

18 STEPS TO DESIGNING AND COMPLETING A CLINICAL STUDY

Ingredient or Product to Study

Which ingredient or product do you want to research?

01

Target Population

Which population do you want to study? Consider age, gender, health condition, and other relevant demographics.

03

Study Sample Size

How many people will you recruit for the study? It is important that the sample size is not too small as it will be difficult to obtain significant findings. However, it also should not be too large as this adds to the costs of the study.

05

Control Group

What will your comparison control group be? Will it be a placebo-controlled study? Will you compare to an existing efficacious treatment?

07

Volunteer Eligibility Criteria

Who will you recruit for the study? What is your inclusion and exclusion criteria? This is important as you do not want the criteria to be too rigid as this will make recruitment difficult. However, making it too wide will also impact on your results.

09

Recruitment Plan

How will you recruit participants for your study? Ninety percent of studies are delayed because of poor recruitment planning.

11

Clinical-Trial Registration

Listing on a clinical-trial registry is important prior to commencing your study. There are several options available.

13

Statistical Analyses

Once all data is collected, how will you analyze the data? What statistical analyses will you use to evaluate the outcomes?

15

Journal Submission

Will you publish the results in a journal? This increases study credibility and helps publicize the study findings. It is important to publish in a high-impact, peer-reviewed journal that is listed on article databases.

17

02 Health Benefits

What are the health benefits associated with your product and which one(s) do you want to investigate?

04 Health Claim vs Medical Claim

Will the outcomes of your study support health claims or medical claims? For dietary supplements it is important that your study is designed so you can make health claims.

06 Study Design

What study design will you use? A randomized-controlled trial is the gold-standard study design and is essential for allowing you to make health claims.

08 Study Duration

How long will the study be? You need to choose a time frame that ensures your product has enough time to work. However, do not make it too long as this will increase the likelihood of study drop-outs and increase study costs.

10 Outcome Measures

What outcome measures will you use? It is important to use reliable and valid assessment instruments to evaluate treatment outcomes.

12 Ethics Approval

All human studies require approval by an ethics/institutional review board. This involves completing all the essential documentation so you can quickly obtain approval.

14 Data Collection

How will you collect data for your study? Choose a method that will be easy for your volunteers. Also, how will you ensure confidentiality of the material?

16 Report Writing

Who will be responsible for writing up the study design outcomes? It is important that this person has expertise in the area.

18 Dissemination of Information

How will you present the study and its findings to the wider public and relevant stakeholders? It is important this is done in a user-friendly way. Easy-to-understand reports and videos can be helpful.



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