



# Basic guidelines for developing surgical research

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# Summary

1. Identify the research question
2. Identify specific endpoints
3. Develop an appropriate study design
4. Plan for data collection, management and statistical analysis
5. Plan and implement Quality assurance
6. Assess your resources to conduct the study
7. Secure ethical approval
8. Build and educate the research team
9. Data analysis
10. Publish and present your data

# Very important First Steps

## I. Identify the research question

- Strive to work on a novel and clinically relevant research idea
- A first step should always be to perform a systematic literature review to identify existing data and previous similar studies
- Consider a meta-analysis
  - Follow PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)
  - <http://www.prisma-statement.org/>
  - Whenever possible, pool the data in a formal meta-analysis, the RevMan software from the Cochrane collaboration is a great tool for this purpose
  - <http://tech.cochrane.org/revman>

# Very important First Steps

## 2. Identify clear and specific endpoints

- Choose **one** *primary* endpoint
  - Imperatively, consider the statistical power of your endpoint
- Choose an endpoint that is *clinically relevant* to patients
- Avoid examining multiple primary endpoints: this will lead to overestimation of effects
  - Consider exploratory secondary endpoints
  - Consider integrating translational research
- Consult the COMET (Core Outcome Measures in Effectiveness Trials) initiative for some guidance on appropriate endpoints
- <http://www.comet-initiative.org/>

# Focus on Methodology

## 3. Develop an appropriate study design

- Consult EARLY with your statistician
- As much as possible, surgical research should be planned and designed *prospectively*
- Randomization in surgical research is difficult, but not impossible
- When considering an RCT, follow the CONSORT guidelines (<http://www.consort-statement.org/>)
- When blinding of surgeon is impossible, outcome assessors must be blinded to the intervention group
- Consider non-inferiority trials for interventions that potentially put patients at risk
- Develop an appropriate and clinically feasible study design

# Focus on Methodology

## 4. Plan for data collection, management and statistical analysis

- Discuss with your study team:
  - What data will be collected
  - Who will collect the data
  - How they will be collected – creation of a database
  - How they will be checked
  - How they will be analyzed

## 5. Plan and implement Quality Assurance

- QA should be a continuous process from beginning to the end and in all aspects of the study
- The whole study team must be committed to QA

# Consider Feasibility

## 6. Assess your resources to conduct the study

- What resources are needed to conduct your study?
- Where can you secure funding? Grants?
  - Apply for funding as early as possible
- Do you have the patients for the study or will they come from other hospitals? Can you collaborate with them?

## 7. Build the research team: Clinical research is teamwork!

- Principal and co-investigators - imperative
- Statistician - imperative
- Research nurse / Data manager - ideal
- Regulatory affairs manager / Project manager – ideal
- Translational research collaborators - ideal



# Securing Ethical Approval

8. Obtain permission from your local Ethical committee or institutional review board

- Written informed consent is mandatory
- Register your trial with [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
  - This is mandatory for many journals when submitting the study results for publication.
  - For Europe, a European registration should be submitted (<https://eudract.ema.europa.eu/>)
- Secure your ICH-GCP training  
<http://www.ich.org/home.html>

# Data analysis

## 9. Execute your data analysis plan as specified in your study proposal

- Report intention to treat analysis
- When comparing groups, use non-parametric statistical tests for small (<30) datasets and/or when data distribution is non Gaussian
- When using multivariable analyses, make sure the number of events is sufficient in relation to the number of variables in the model (ideally, at least 10 events per variable).
- Always report 95% confidence intervals in addition to P-values

# Presenting your data

## 10. Aim to publish and present your results internationally

- Choose the right conference/journal for your work
  - Evaluate if your research fits into the scope of the conference or the journal
- Be familiar with the scientific journals and their requirements
- Edit and proofread your manuscript
  - Use correct and scientific language
- Make use of professional graphs/charts

# Take it to the next level

- Don't stop with one research study!
- Think of the next one based on what you have accomplished.
  
- For comments and suggestions, please do not hesitate to contact <http://www.essoweb.org/eursso/about-esso/esso/secretariat.html>