What you need to know before you start your research

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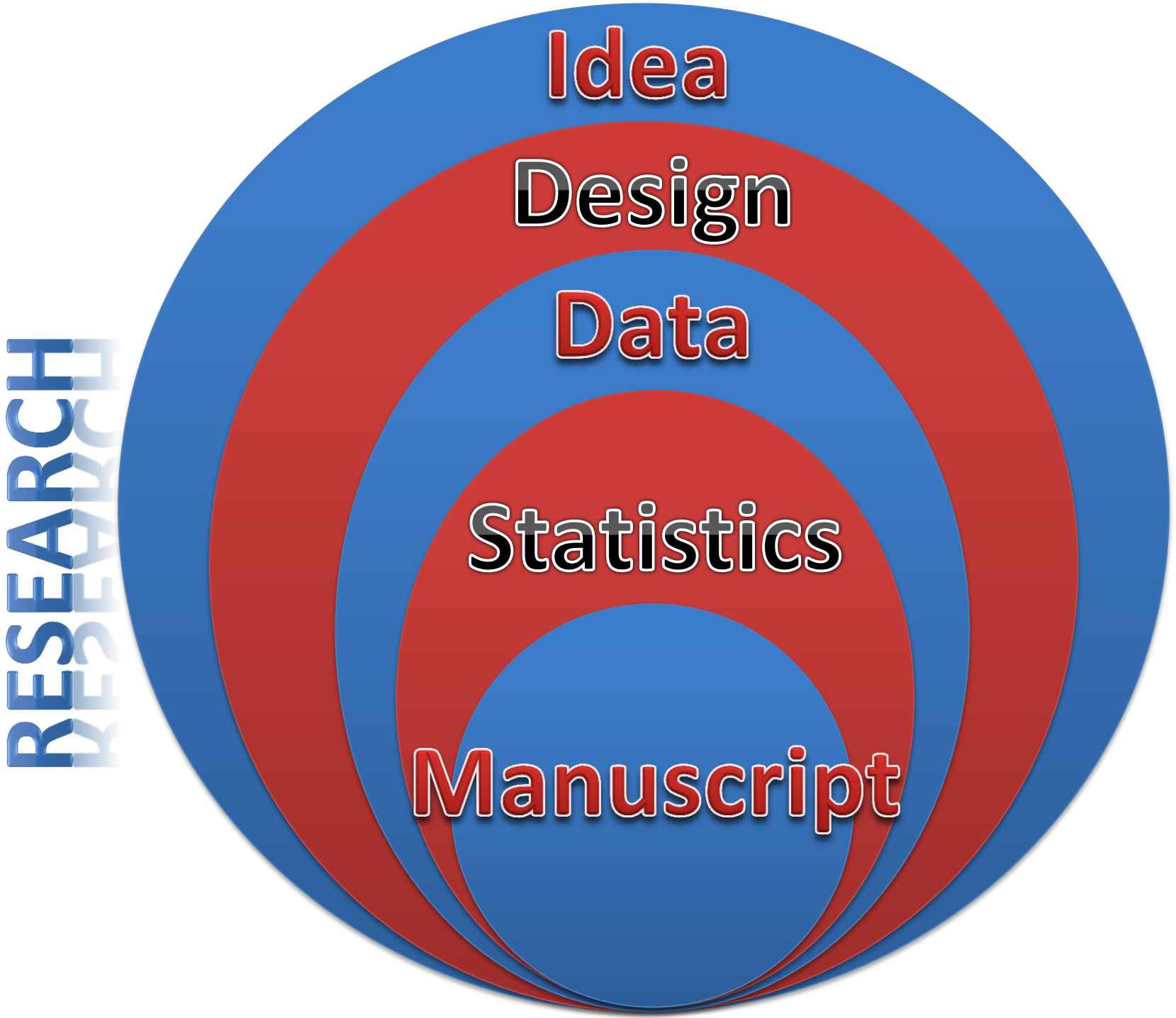
Think before you act !

https://www.youtube.com/watch?v=LI92DLRdKYE


RESEARCH
Idea
Design
Data
Statistics
Manuscript

1st Step - Literature Review

A critical summary of research on a topic of interest

Prepared to put a research problem in context

or

To identify gaps and weaknesses in prior studies

In other words - To justify a new investigation !

Recent meta-analysis ?

Systematic review ?

2nd Step-Think

1. Why your study should be done
2. What you intend to accomplish
3. How you will do it

Prepare a step by step workplan presenting all the elements of your project !

2nd Step-Think

- Why is the research important?
- Has it been done before?
- Will the study benefit patients, increase knowledge and/or influence policy?
- Will research resolve controversies?
- Would the answers have clinical value?

3rd Step - Research Objectives

- Explicitly state what you propose to study.
  - Testable
  - Logically derived from the literature review
- Includes:
  - Population of interest (person, place, time)
  - Variables (independent and dependent)
  - Relationship between variables being investigated

3rd Step - Research Objectives

Keys to success:

- Be clear and consistent
- Generally have only one or two primary research objectives
- Your objectives must be measurable.
- Objectives must be novel

4th Step - Issues to consider

Issues to consider in design

- Potential biases that may emerge
- Feasibility (logistics)
- Cost
- Level of evidence
- Limitations
- Ethics

5th Step – Study design

Intervention (experimental) studies

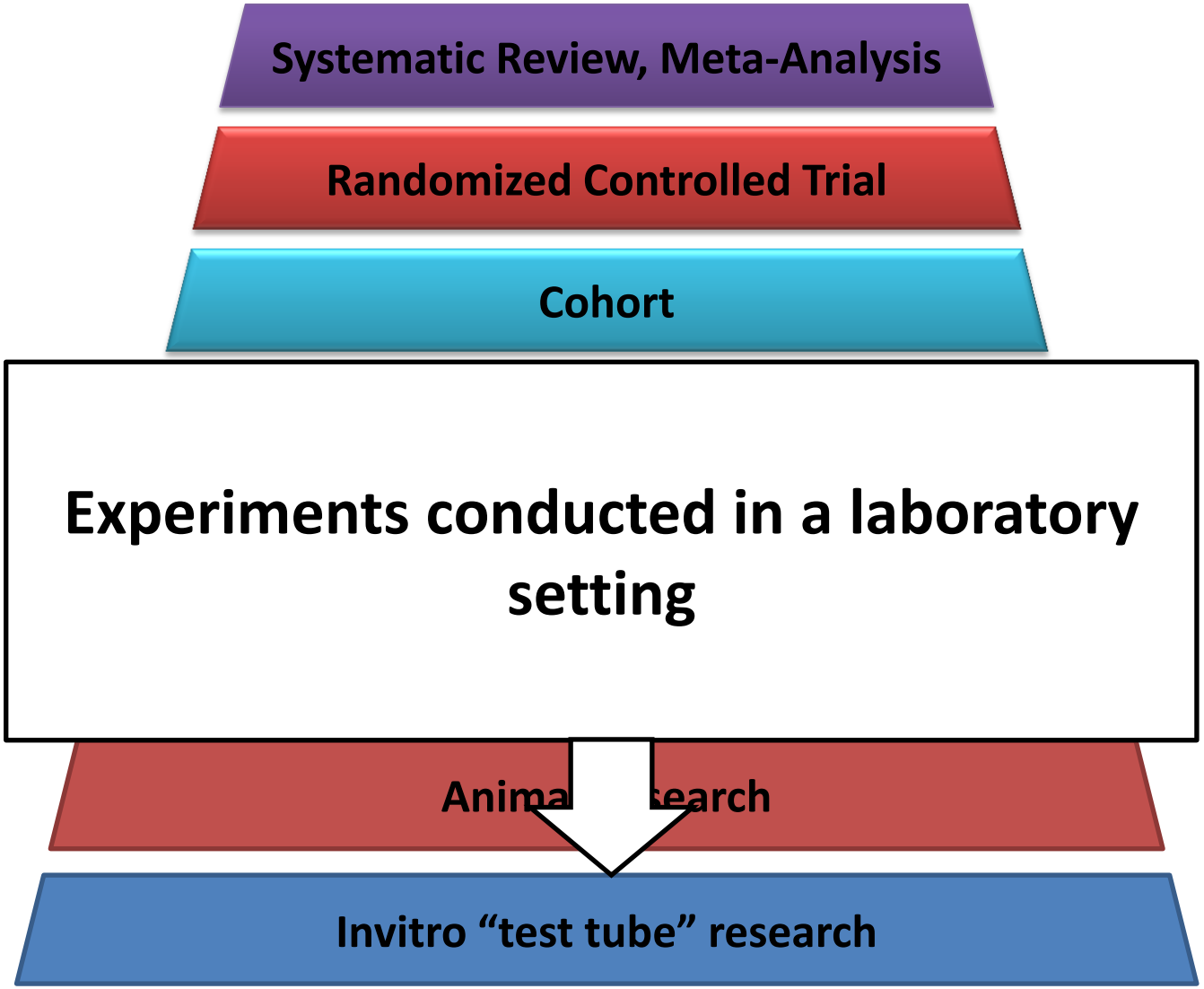
- Clinical trials
- Field trials (community trials)

Observational (non-experimental) studies

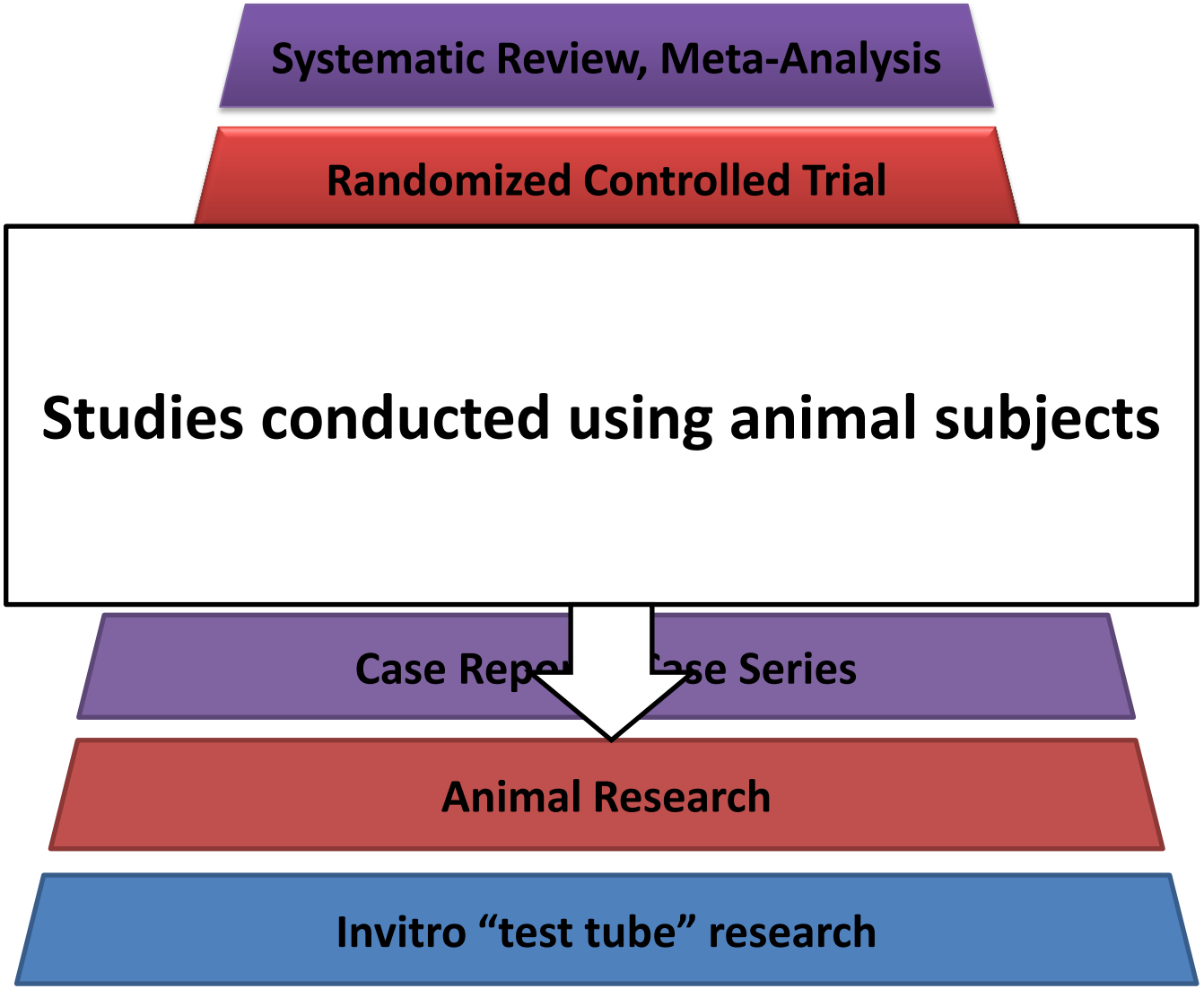
- Cohort
- Case-control
- Cross-sectional
- Ecological

Remember the evidence pyramid !

The Evidence Pyramid


Systematic Review, Meta-Analysis
Randomized Controlled Trial
Cohort
Experiments conducted in a laboratory setting
Anima search
Invitro “test tube” research

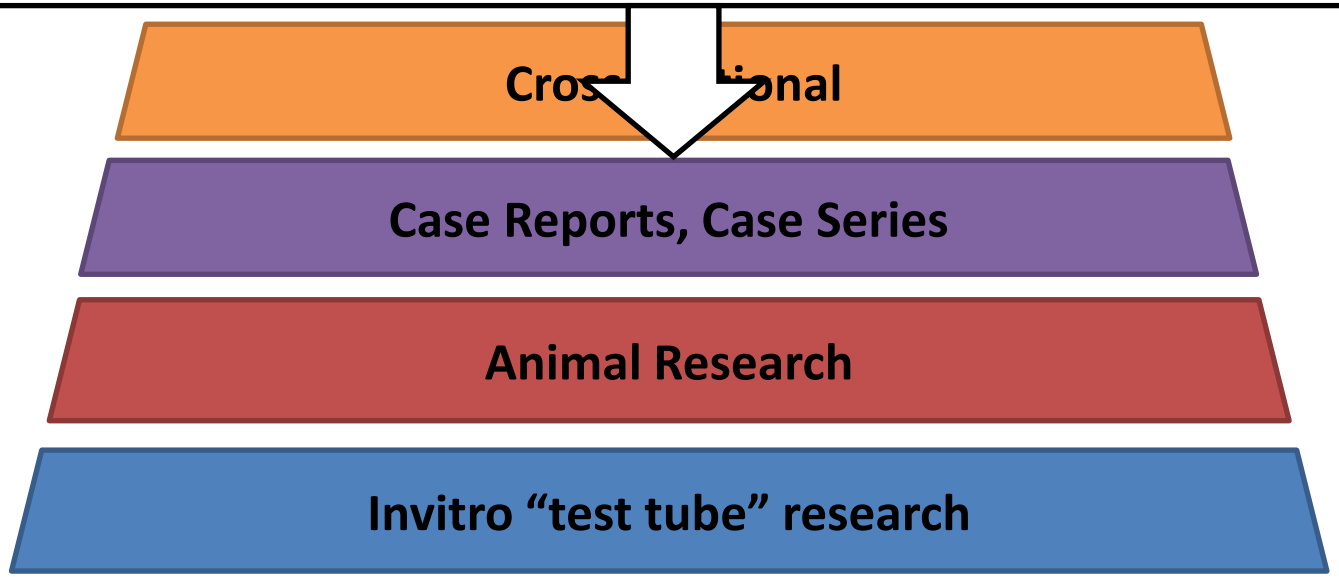
The Evidence Pyramid



The Evidence Pyramid

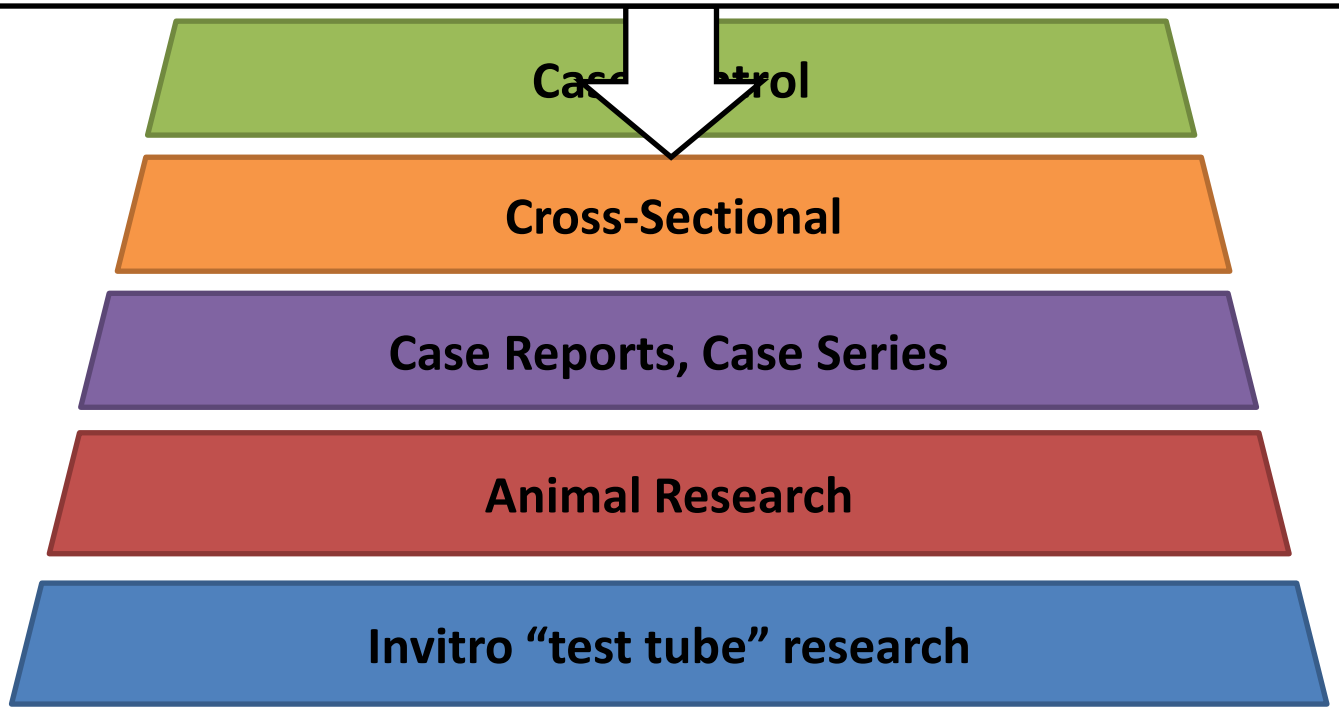
- A summary of one individual's experience with the disease or outcome

- A summary of a small group of individuals' experience with a similar disease or outcome

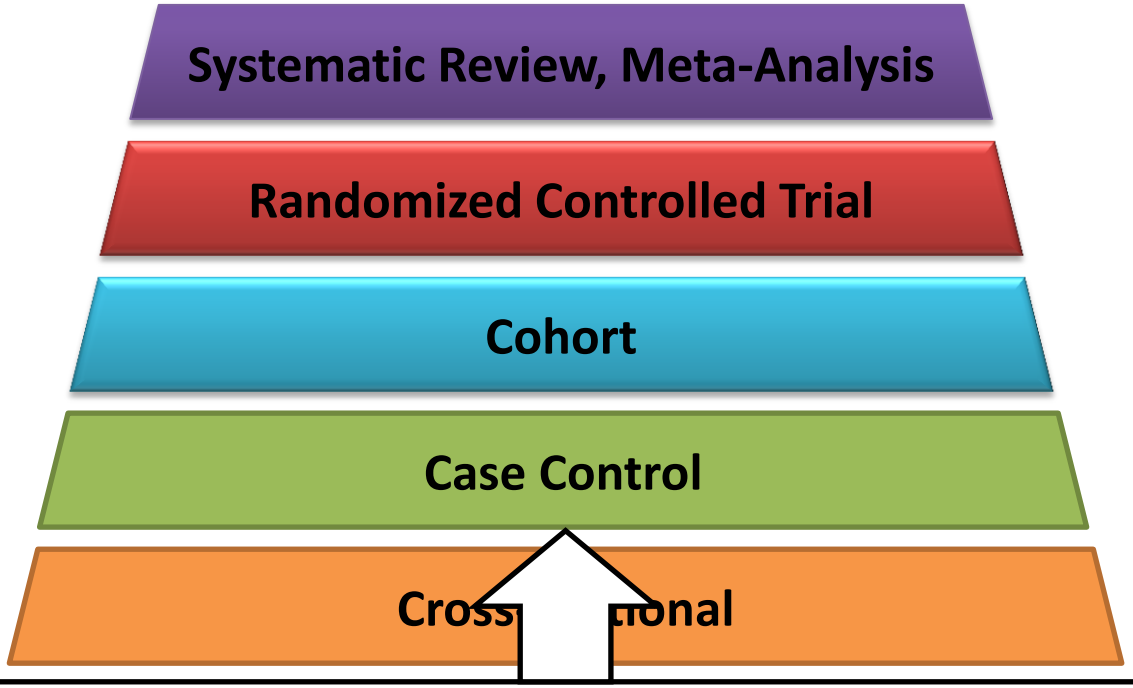


The Evidence Pyramid

Study that observes the relationship between a characteristic/risk factor (the exposure) and the prevalence of the disease or outcome of interest in a specific population at a single point in time

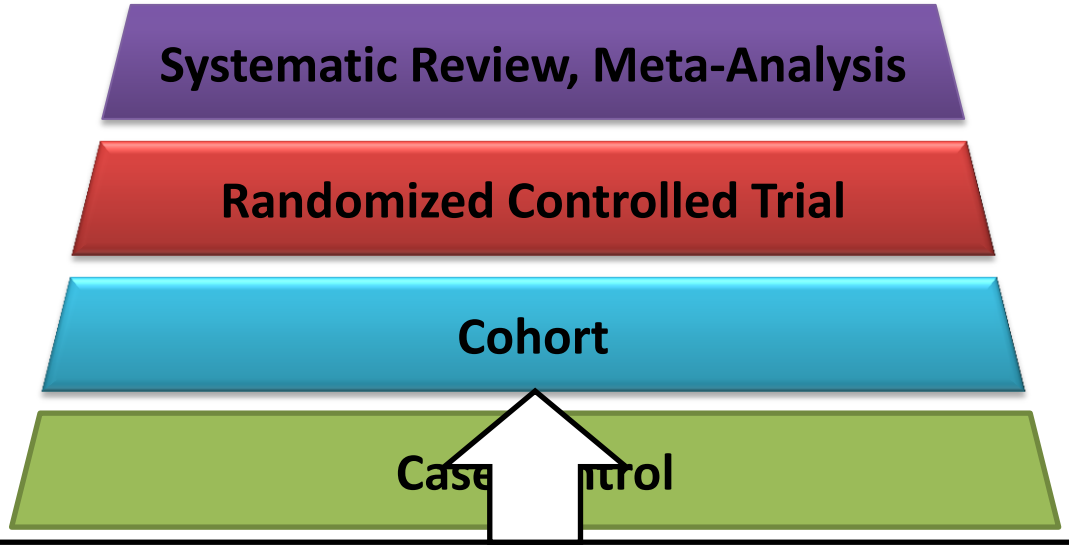


The Evidence Pyramid



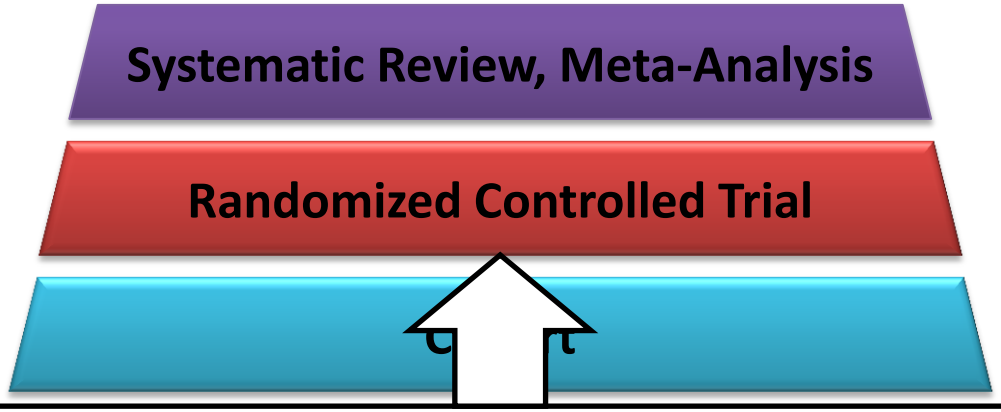
Study that compares individuals who have a disease or outcome of interest (cases) with those who do not (controls). Researchers look retrospectively to evaluate how frequently exposure to a risk factor is present in each group to identify the relationship between the risk factor and the disease or outcome of interest

The Evidence Pyramid

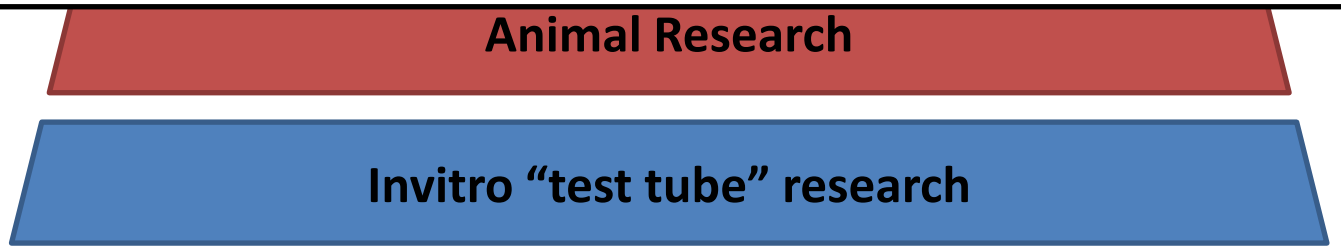


Study design where the population are classified according to their level of exposure to a given risk factor and followed over time to determine if this exposure is related to the occurrence of a disease or outcome of interest.

The Evidence Pyramid



Study where participants are randomly assigned to receive a given exposure and then followed to examine the effects of the exposure on outcomes.



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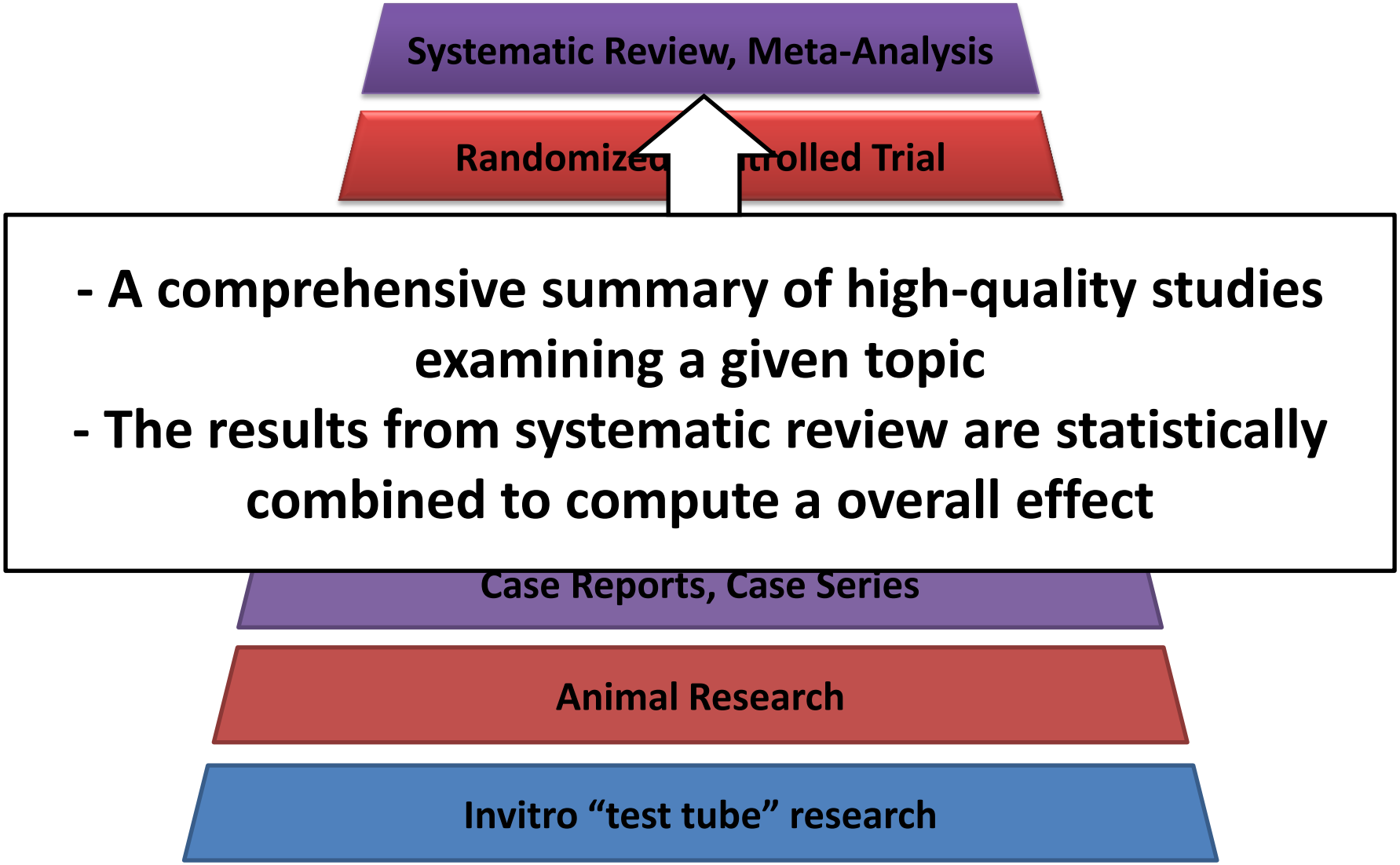
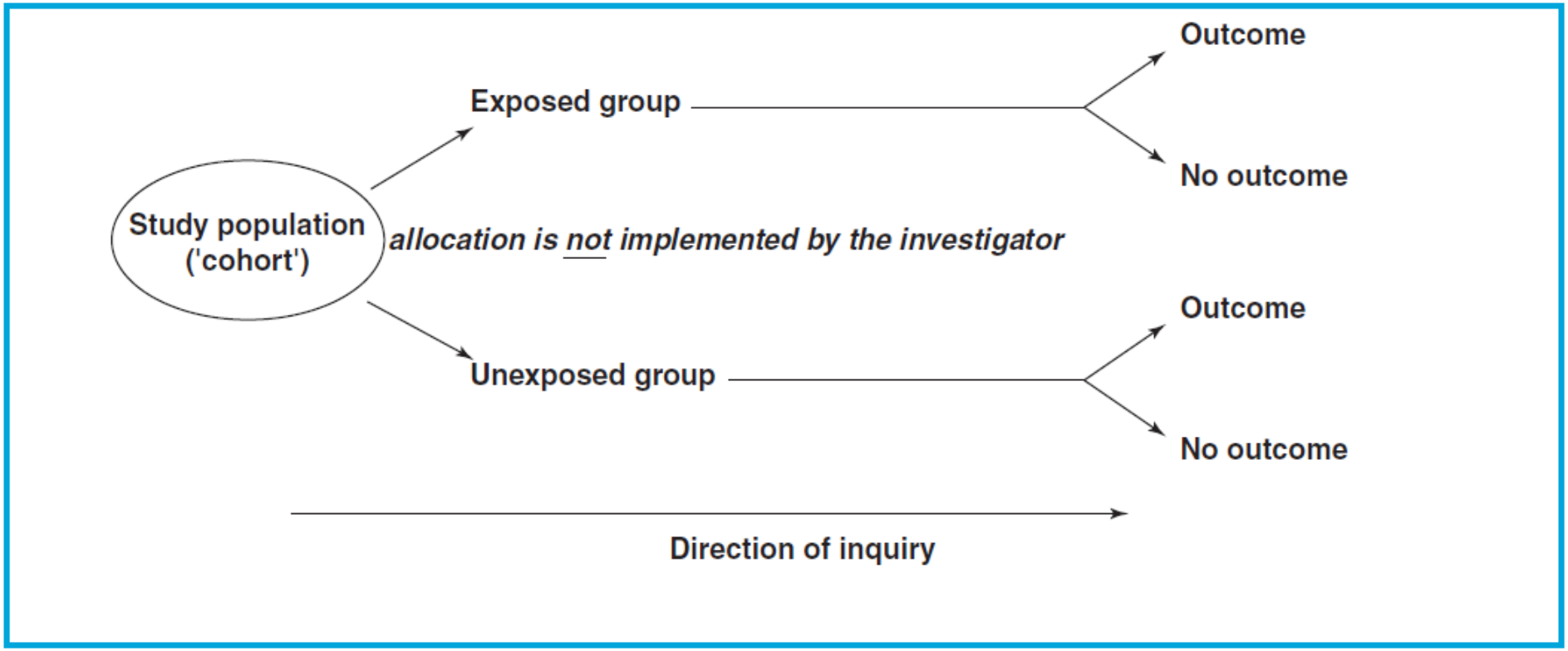
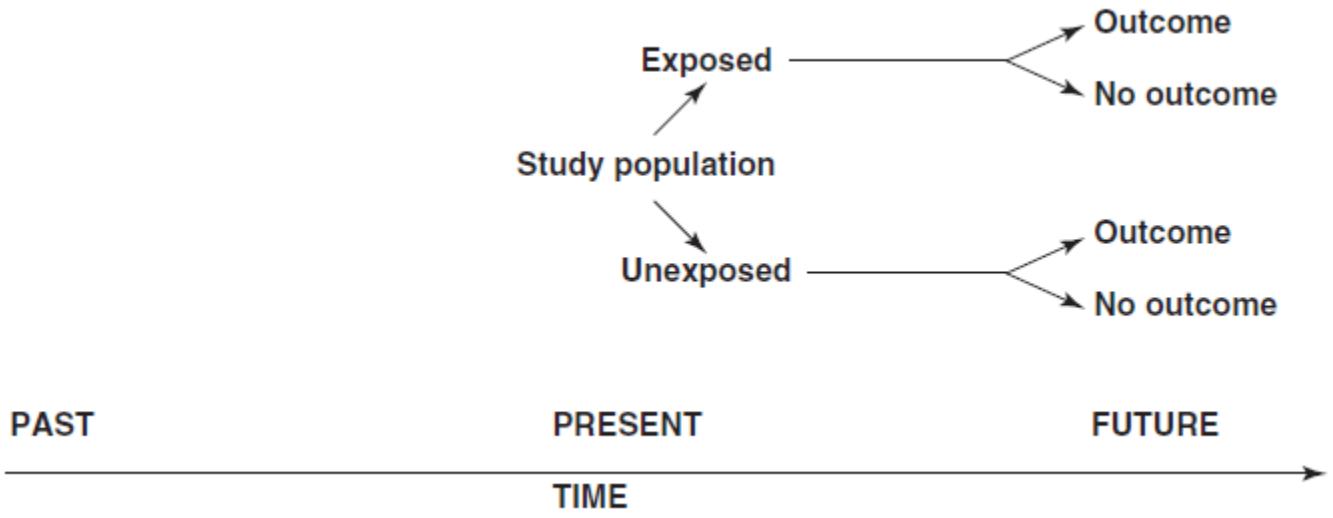


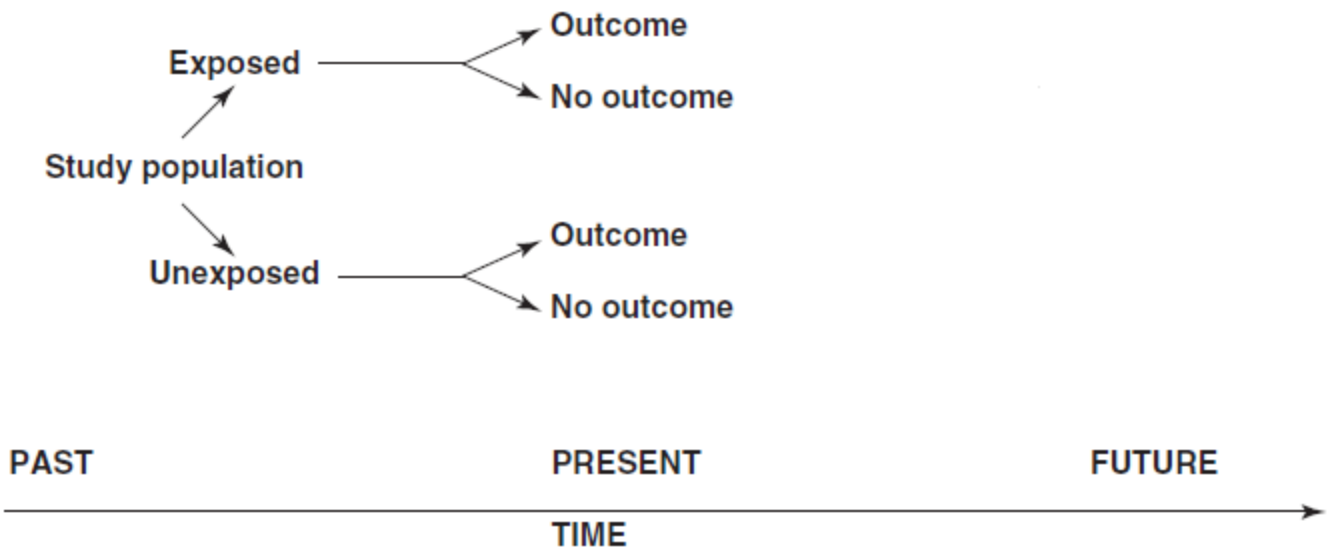
Cohort studies design



Prospective cohort study



Historical cohort study



Duration of follow-up

Until the first occurrence of either of these following events:

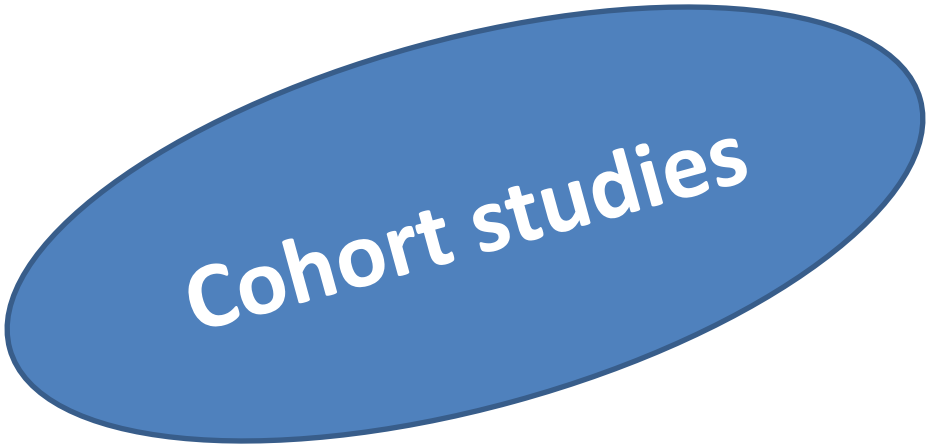
- Disease onset
- Loss of follow-up
- End of the study period

Limitations

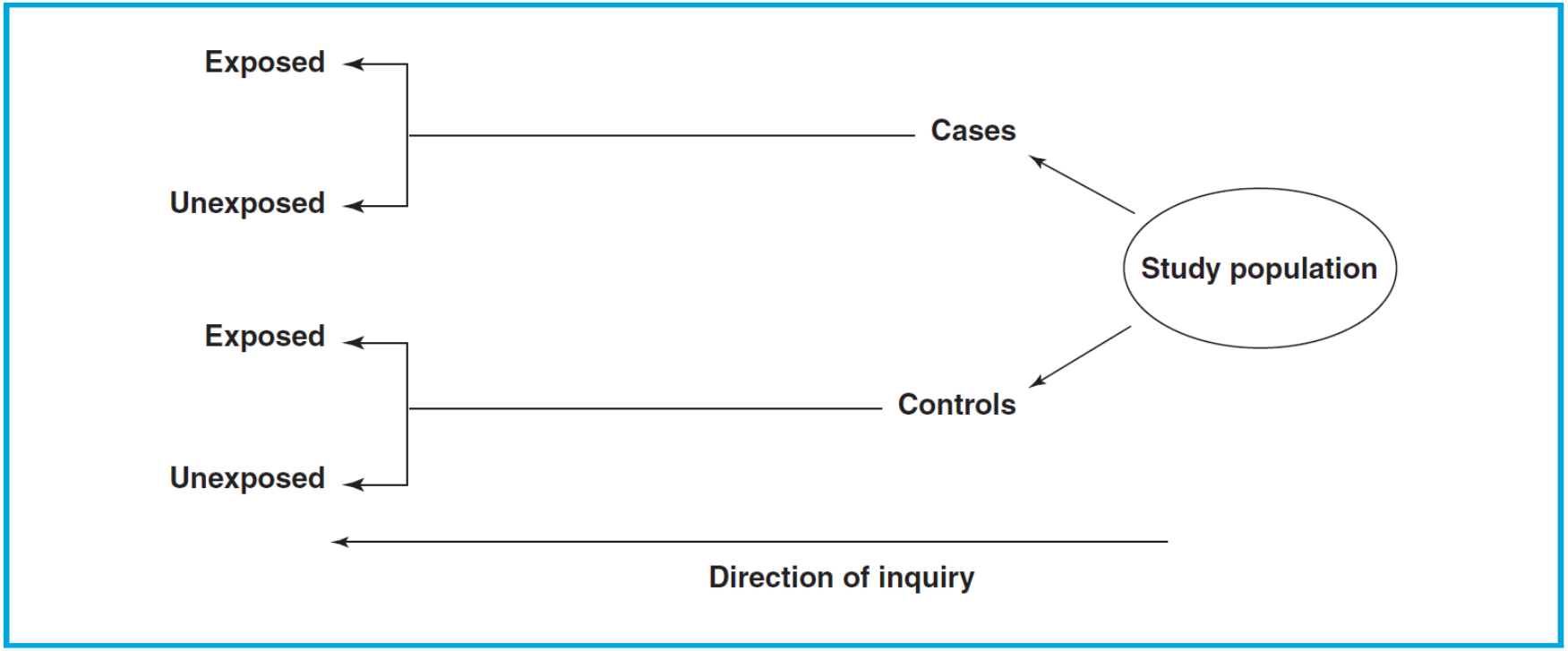
- Results may be available after a long period of time (prospective cohort study)
- Lost to follow up (may cause a bias)
- Usually more expensive (prospective cohort study)
- Changes in diagnostic criteria and/or methods during the time of follow up
- Not suitable for rare diseases
- Exposure status may change during follow up

Advantages

- ✓ Evaluation of Risk / Incidence
- ✓ Many outcomes could be studied
- ✓ Suitable for rare exposures



Case - Control studies design



Limitations

- Can not give evaluation of Risk / Incidence
- Not suitable for rare exposures

Advantages

- ✓ Many exposures could be studied
- ✓ Results available after a short period of time
- ✓ Suitable for rare diseases

Research Proposal – METHODS
Subjects

Who will you study? Why?

Specify eligible subjects

- Target population: clinical & demographic characteristics
- Accessible population: temporal & geographic characteristics

6th Step – Study population and Comparison groups

Who will you study? Why?

Specify eligible subjects

- Target population: clinical & demographic characteristics
- Accessible population: temporal & geographic characteristics

It is important that the groups being compared are as similar as possible with respect to all other factors that may be related to the disease.

6th Step – Study population and Comparison groups

- Prepare appropriate inclusion/exclusion criteria
- Justify the use of the study population and the sampling method
- Will you use sampling ?
- What are the recruitment methods ?

Do not confuse randomization with random selection !

7th Step – Prepare data collection plan

A detailed plan for collecting and handling data, including procedures for:

- Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers.
- Give diagnostic criteria.
- Recording, storing and reducing data
- Assessing data quality

Measurement instruments / questionnaire !

Measurement scales

Gold standards ?

8th Step – Statistical plan

In observational studies the investigator has no control over who is or is not exposed.

Therefore, it is likely that the exposure groups will differ in relation to factors other than the one being investigated !

Special techniques must be applied in the analysis in order to ensure that these uneven distributions are taken into account !

- Multivariate analysis ?
- Matching ?

9th Step – Sample Size

We usually can't measure everyone !

- Forced to make inferences regarding "true" or underlying characteristics of a population on the basis of data collected from a sample.
- The more subjects we use or measure, the more accurate our estimates will be.
- If we measure too many, we will waste resources !
- If we measure too few, we won't be able to detect effects of interest !

10th Step – Limitations

- Be upfront about the limitations of your study.
- This is one of the most important steps that shows you have thought through all aspects of your study.
- Be clear about why you are not able to overcome these limitations a priori.
- How might these limitations impact the findings?
- If there are clear issues, better to talk about them than leave them open.

Summary - Checklist

- ✓ Informative title
- ✓ Clear research questions
- ✓ Thorough and relevant background
- ✓ Convincing rationale/significance
- ✓ Clearly defined (and measurable) research objectives
- ✓ Appropriate population and sample
- ✓ Appropriate measurement and intervention methods
- ✓ Adequate sample size
- ✓ Sound analysis plan
- ✓ Ethical issues well addressed
- ✓ Tight budget
- ✓ Realistic timelines