutional ethics committee for approval. (You may have to adapt your protocol to conform to a format required by the ethics committee).

9 Conduct your study

Recruit your subjects, collect your data - follow your study protocol.

10 Analyse and write up your results

It is strongly recommended that you document all computer code to make sure that your results are reproducible. Write your manuscript using the IMRAD (Introduction, Methods, Results, Discussion and conclusion) structure. For a concise but comprehensive guide to statistical reporting see SAMPL guidelines. For tips on getting started writing your paper, see How to write a paper.

11 Submit your manuscript

Submit your manuscript to a suitable journal, aiming to reach your target audience.

12 Address the reviewer's comments

Almost always, even if your manuscript is accepted you will need to address the reviewer's comments. Address these as fully as you possibly can. Remember

that reviewers work for nothing, and their comments will only improve your communication.

13 Your paper is accepted! Congratulations and well done!