Research Methods

Why Health Research

- "**Research**" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- **Research** is "creative and systematic work undertaken to increase the stock of knowledge".
- It involves the collection, organization, and analysis of information to increase understanding of a topic or issue.

- **Health research** has high value to society. It can provide important information about disease trends and risk factors, outcomes of treatment or public health interventions, functional abilities, patterns of care, and health care costs and use.
- The term **"health research**," sometimes also called "**medical research**" or "**clinical research**," refers to research that is done to learn more about human health. Health research also aims to find better ways to prevent and treat disease.

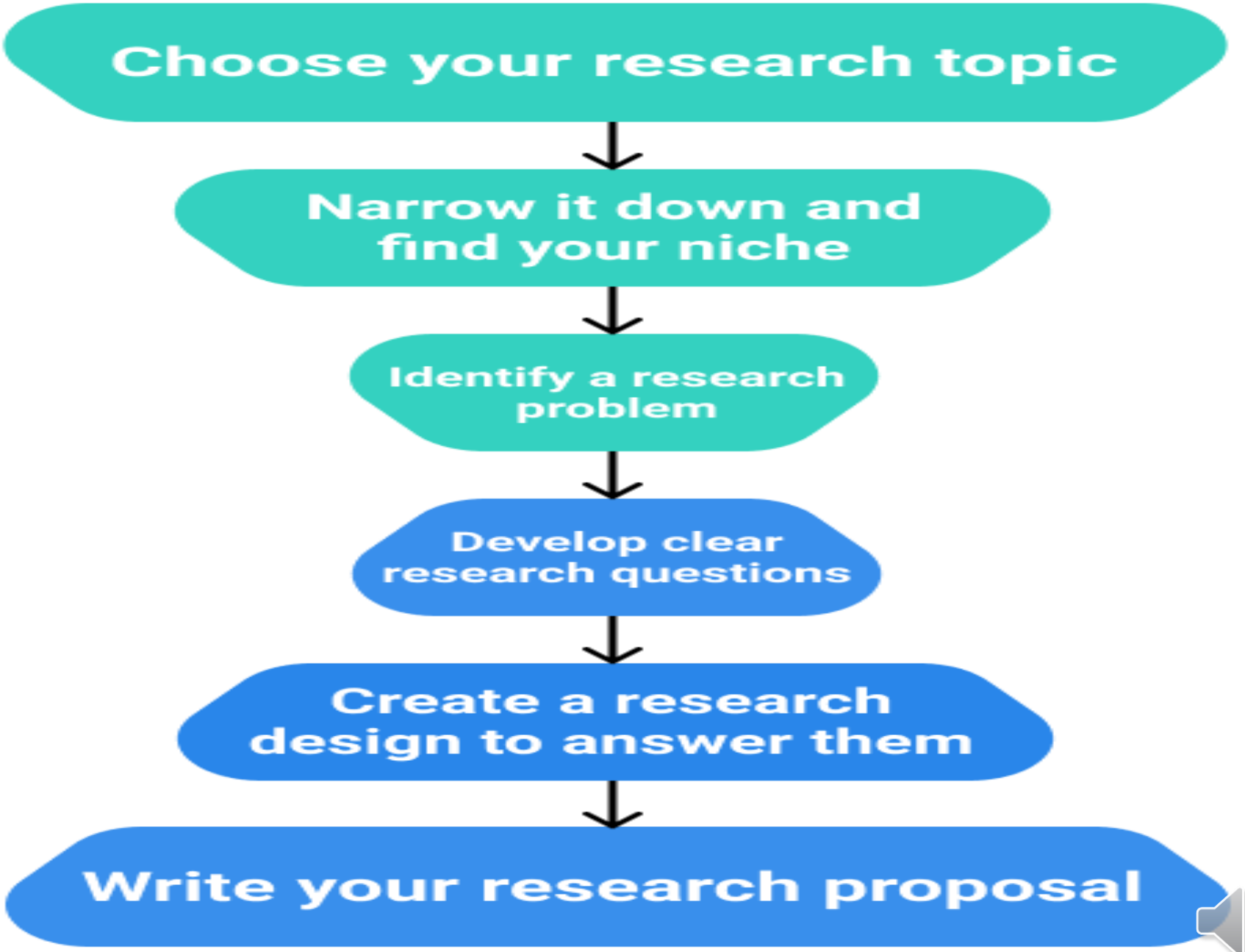
Why Health Research

Health research is an important way to help improve the care and treatment of people worldwide.

- To gain more knowledge about illness and how the human body and mind work.
- Testing new drugs, vaccines, surgical procedures, or medical devices
- New diagnostic technique

How to Start Research

- The research process often begins with a very broad idea for **a topic** you'd like to know more about. You do some preliminary research to identify a **problem**. After refining your **research questions**, you can lay out the foundations of your **research design**, leading to a **proposal** that outlines your ideas and plans.


Choose your research topic
Narrow it down and find your niche
Identify a research problem
Develop clear research questions
Create a research design to answer them
Write your research proposal

A research problem.

- It is a specific issue, difficulty, contradiction, or gap in knowledge that you will aim to address in your research. You might look for practical problems aimed at contributing to change, or theoretical problems aimed at expanding knowledge

Research Question

A good research question is essential to guide your research paper, project or thesis. It pinpoints exactly what you want to find out and gives your work a clear focus and purpose. All research questions should be:

- Focused on a single problem or issue
- Researchable using primary and/or secondary sources
- Feasible to answer within the timeframe and practical constraints
- Specific enough to answer thoroughly
- Complex enough to develop the answer over the space of a paper or thesis
- Relevant to your field of study and/or society more broadly

Research question type	Formulation
Descriptive research	*What are the characteristics of X?*
Comparative research	*What are the differences and similarities between X and Y?*
Correlational research	*What is the relationship between variable X and variable Y?*
Exploratory research	*What are the main factors in X? What is the role of Y in Z?*

Explanatory research	*Does X have an effect on Y? What is the impact of Y on Z? What are the causes of X?*
Evaluation research	*What are the advantages and disadvantages of X? How well does Y work? How effective or desirable is Z?*
Action research	*How can X be achieved? What are the most effective strategies to improve Y?*

Research objectives

- They **describe concisely** what the research is trying to achieve. They summarize the accomplishments a researcher wishes to achieve through the project and provides direction to the study

- **A research aim (main Objectives)**

  expresses the intention or an aspiration of the research study; it summarises in a single sentence what you hope to achieve at the end of a research project. Your aim should be specific and phrased in such a way that it is possible to identify when it has been achieved.

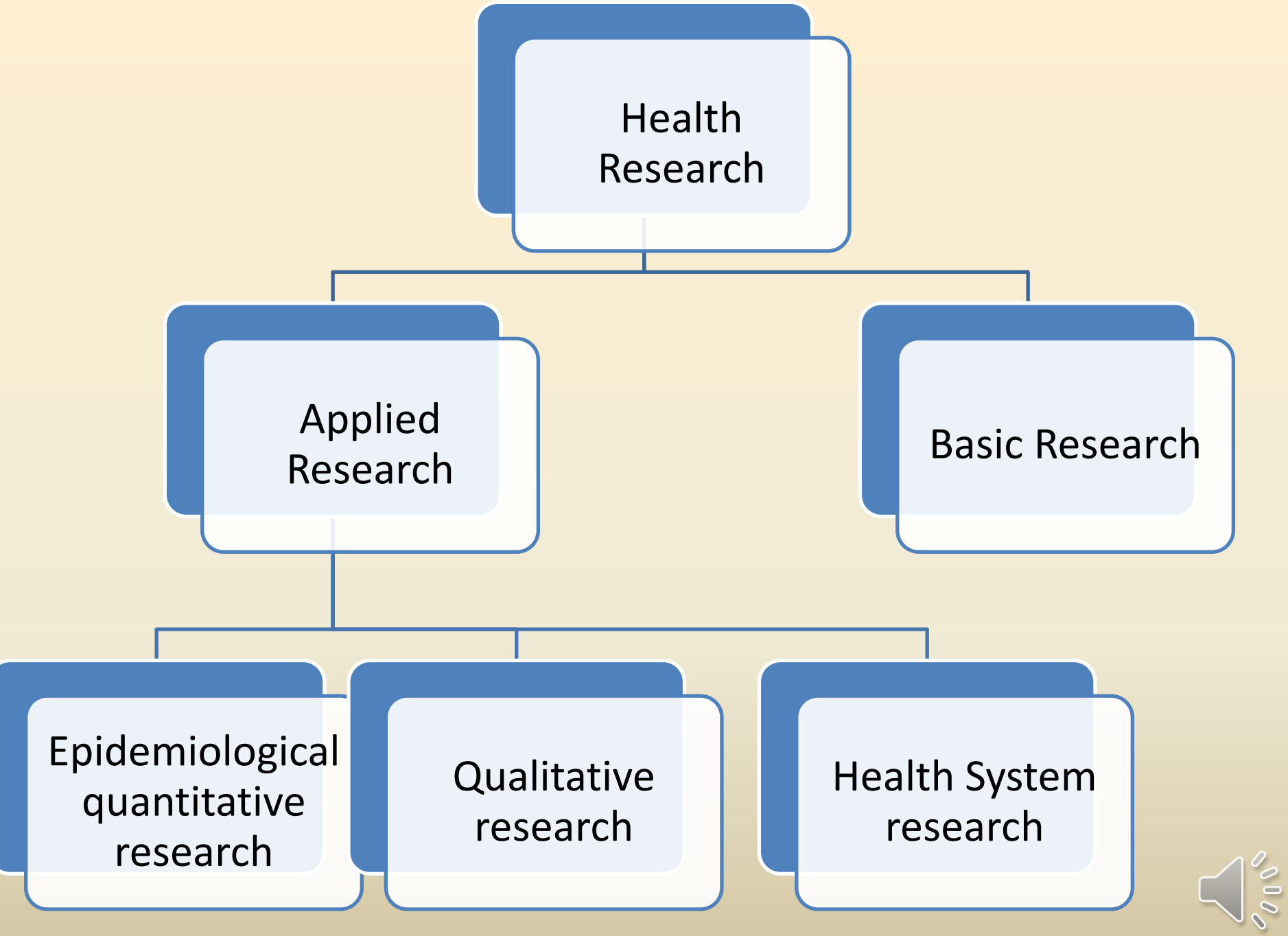
- **Research objectives(Specific Objectives)** outline the specific steps that you will take to achieve your research aim. Objectives define the what, why, who, when and how questions.

Your research aim and objectives should be **SMART**:

- **S**pecific – be precise about what you are going to do.
- **M**easureable – what evidence will you have that you have reached your goal?
- **A**chievable – Don't attempt too much. A less ambitious but completed objective is better than an over-ambitious one that you cannot possibly achieve.

- **R**ealistic – do you have the necessary resources (time, money, skills etc) to achieve the objective?
- **T**ime constrained – determine when each stage needs to be completed. Is there time in your schedule to allow for unexpected delays?

Your **aim and objectives** should drive your research project and ***answer*** your research questions


Health Research
Applied Research
Basic Research
Epidemiological quantitative research
Qualitative research
Health System research

- **Epidemiology** is "the study of the distribution and determinants of health-related states or events in specified populations

- **Epidemiology studies** are conducted using human populations to evaluate whether there is a **correlation or causal relationship** between exposure to a substance and adverse health effects.

- Measurement diseases frequency
- Diseases Determinant Risk factors
- Evaluate screen test
- Determination of natural history (Case fatality and survival time)
- Determination of prognostic factors
- Test new treatment

Qualitative research

- Underlying behaviors for certain phenomena
- WHY this most important thing we get

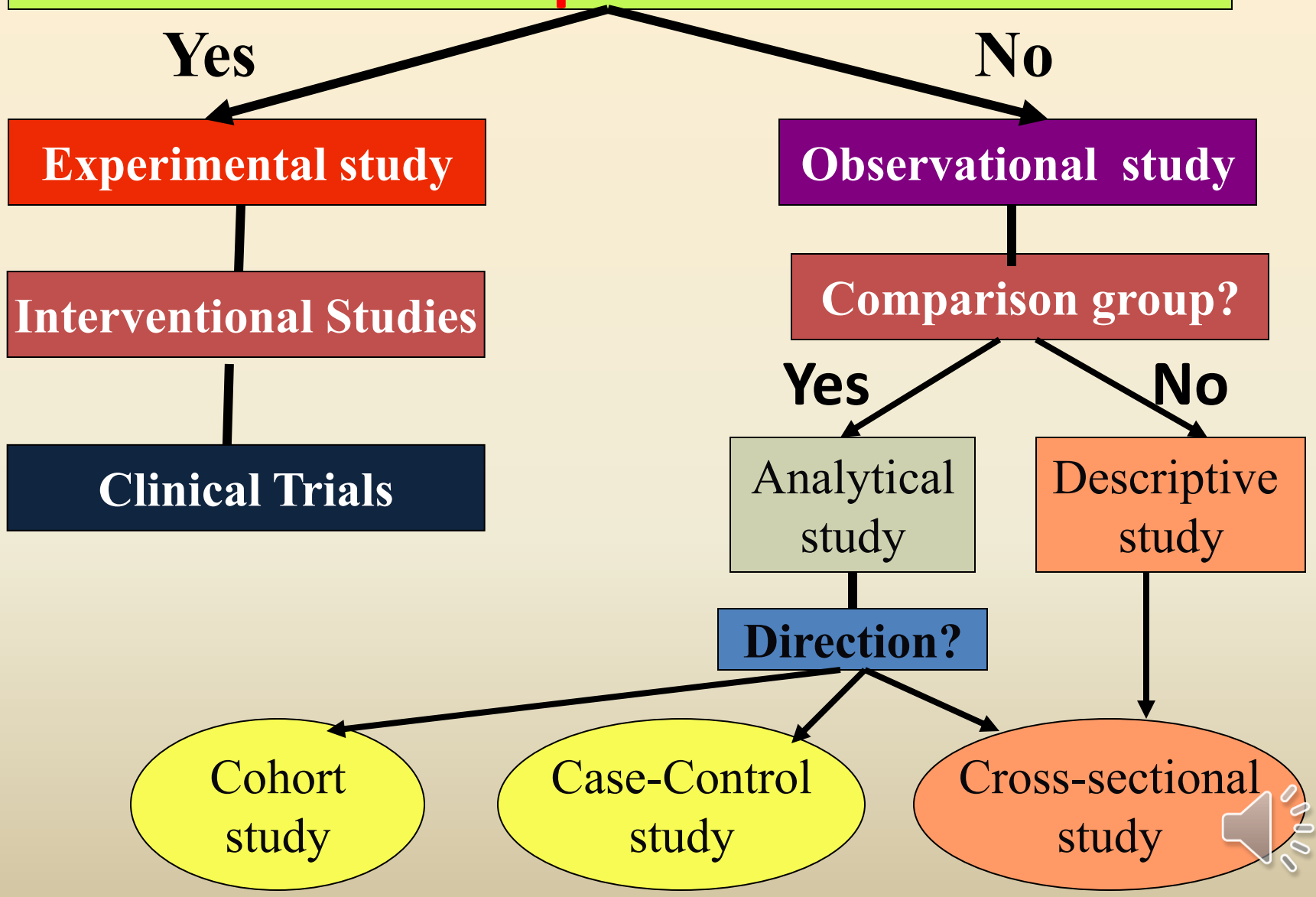
Health System Research

- Evaluate policies and programs
- We study here health unites that deliver the service

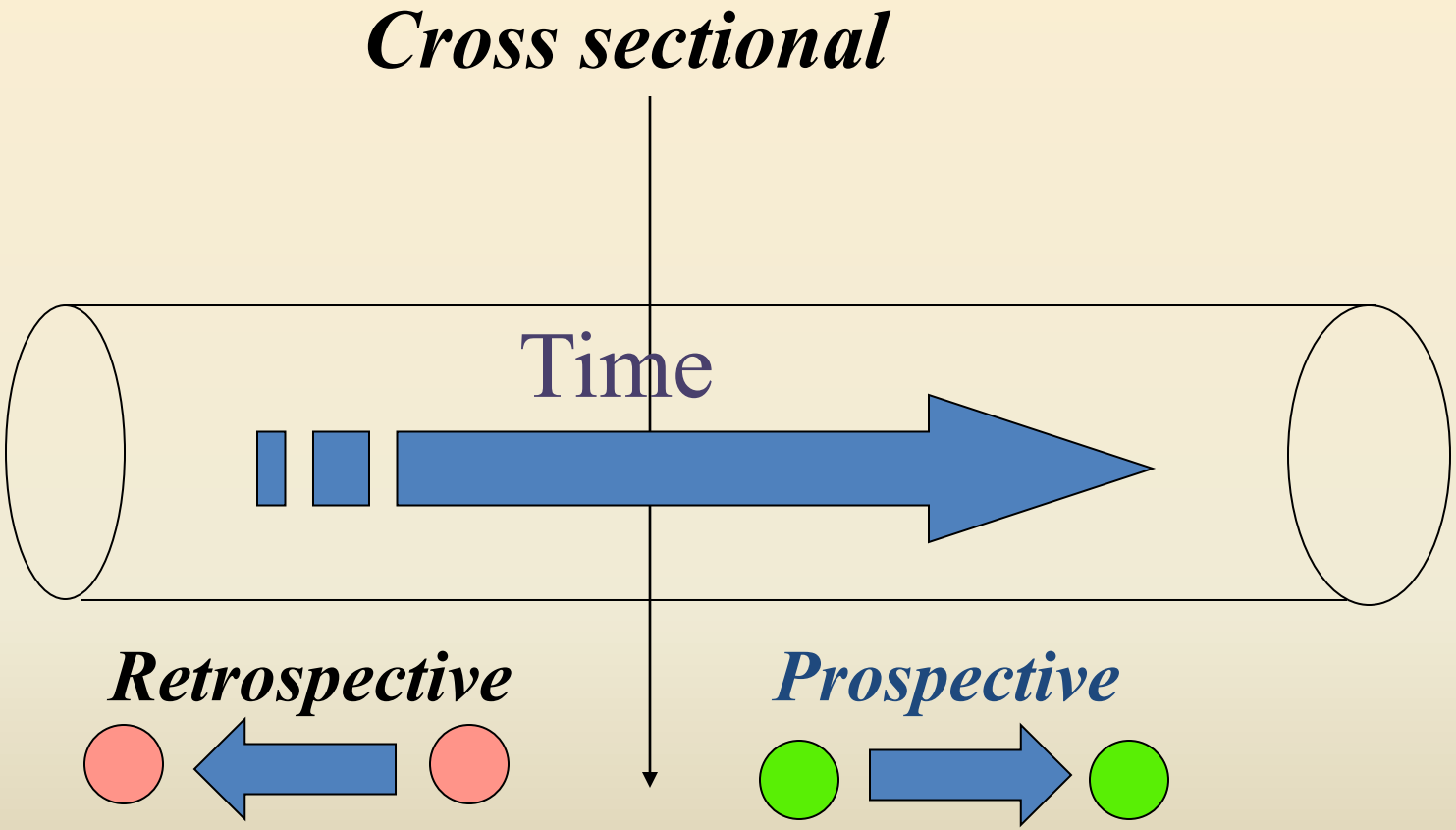
- *Incidence* refers to the new number of individuals who develop a specific disease or experience a specific health-related event during a particular time period (such as a month or year).

- *Prevalence* refers to the total number of individuals in a population who have a disease or health condition at a specific period of time, usually expressed as a percentage of the population.

Types of the study design according to Exposure



انواع الدراسات بالنسبة للزمن



- Descriptive studies include activities related to characterizing the patterns of disease occurrence in terms of person, place, and time, leading to generation of hypothesis. It studies the distribution of disease or the health event in the population

In descriptive epidemiology we

1. Observe
2. Count cases (events)
3. Describe a health-related event in terms of time, place, and person
4. Calculate rates
5. Compare rates
6. Develop hypotheses

Descriptive epidemiology is characterized by being inexpensive, and time saving. It describes disease patterns and it formulates research questions and hypotheses. It is unable to test hypotheses.

It is concerned with studying the distribution of the disease or the health condition in the community in terms of:

- How common is the disease?
- Who gets the disease?
- Where does the disease occur?
- When does the disease occur?

Types of descriptive studies

- Case reports and case series
- Descriptive incidence studies
- Ecologic (correlational) studies
- Cross-sectional studies (descriptive prevalence studies)

Case reports and case series

- They describe a profile of a case or series of cases.
- They may generate new hypotheses.
- They form an interface between clinical medicine and epidemiology.
- They only provide numerator data.
- They don’t provide measures of disease occurrence.

A case report is considered to be the most basic type of descriptive study of individuals, consisting of a careful, detailed report by one or more clinicians of the profile of a single patient.

- **Descriptive incidence studies and Ecological study**

They study the patterns of occurrence of incident cases (often from surveillance data) in a defined population (denominators from census) during a specified period of time and study the distribution of cases by factors of interest.
Ecologic (correlational) studies

Characteristics:

- Exposure and disease at aggregate (e.g., country) level
- Data from groups, not individuals
- Unit of observation is a population not individuals
- These studies provide a crude way of exploring associations between factors and disease
- They are considered to be hypothesis generating rather than hypothesis testing
- The group rather than the individual is the unit of comparison

Limitation: No individual link between exposure and disease and the aggregate association may not lead to individual association

Main advantages: It is quick to conduct, inexpensive, and it uses available data

Descriptive study

- It is the first phase of epidemiological investigation.
- Observing the distribution of disease or health

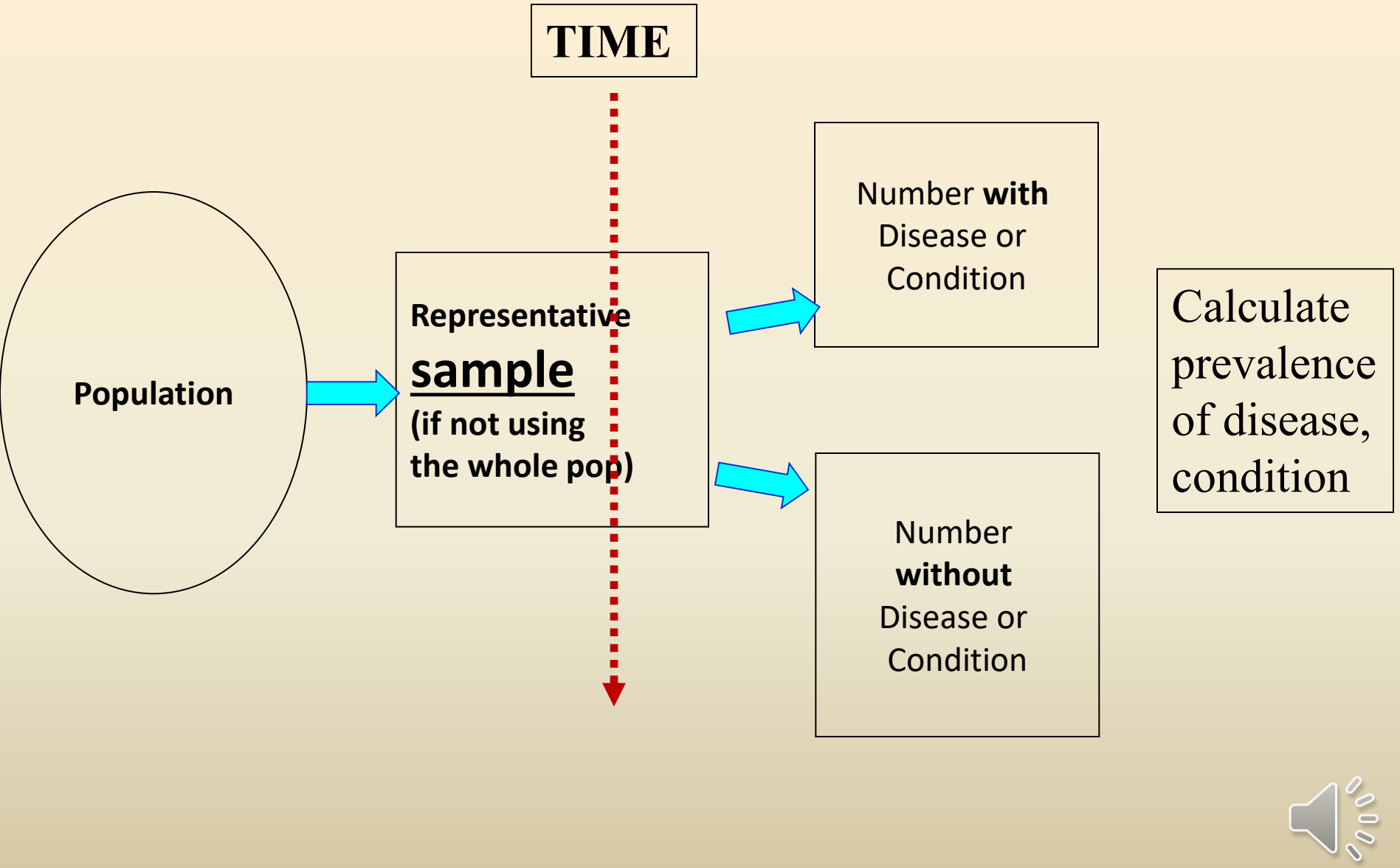
related events in human population.

- Identify the characteristics with which the disease is associated.

Basically 3 questions are asked who, when and where.

- Who means the person affected, where means the place and when is the time distribution.

Cross-sectional Study Design: Descriptive



- development of possible hypothesis regarding cause and effect relationship

- Only one group studies

Advantages

- Relatively short duration
- Inexpensive
- Study distribution of diseases
- Identify priorities
- Suggest risk factors of diseases

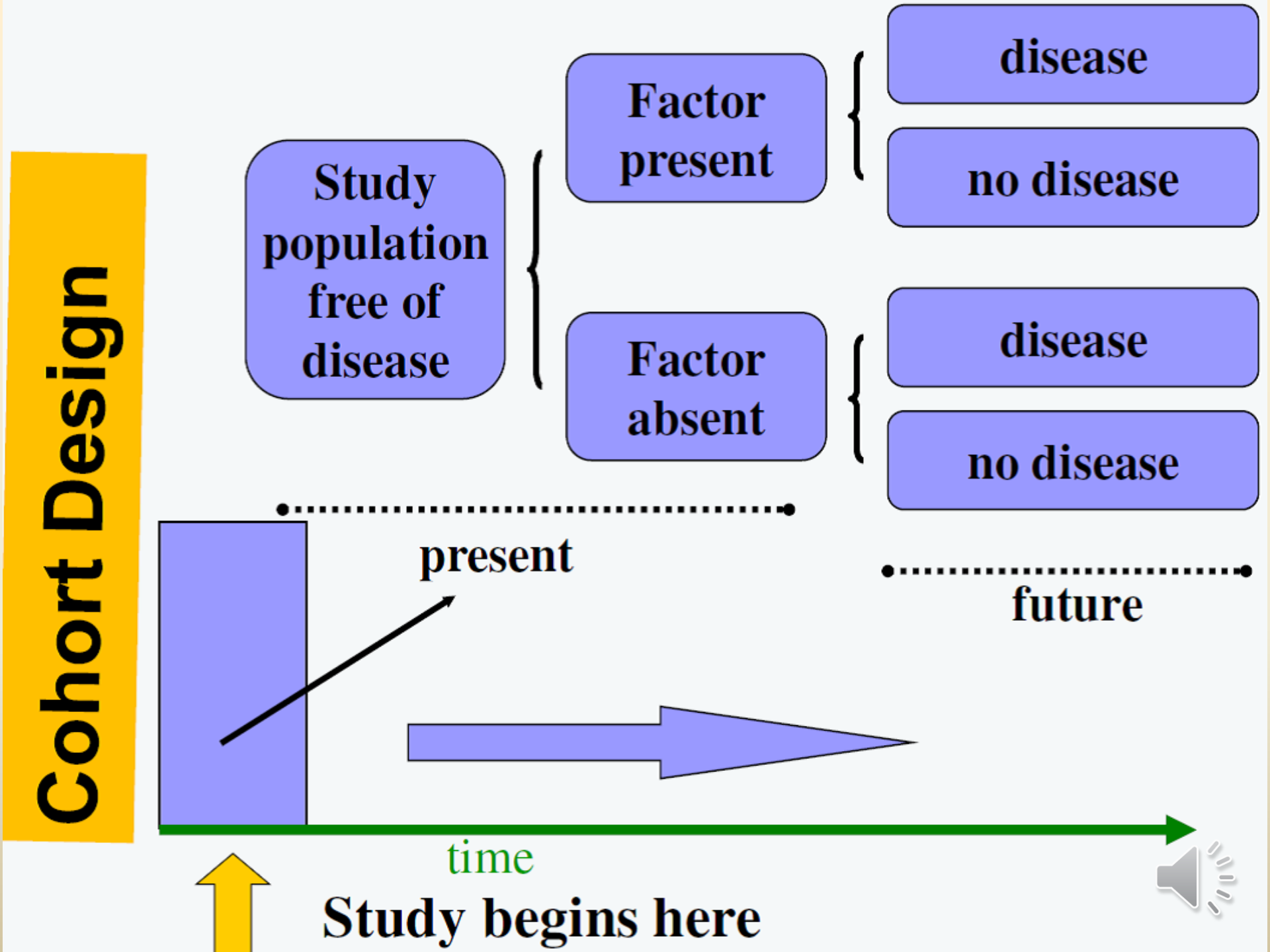
Disadvantages

- Measure only prevalence
- Not allow assessment of association

- **Implementation Research** systematically examines the different aspects affecting the use, uptake, and implementation of an evidence-based public health intervention in real-life settings, which in health research, is usually programs and/or policies.
- It is an interdisciplinary collaborative scientific study of the processes used to implement interventions and policies along with a multidisciplinary analysis of contextual factors that influence these processes, including social, political, economic, individual, system, and environmental factors that impact the implementation of interventions..

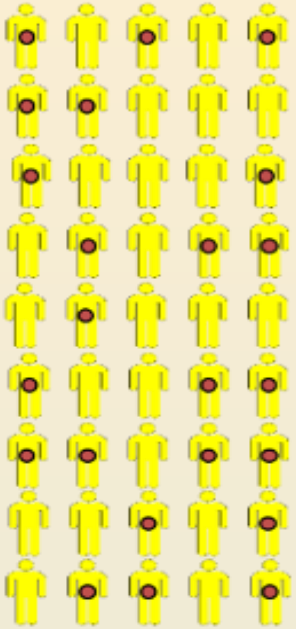
- It is also the study of the outcomes of implementation, such as how to encourage the widespread application and sustainability of evidence-based solutions or how to integrate them into a health system.
- The way that research questions are framed depends on the needs identified by implementers and relevant stakeholders, and this is an evolving and dynamic process, adapting to the needs of the particular setting

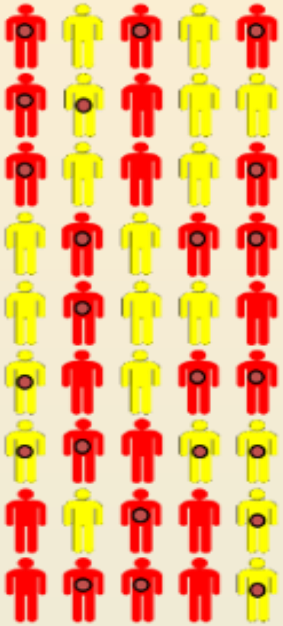
Cohort Study


Cohort Design
Study population free of disease
Factor present
Factor absent
disease
no disease
disease
no disease
present
future
time
Study begins here

Cohort Study

Prospective Cohort Study

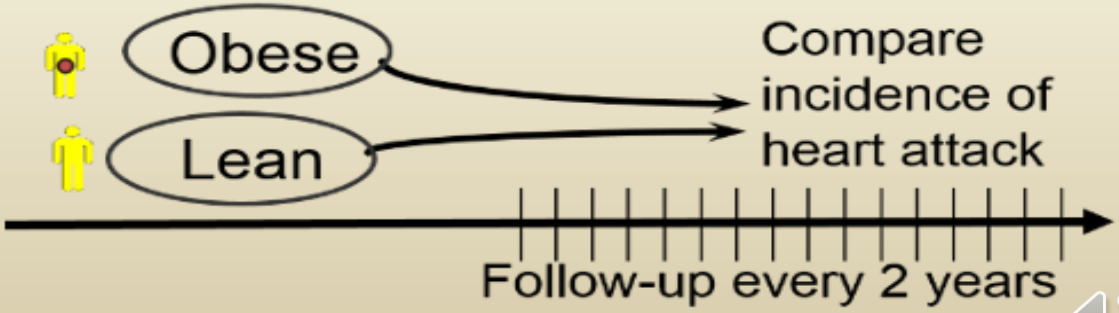




We need to understand determinants of heart disease in women.

Enroll & assess exposures

Start of Study



- **In prospective cohort studies,** when the study starts, the relevant events (exposure) may or may not have occurred, but the outcomes have certainly not yet occurred.

Exposure……. Study starts ……Time…… Disease occurrence

Study starts…… Exposure……. Time…… Disease occurrence

- **In retrospective cohort studies**, the relevant events (both the exposures and outcomes of interest)

have already occurred when the study is initiated.

Exposure……Time……Disease occurrence……Time……. Study starts

Synonyms for cohort studies

- Follow up studies
- Prospective studies
- Incidence studies
- Longitudinal studies
- Forward-looking studies
- Concurrent studies

Presentation of Cohort data:
2 x 2 table

	ill	not ill		
Smoking	45	45	90	50%
Did not smoke	2	8	10	20%

- Incidence of diseases among exposed = 45/90
- Incidence of disease among non exposed =2/10
- Relative risk : Compare risk of develop diseases among exposed to risk factors to those with no risk factors = incidence of diseases among exposed /incidence of disease among non exposed = (45/90)/(2/10)=50/20=2.5

Interpretation this means that smokers develop diseases 2.5 times more than non smokers

Advantages of cohort studies

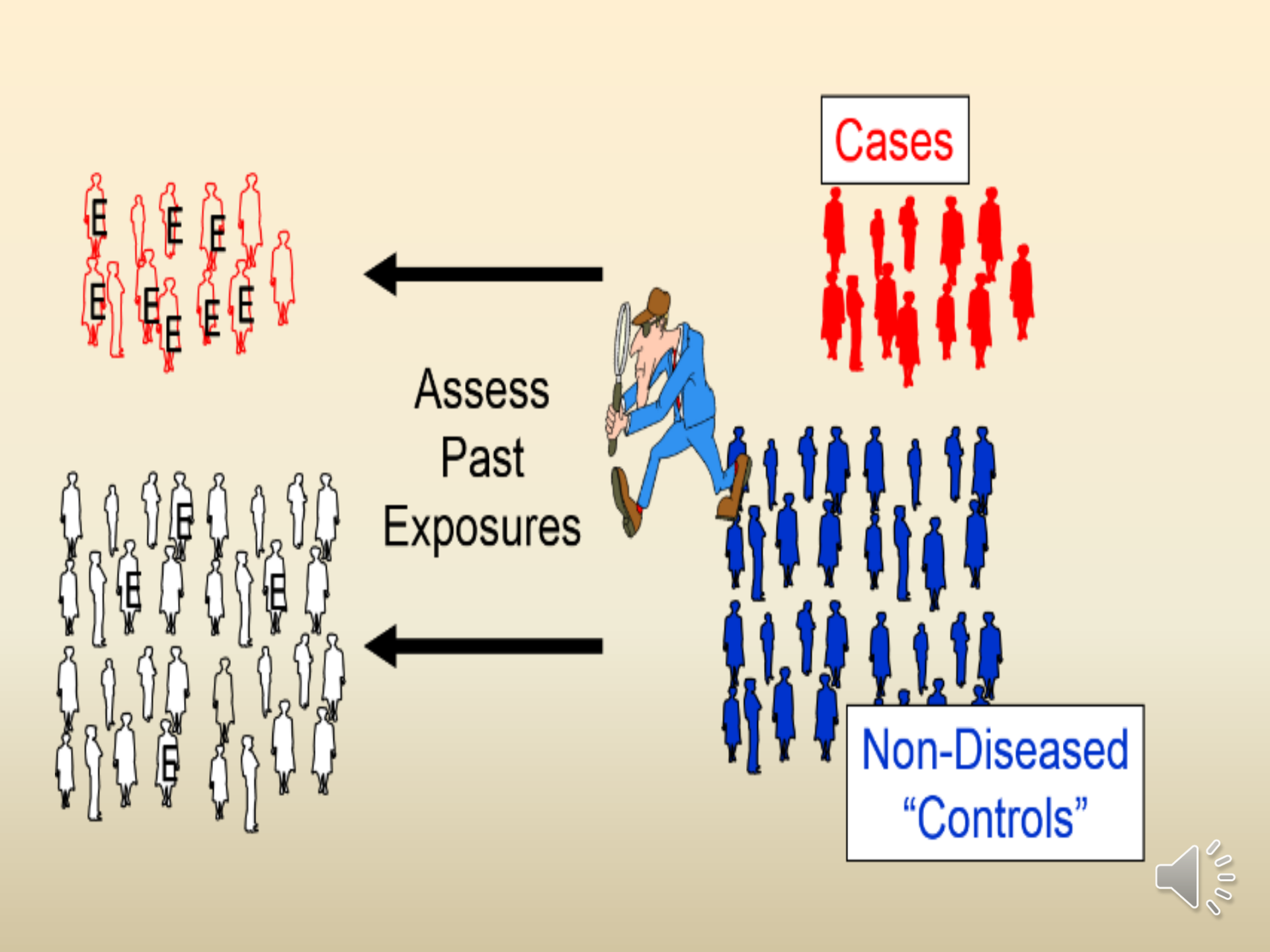
- Multiple outcomes can be measured for any one exposure.
- Can look at multiple exposures.
- Exposure is measured before the onset of disease (in prospective cohort studies).
- Good for measuring rare exposures, for example among different occupations.
- Demonstrate direction of causality.
- Can measure incidence and prevalence.

Disadvantages of cohort studies

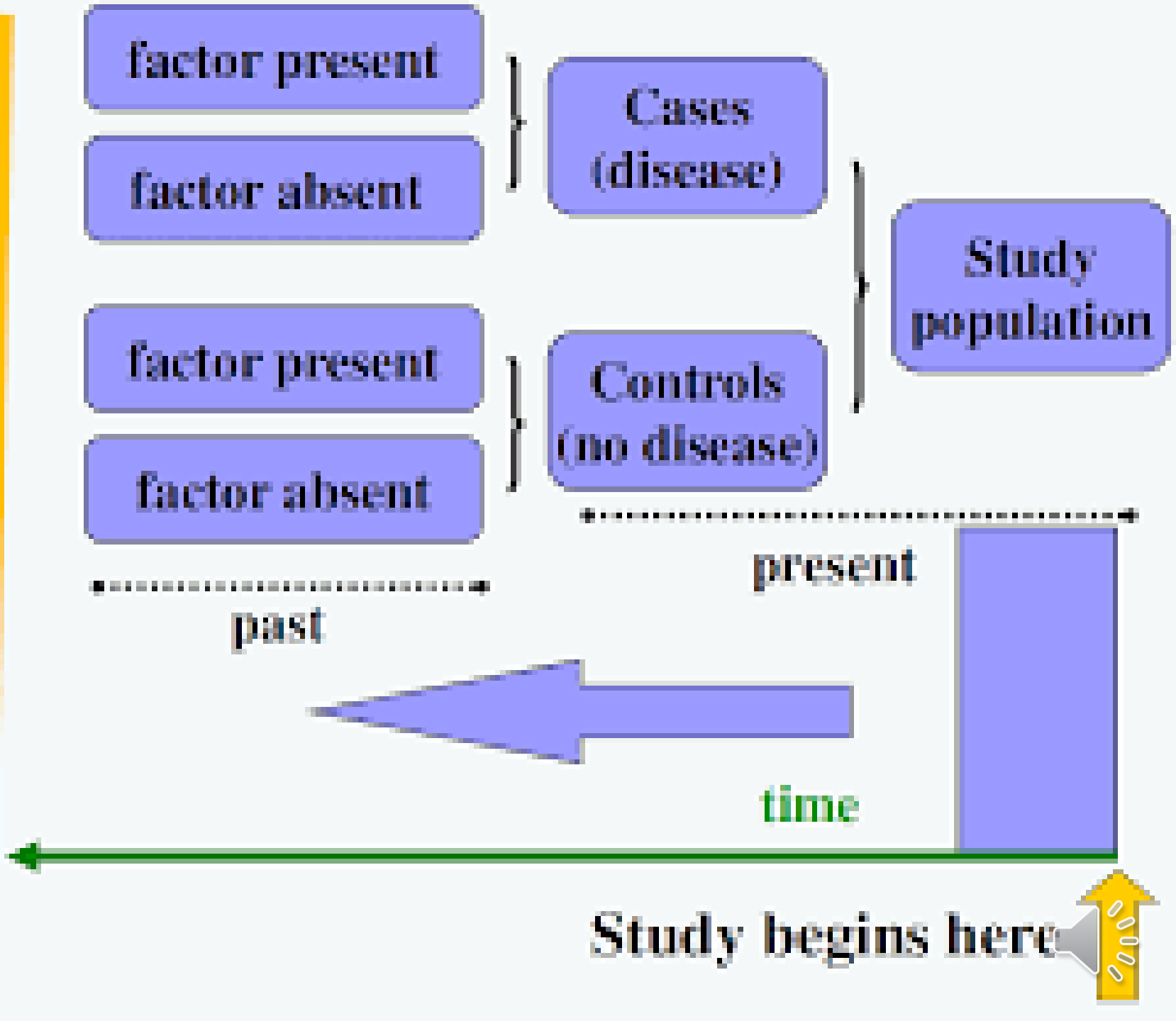
- Costly and time consuming.
- Prone to bias due to loss to follow-up..
- Being in the study may alter participant's behavior.
- Poor choice for the study of a rare disease.
- Classification of individuals (exposure or outcome status) can be affected by changes in diagnostic procedures.

- Relative risks (RR) is a direct estimator of the exposure risk
  - **When RR value is one** then the risk of disease is the same in the exposed and unexposed. ***This means that the studied exposure factor is not a risk factor.***
  - **When RR value is more than one** then the risk of disease in the exposed group is greater than the risk in the unexposed group. ***This means that the factor is a risk factor, or an etiological factor for disease.***
  - **When RR is less than one** then the risk of disease in the exposed group is less than the risk in the unexposed. ***This means that the factor is a protective factor.***

Case Control Study


Cases
Assess
Past
Exposures
Non-Diseased
"Controls"

Case-Control Design



Sources of Control

- Family
- Friends
- Neighbors
- Same place
- Hospital based

Analysis of Case-Control Studies

	Cases	Control
Exposed	A	B
Not Exposed	C	D

THE PROPORTION OF THE CAUSE IN THE CASES (a/a+c)

AND THAT IN CONTROLS (b /b+d) ARE MEASURED

- Proportion of exposure among cases =A/(A+C)=30/50
- Proportion of non exposure among cases =C/(A+C)=**20/50**
- Odds of **Exposure** among cases =[A/(A+C)] /[C/(A+C)]=A/C=**30/20**

	Cases	Control
Exposed	A=30	B=10
Not Exposed	C=20	D=40

- Proportion of exposure among control =B/(B+D)=10/50
- Proportion of non exposure among control =D/(B+D)=40/50
- Odds of **Exposure** among control =[B/(B+D)] /[D/(B+D)]=B/D=10/40

- To evaluate odds of exposure among cases different from odds of exposure among controls

- We create ratio between two odds so OR
- OR= (a/c) /(b/d) =(ad)/(bc)=(30*40)/(10*20)

=1200/200=6

Interpretation of odds ratio:

Odds Ratio equal 1 the risk of exposure is the same between cases and controls so the exposure is not risk .

Odds Ratio more than 1 so the exposure is risk increase occurrence of the disease

Odds ratio less than 1the exposure is protective

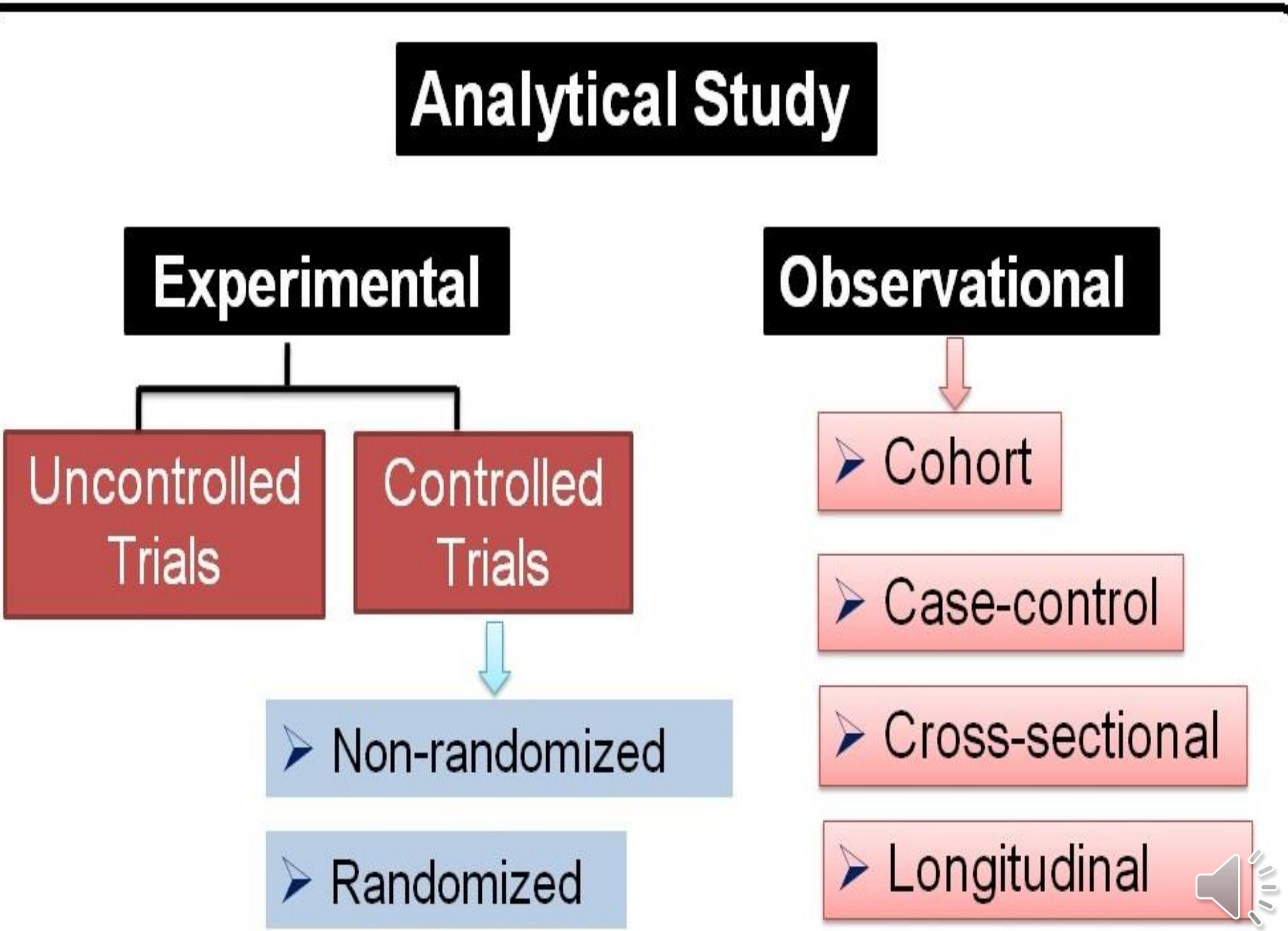
Advantages and Disadvantages of Case Control study

Advantages

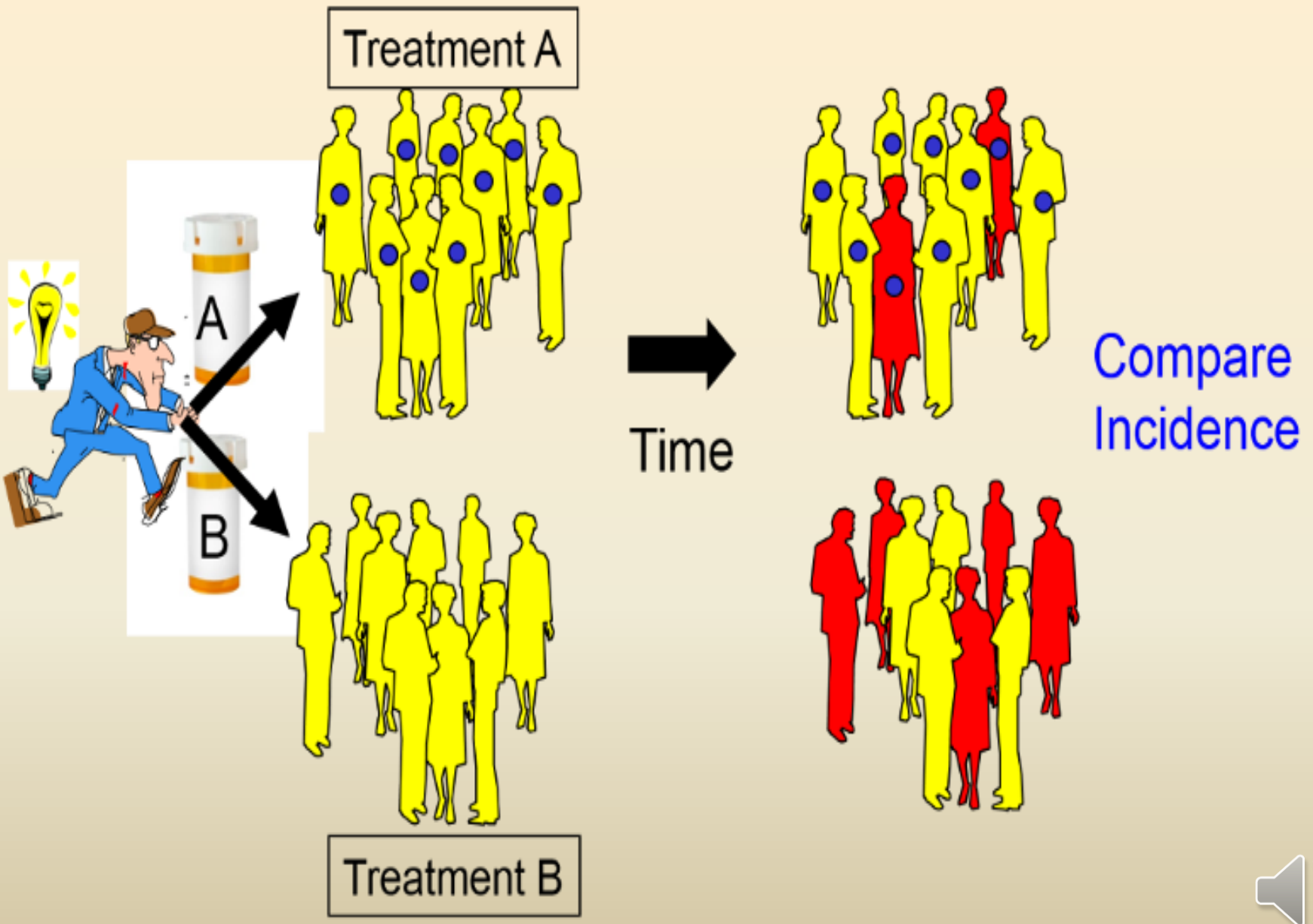
- Rare diseases
- Several exposures
- Long latency
- Rapidity
- Low cost
- Small sample size
- Available data
- No ethical problem

Disadvantages

- Cannot compute directly relative risk
- Not suitable for rare exposure
- Relationship exposure-disease difficult to establish (association not causality)
- Biases +++
  - control selection
  - recall biases when collecting data


Analytical Study
Experimental
Uncontrolled Trials
Controlled Trials
Non-randomized
Randomized
Observational
Cohort
Case-control
Cross-sectional
Longitudinal

Clinical Trial

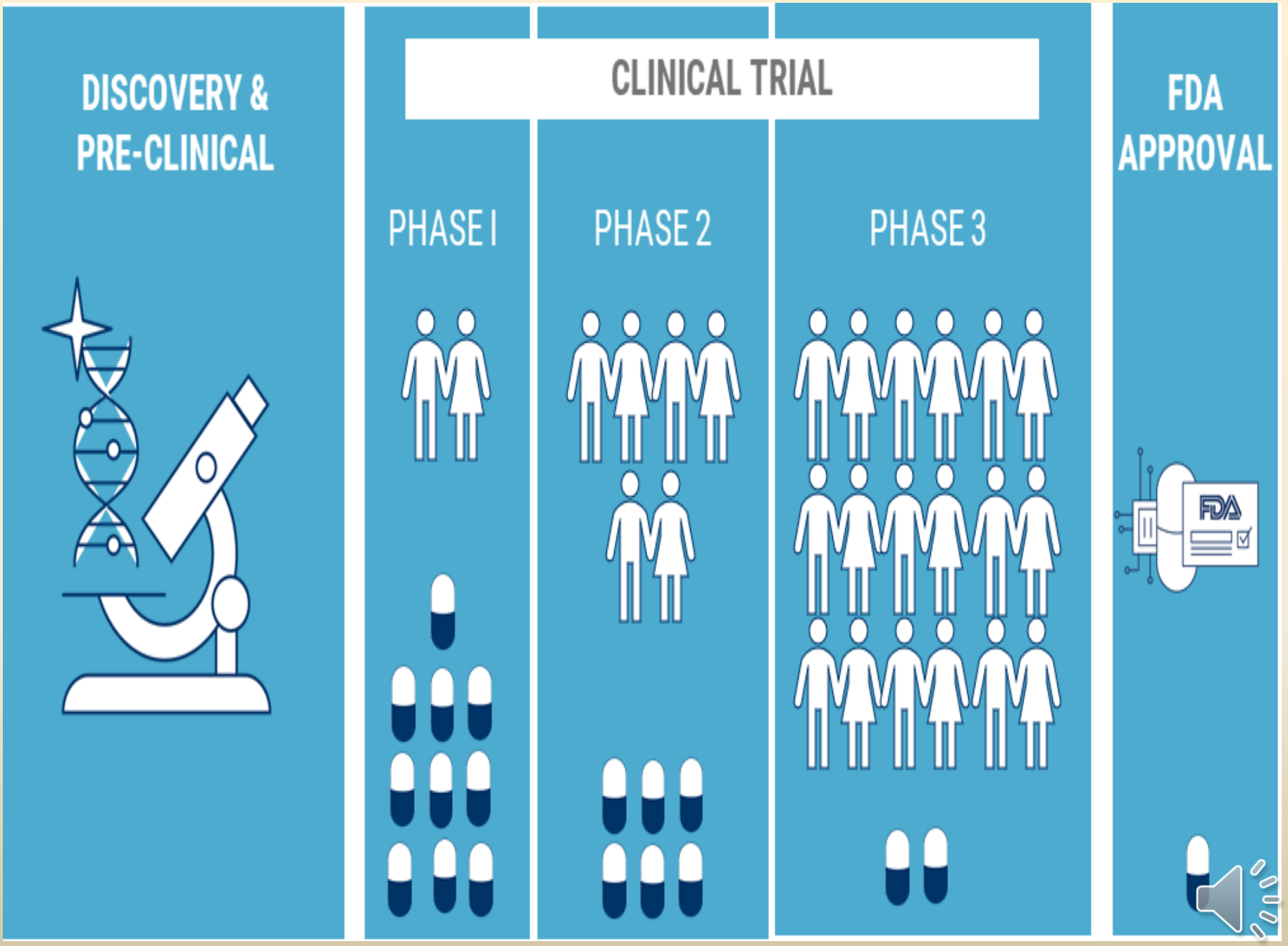

Treatment A
A
B
Time
Compare
Incidence
Treatment B

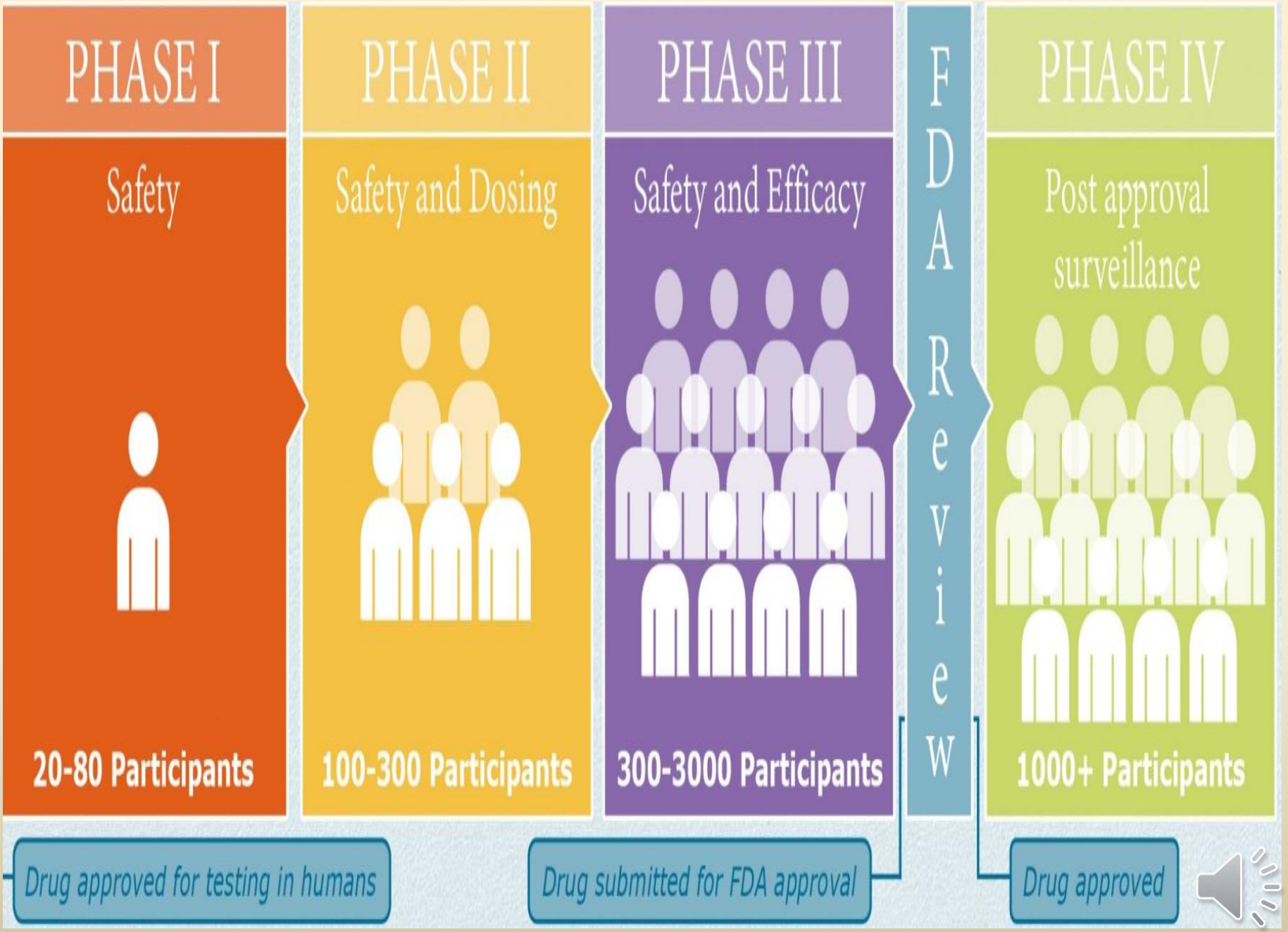
Clinical Trial

- **Clinical trials** are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention.

There are **4 phases** of biomedical clinical trials:

- **Phase I studies** usually test new drugs for the first time in a small group of people to evaluate a safe dosage range and identify side effects.
- **Phase II studies** test treatments that have been found to be safe in phase I but now need a larger group of human subjects to monitor for any adverse effects.


DISCOVERY &
PRE-CLINICAL
CLINICAL TRIAL
PHASE I
PHASE 2
PHASE 3
FDA
APPROVAL
FDA


PHASE I
Safety
20-80 Participants
PHASE II
Safety and Dosing
100-300 Participants
PHASE III
Safety and Efficacy
300-3000 Participants
FDA Review
PHASE IV
Post approval surveillance
1000+ Participants
Drug approved for testing in humans
Drug submitted for FDA approval
Drug approved

A PRECLINICAL TESTING

Laboratory tests

1

Research protocol

2

Animal testing

3

B CLINICAL RESEARCH

1 DOSE FINDING

Assessment of drug/therapy

20-100 healthy patients

20-100

2 PROOF OF CONCEPT

Testing of beneficial effects

and undesireable effects

Over 100 diagnosed patients

100 +

3 COMPARATIVE EFFICACY

Comparison of new with standard therapy

Conducted in multiple locations throughout the world

Over 1000 diagnosed patients

1000 +

C FINAL DATA ANALYSIS

Biostatistical analysis

Determine medically compelling and statistically significant results

D FOLLOW UP

New therapy shown to be safe and effective

1

Approval by medical authorities

2

Continuing testing

3

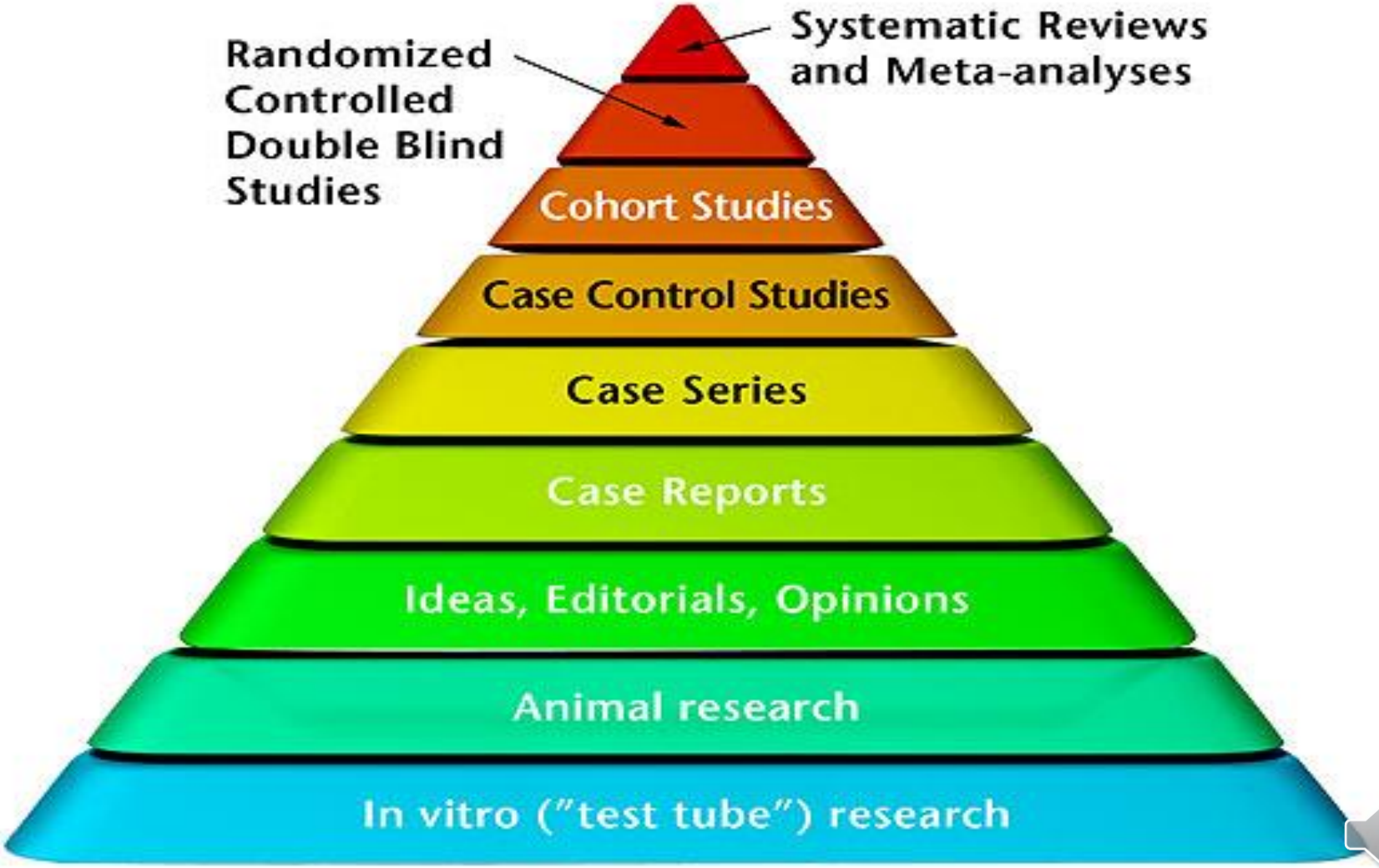
Therapy/drug is continuously tested for efficacy and safety through register studies and pharmacoepidemiology

Infographics: Commando Group

Limitation of clinical trials

- Ethical issues need to be considered
  - Risks to subjects versus potential benefits
  - Does equipoise exist? Some questions cannot be answered ethically with a clinical trial.
- They are usually time consuming and costly
- Lengthy trials run the risk of loss to follow up
- Invariably, some subjects will fail to adhere to the protocol, and non-adherence will cause an underestimated measure of association

Level of Evidence from the study



- **Phase III studies** are conducted on larger populations and in different regions and countries, and are often the step right before a new treatment is approved.

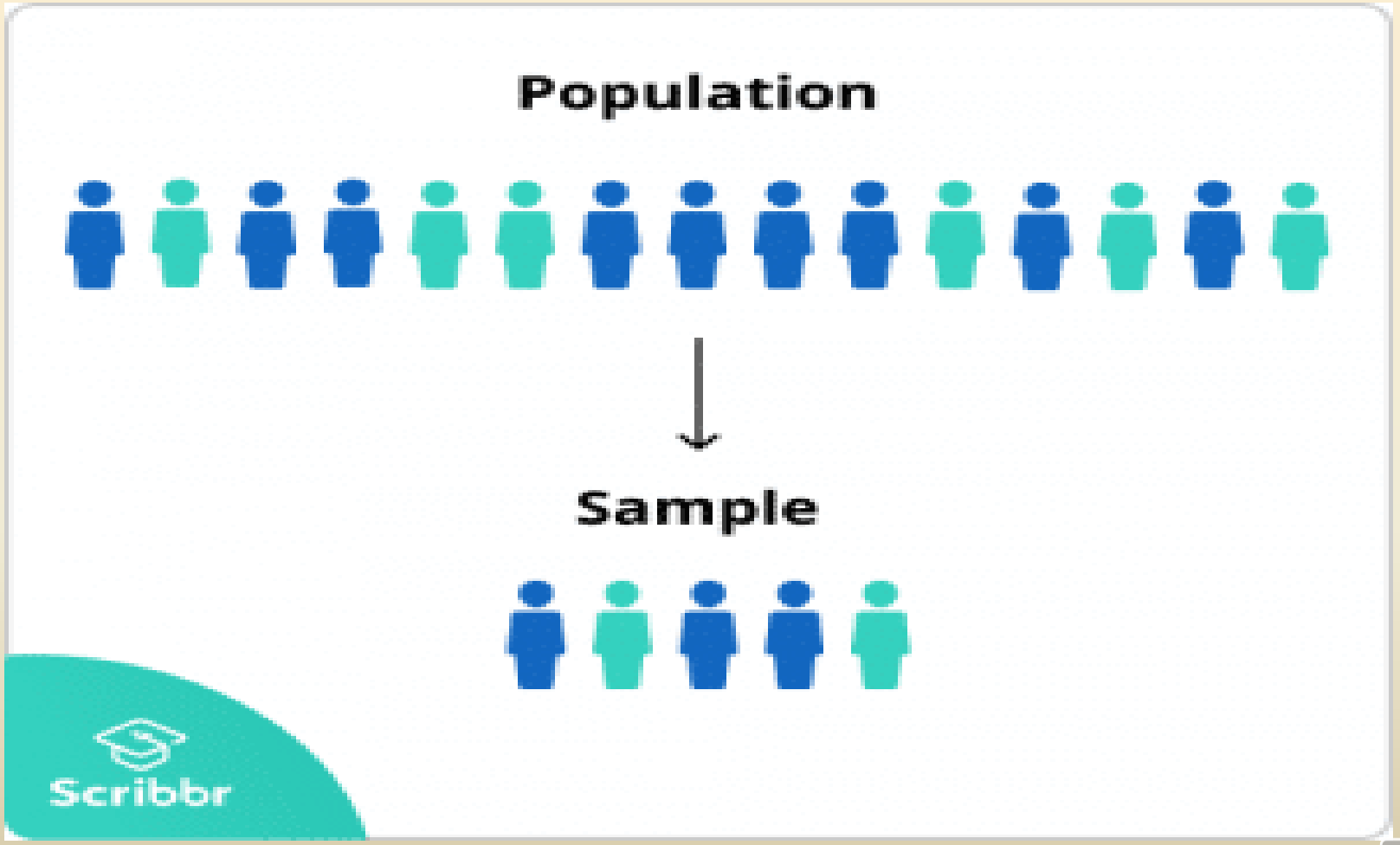
- **Phase IV studies** take place after country approval and there is a need for further testing in a wide population over a longer timeframe

Sample

- The sample is the group of individuals who will actually participate in the research.
- To draw valid conclusions from your results, you have to carefully decide how you will select a sample that is representative of the group as a whole

There are two types of sampling methods:

- **Probability sampling** involves random selection, allowing you to make statistical inferences about the whole group.
- **Non-probability sampling** involves non-random selection based on convenience or other criteria, allowing you to easily collect initial data.


Population
Sample
Scribbr

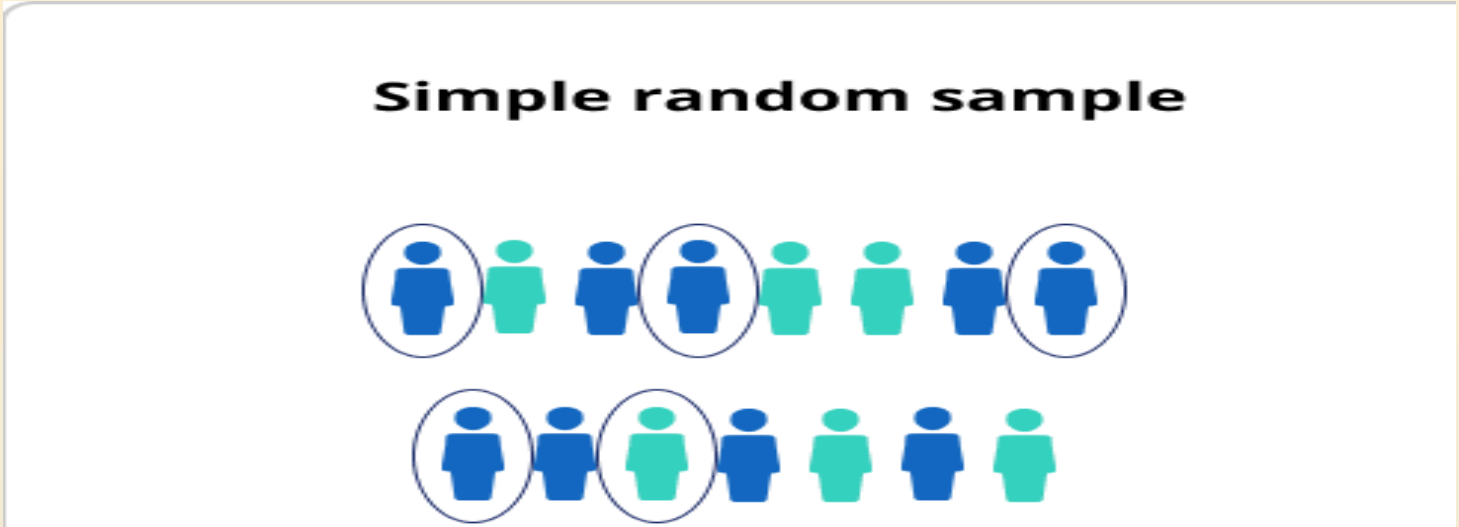
Sampling frame

- The sampling frame is the actual list of individuals that the sample will be drawn from. Ideally, it should include the entire target population (and nobody who is not part of that population).

Sample size

- The number of individuals in your sample depends on the size of the population, and on how precisely you want the results to represent the population as a whole.

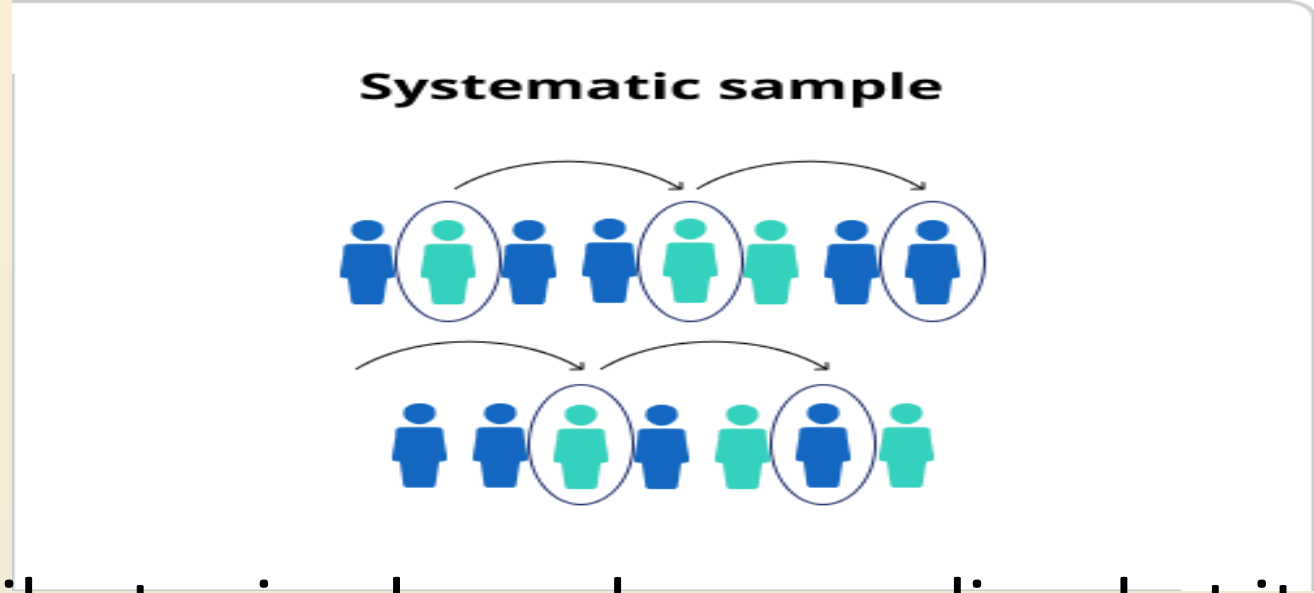
Probability sampling methods



In a simple random sample,

- every member of the population has an equal chance of being selected. Your sampling frame should include the whole population.
- To conduct this type of sampling, you can use tools like random number generators or other techniques that are based entirely on chance.

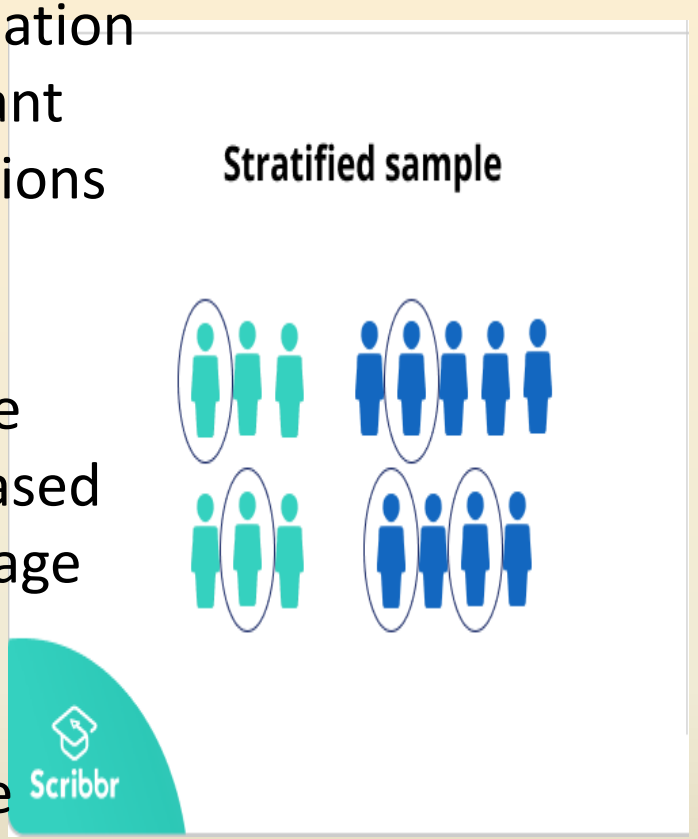
Systematic sampling



is similar to simple random sampling, but it is usually slightly easier to conduct. Every member of the population is listed with a number, but instead of randomly generating numbers, individuals are chosen at regular intervals.

Stratified sampling

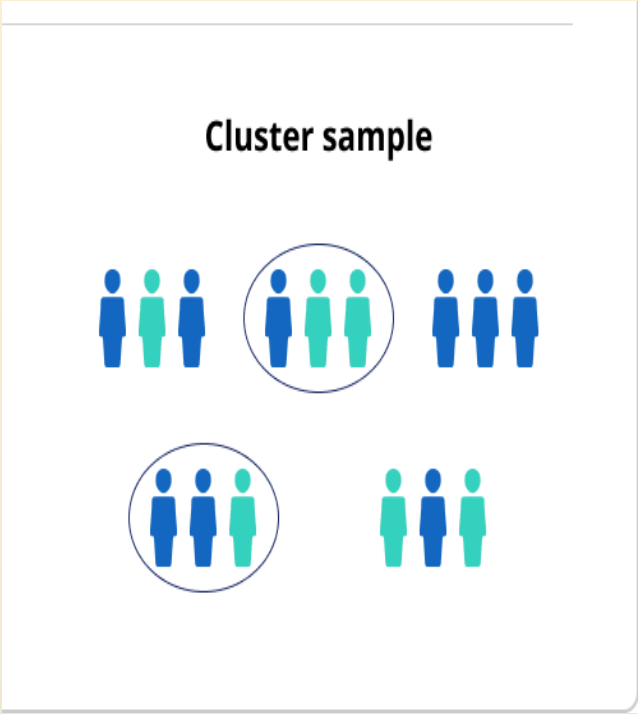
Stratified sampling involves dividing the population into subpopulations that may differ in important ways. It allows you draw more precise conclusions by ensuring that every subgroup is properly represented in the sample.



- To use this sampling method, you divide the population into subgroups (called strata) based on the relevant characteristic (e.g. gender, age range, income bracket, job role).
- Based on the overall proportions of the population, you calculate how many people should be sampled from each subgroup. Then you use random or systematic sampling to select a sample from each subgroup.

Cluster sampling

Cluster sampling also involves dividing the population into subgroups, but each subgroup should have similar characteristics to the whole sample. Instead of sampling individuals from each subgroup, you randomly select entire subgroups.



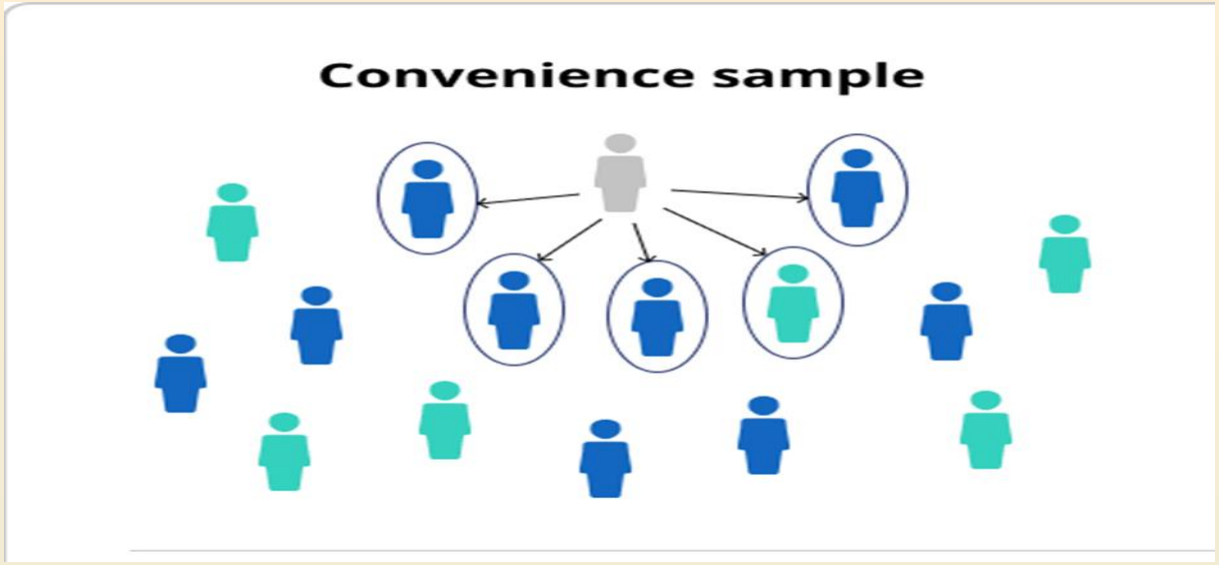
This method is good for dealing with large and dispersed populations, but there is more risk of error in the sample, as there could be substantial differences between clusters.

Non-probability sampling methods

- This type of sample is easier and cheaper to access, but it has a higher risk of sampling bias, and you can’t use it to make valid statistical inferences about the whole population.

- Non-probability sampling techniques are often appropriate for exploratory and qualitative research. In these types of research, the aim is not to test a hypothesis about a broad population, but to develop an initial understanding of a small or under-researched population.

Convenience sampling

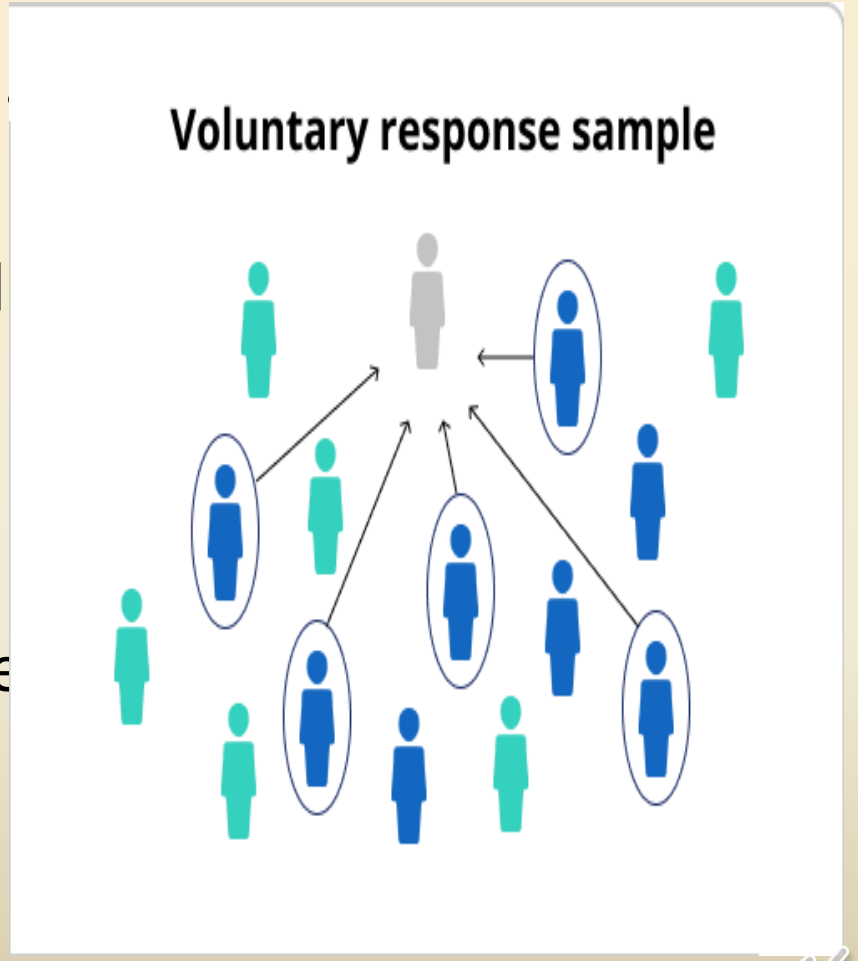


- A convenience sample simply includes the individuals who happen to be most accessible to the researcher.
- This is an easy and inexpensive way to gather initial data,

Voluntary response sampling

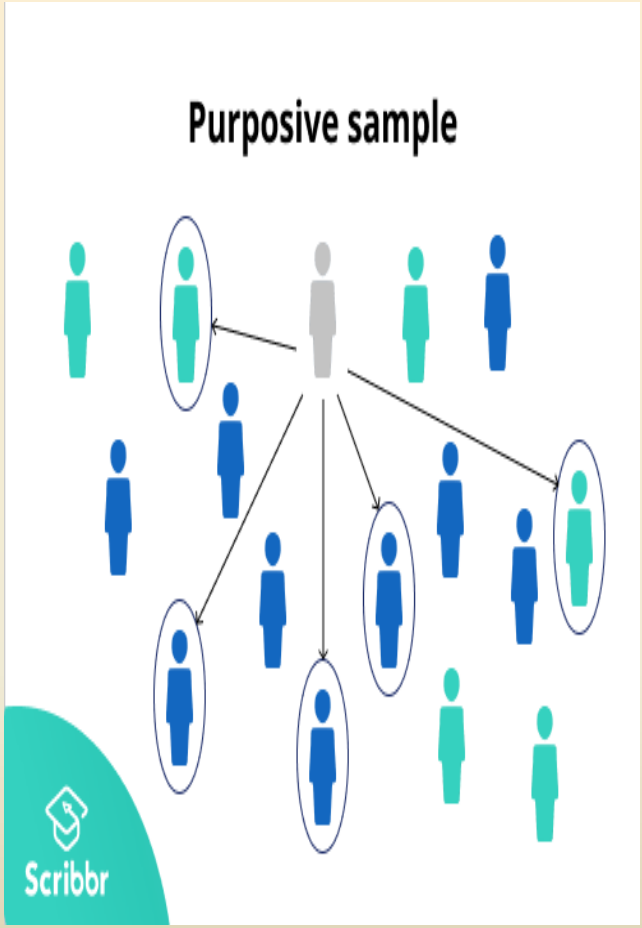
- voluntary response sample is mainly based on ease of access. Instead of the researcher choosing participants and directly contacting them, peopl volunteer themselves (e.g. by responding to a public online survey).

- Voluntary response samples are always at least somewhat biased, as some people will inherently be more likely to volunteer than others.



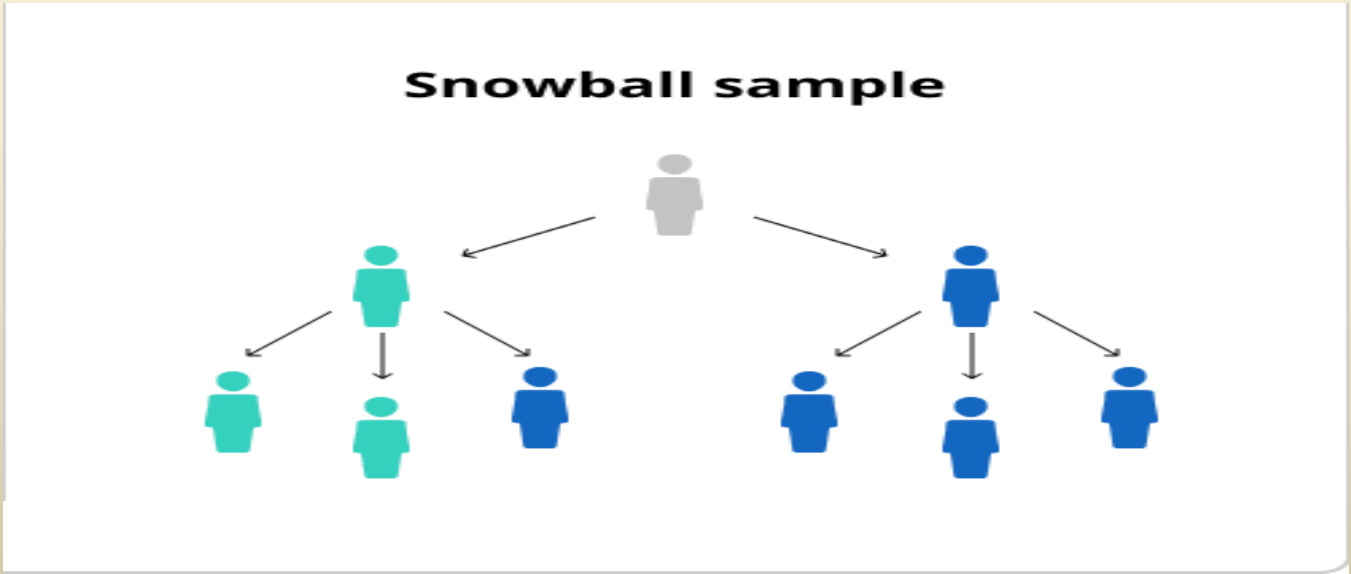
Purposive sampling

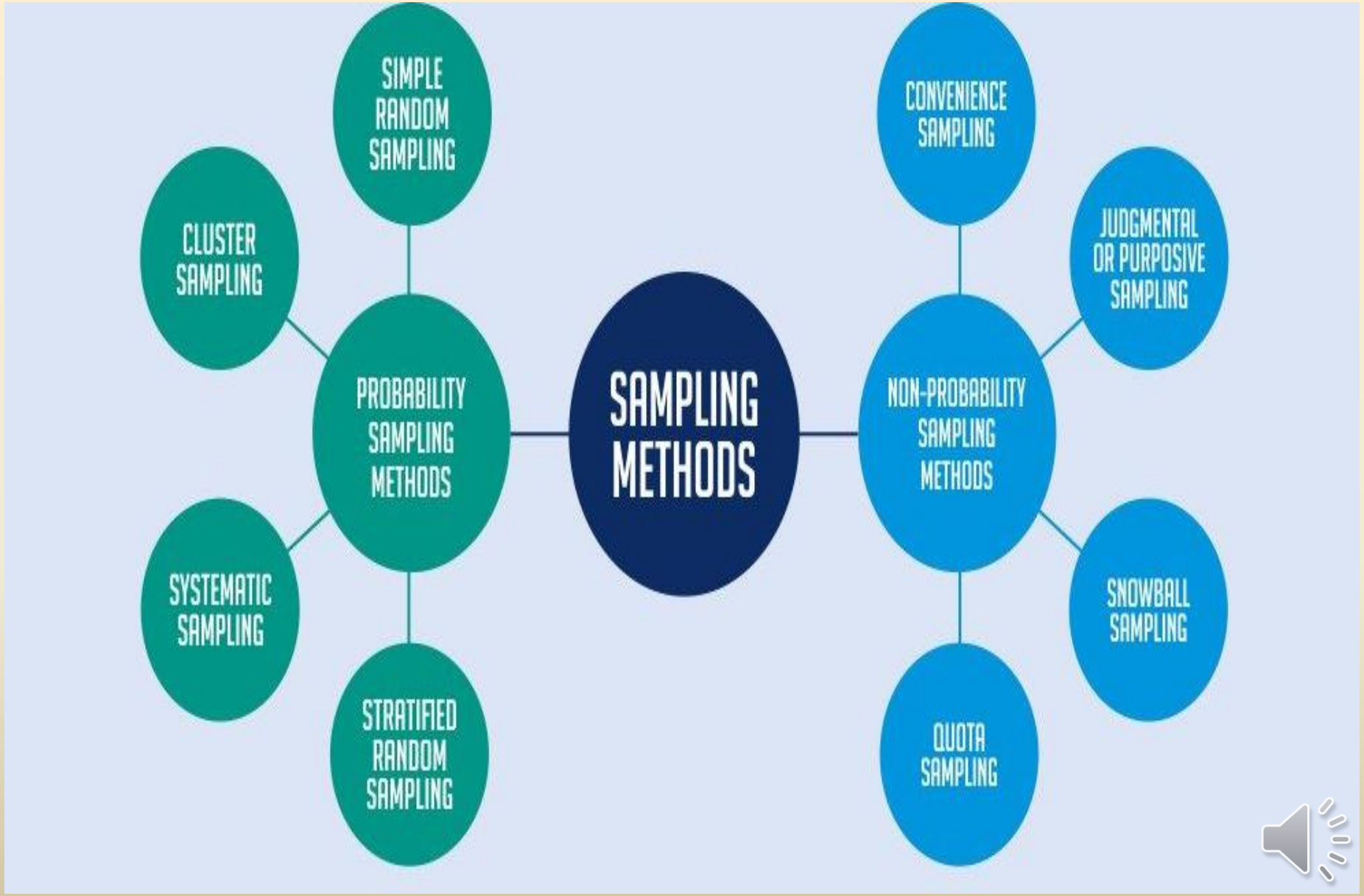
This type of sampling involves the researcher using their judgement to select a sample that is most useful to the purposes of the research.
It is often used in qualitative research, where the researcher wants to gain detailed knowledge about a specific phenomenon rather than make statistical inferences. An effective purposive sample must have clear criteria and rationale for inclusion.



Snowball sampling

- If the population is hard to access, snowball sampling can be used to recruit participants via other participants. The number of people you have access to “snowballs” as you get in contact with more people.




SAMPLING METHODS
PROBABILITY SAMPLING METHODS
SIMPLE RANDOM SAMPLING
CLUSTER SAMPLING
SYSTEMATIC SAMPLING
STRATIFIED RANDOM SAMPLING
NON-PROBABILITY SAMPLING METHODS
CONVENIENCE SAMPLING
JUDGMENTAL OR PURPOSIVE SAMPLING
SNOWBALL SAMPLING
QUOTA SAMPLING