Study Designs

Research Skill 2

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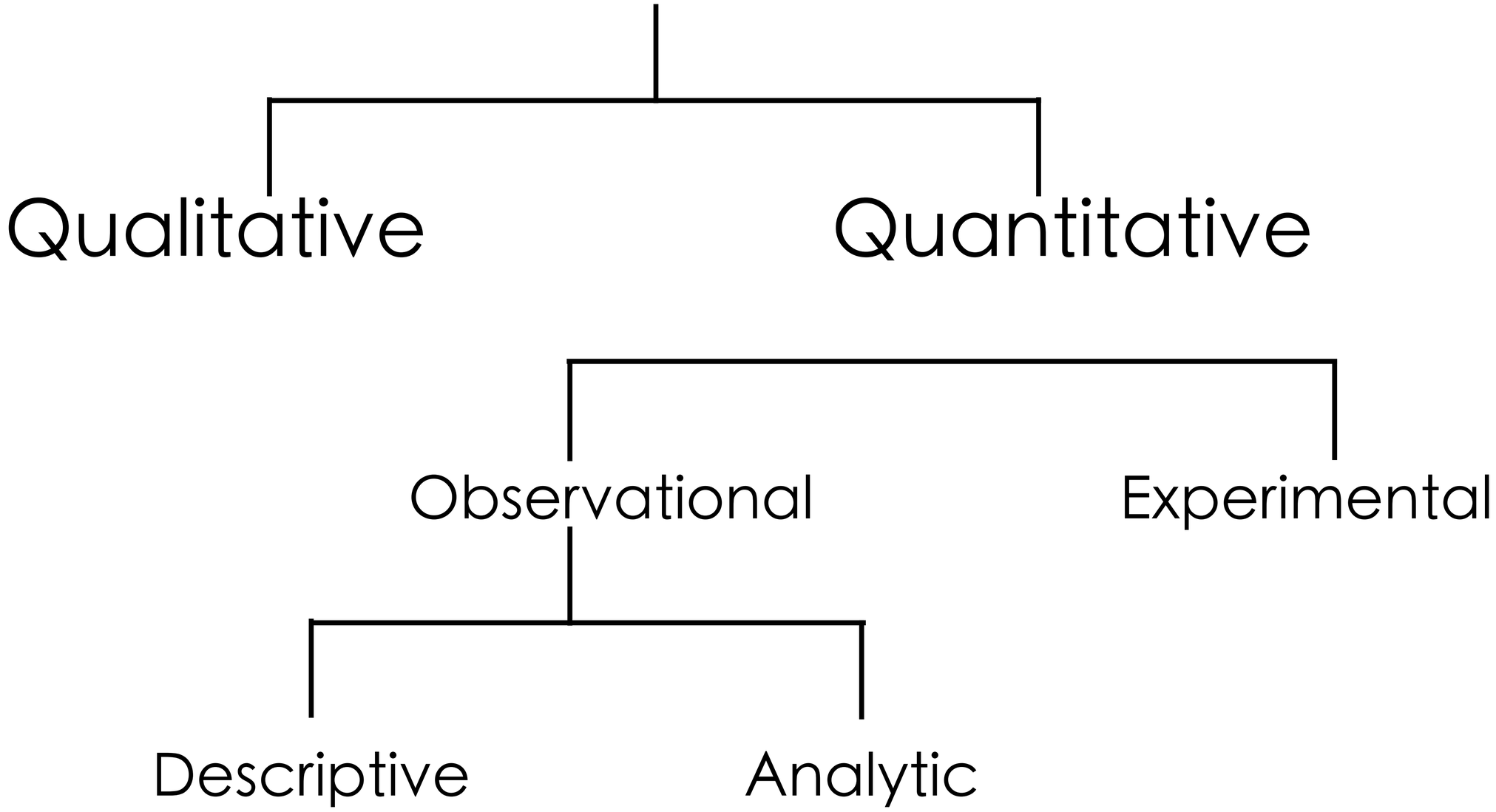
Study Design

- A framework, or the set of methods and procedures used to collect and analyze data on variables specified in a particular research problem

Research Designs

	Qaulitative	Quantitative
Focus	Quality	Quantity
Goals	Understanding, hypothesis generating	Prediction, hypothesis testing
Data collection	Interview, Observation	Survey, constructed questionnaire, experiment
Data	Text, stories	Numbers
Sample size	Small	Large

Research Designs



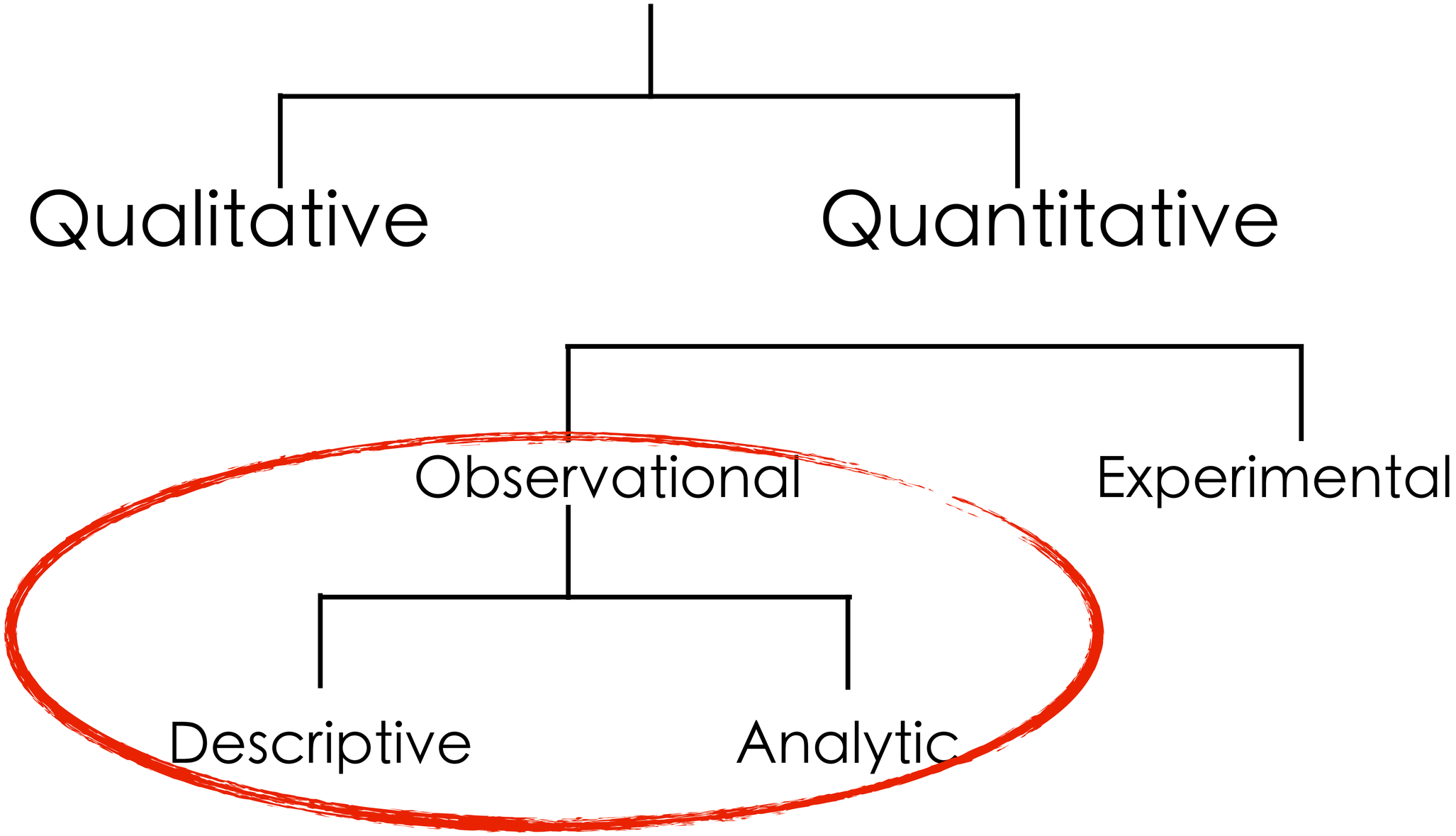
Observational Study

- Documenting a naturally occurring relationship between the exposure and the outcome
- The researcher does not do any active intervention.
- e.g. evaluate the incidence of diabetes in Thailand, compare the treatment result between patients who have high and low educational levels
- Divided into Descriptive and Analytical study

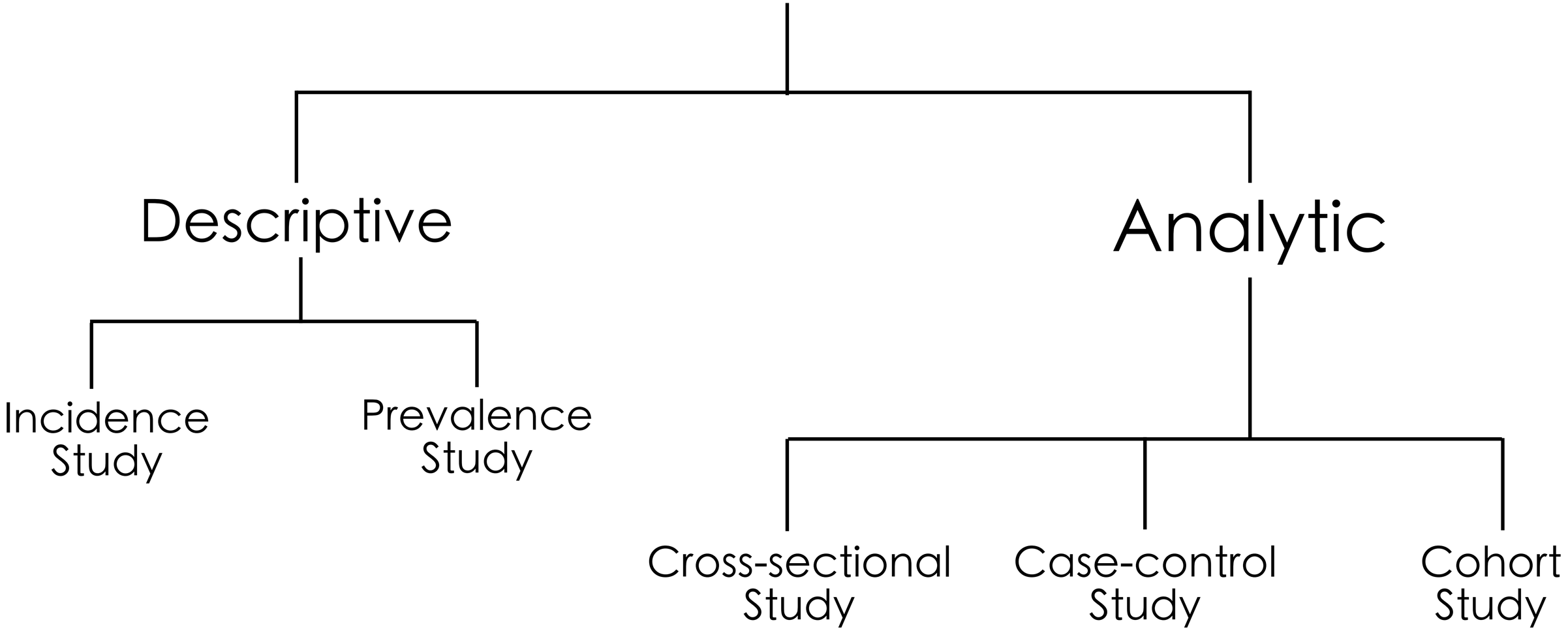
Experimental Study

- Intervention study
- Conditions are under the direct control of the researcher.

Research Designs



Observational Study

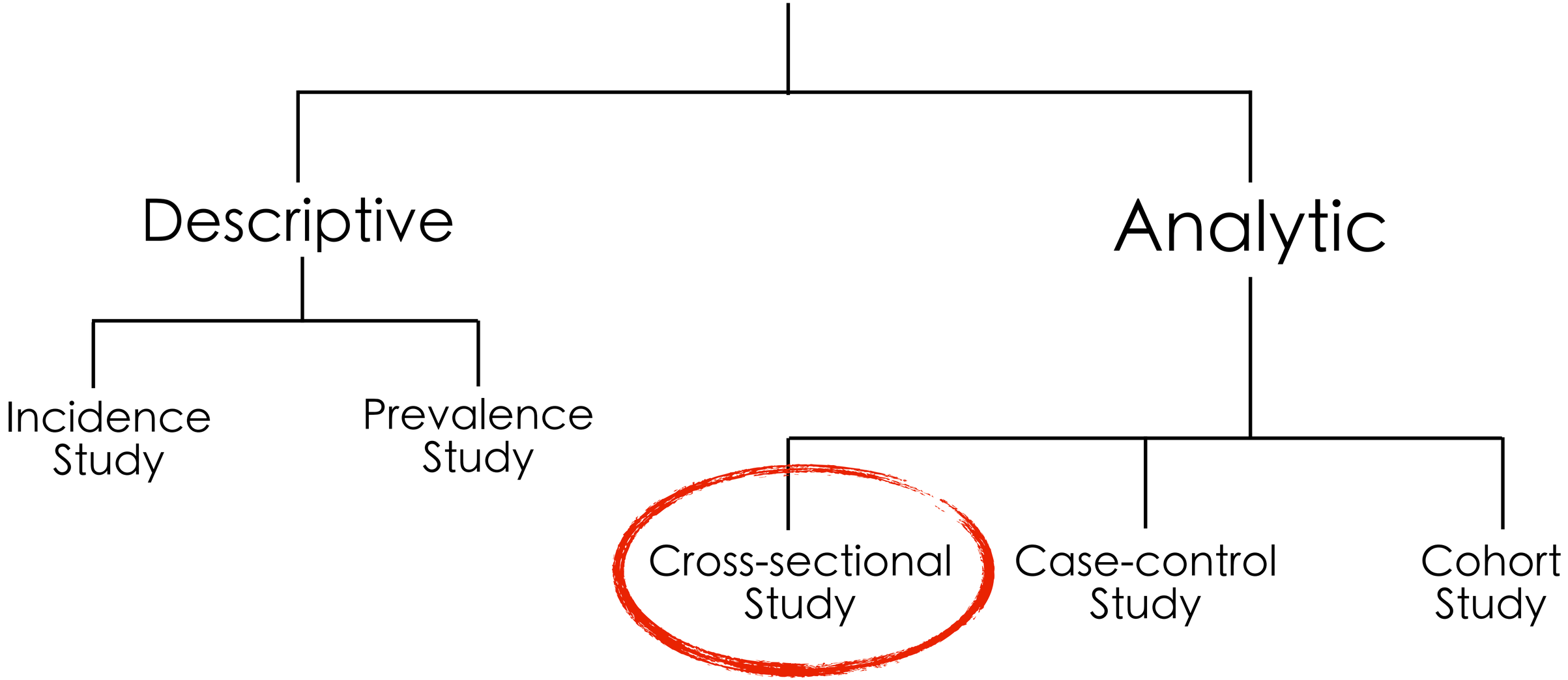


Prevalence

- Proportion of individuals who have a specific characteristic in a given time period

$$\text{Prevalence} = \frac{\text{Number of cases}}{\text{Number of population}}$$

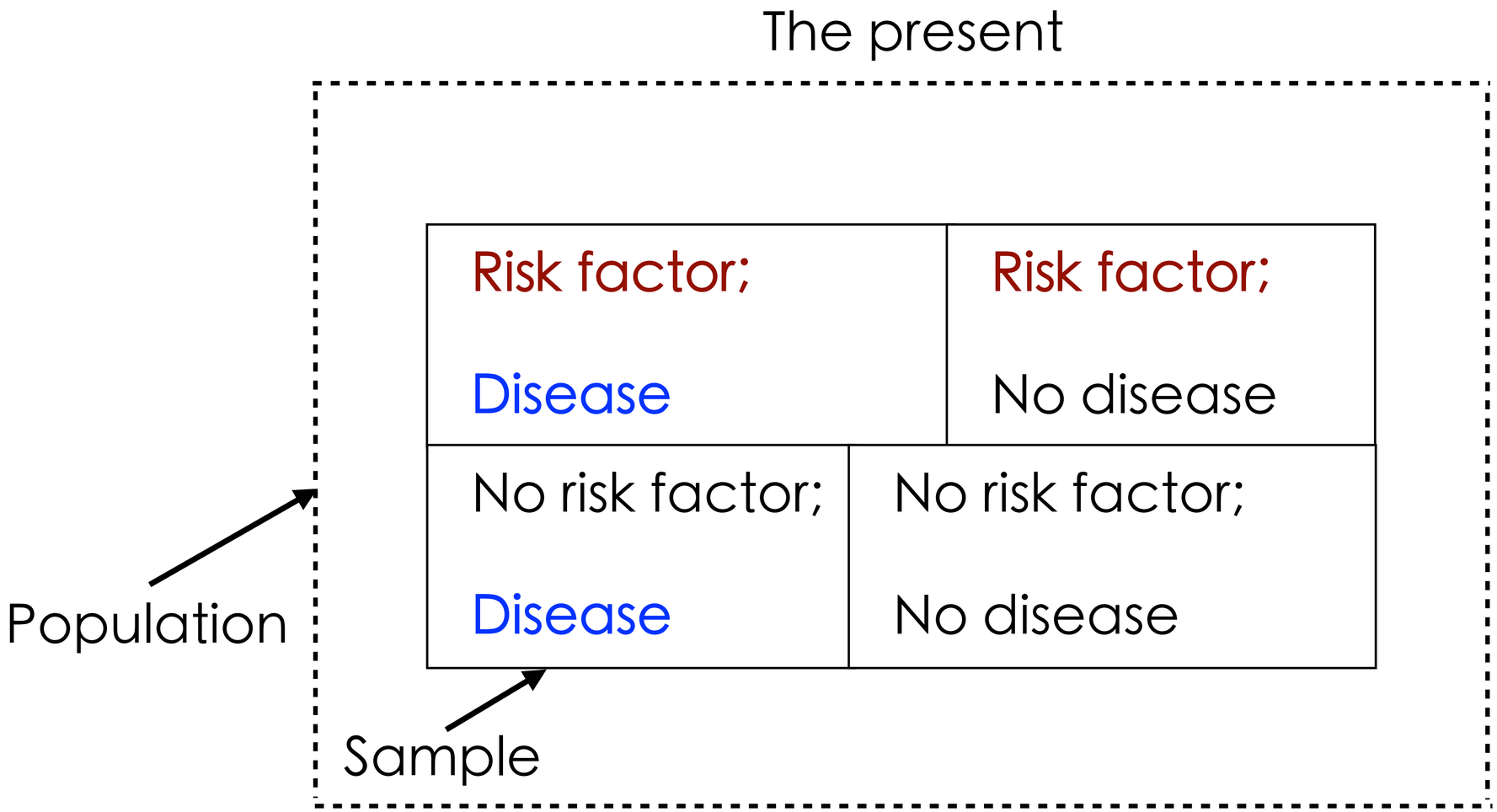
Observational Study



Cross-sectional study

- The outcome and the exposures in participants were measured at the same time
- Estimate Prevalence
- Calculate Odds Ratio
- Prevalence in exposed > un-exposed —> the exposure may be a cause of disease
- Pros: quick, cheap, yields prevalence
- Cons: difficult to derive causal relationships

Cross-sectional study



Prevalence Ratio

$$PR = \frac{\text{Prevalence of disease in exposed}}{\text{Prevalence of disease in Unexposed}}$$

	Disease	No disease	
Exposed	a	b	a+b
Unexposed	c	d	c+d
	a+c	b+d	a+b+c+d

$$PR = \frac{\text{Prevalence of disease in exposed}}{\text{Prevalence of disease in non-exposed}}$$

$$= \frac{a / (a+b)}{c / (c+d)}$$

	Cirrhosis	No cirrhosis	
	80	20	100
	10	50	60
	90	70	160

Prevalence Ratio

	Cirrhosis	No cirrhosis	
Alcohol	80	20	100
No alcohol	10	50	60
	90	70	160

PR = ?

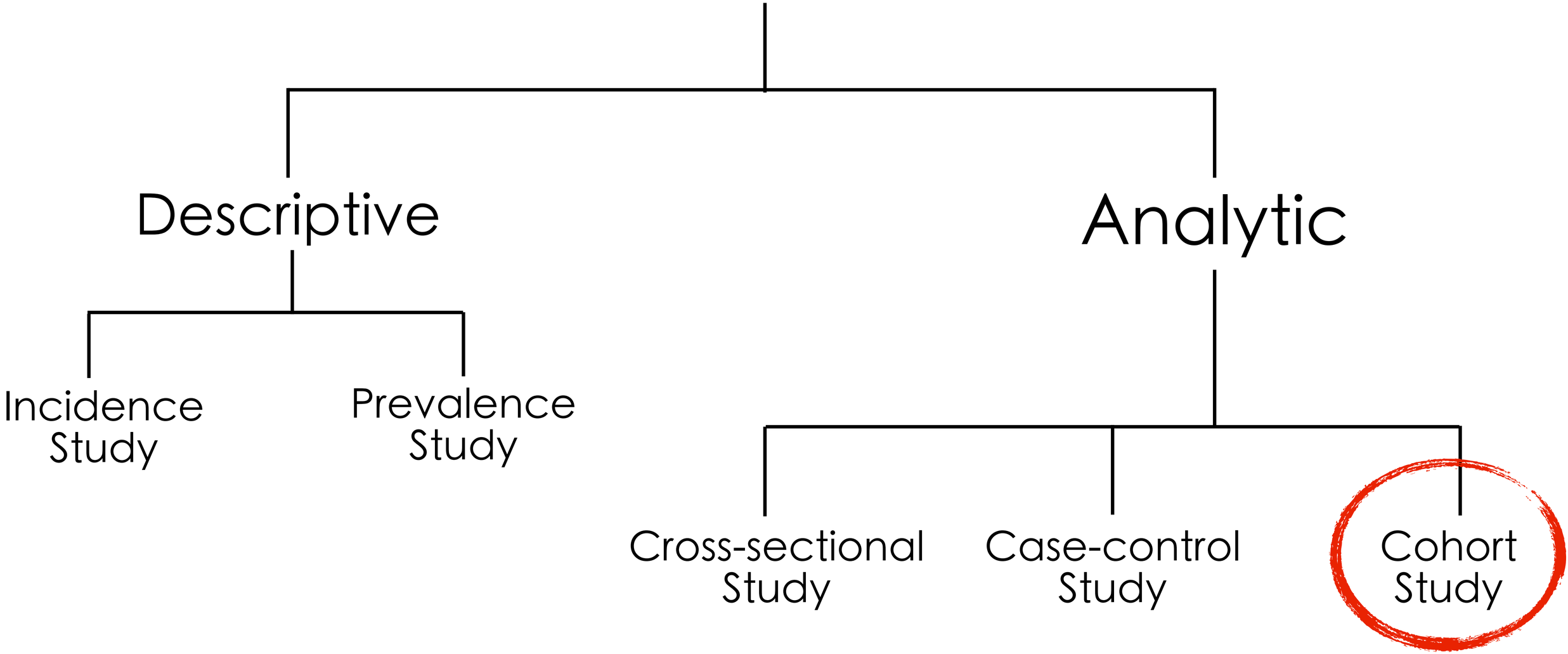
Interpretation ?

Incidence

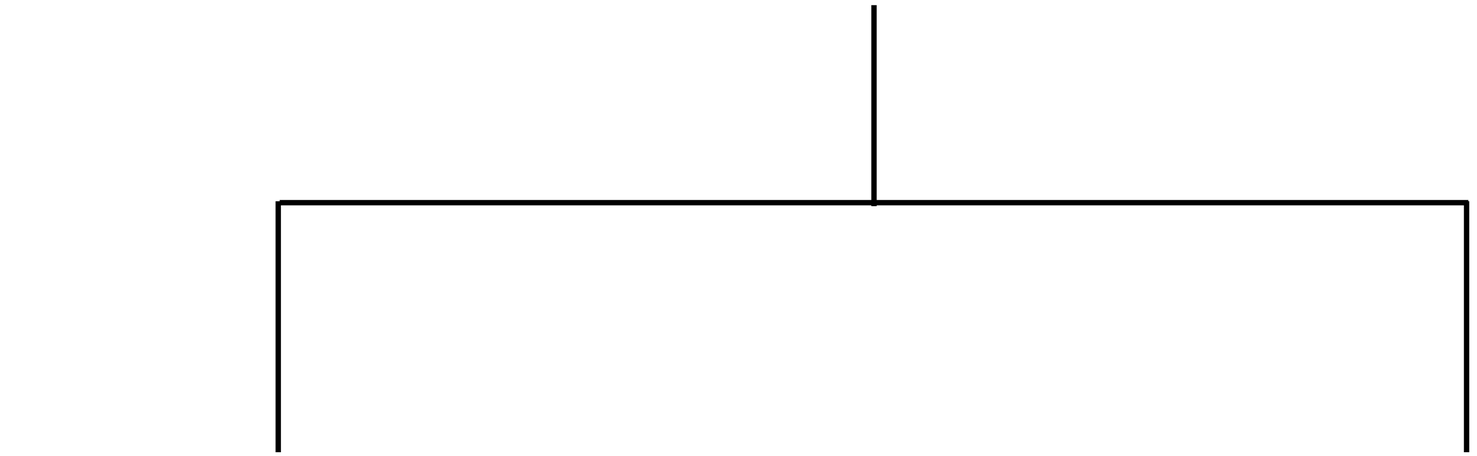
- The occurrence of new cases of disease or injury in a population over a specified period of time

$$\text{Cumulative incidence} = \frac{\text{Number of new cases within a specific time period}}{\text{Population at risk}}$$

Observational Study



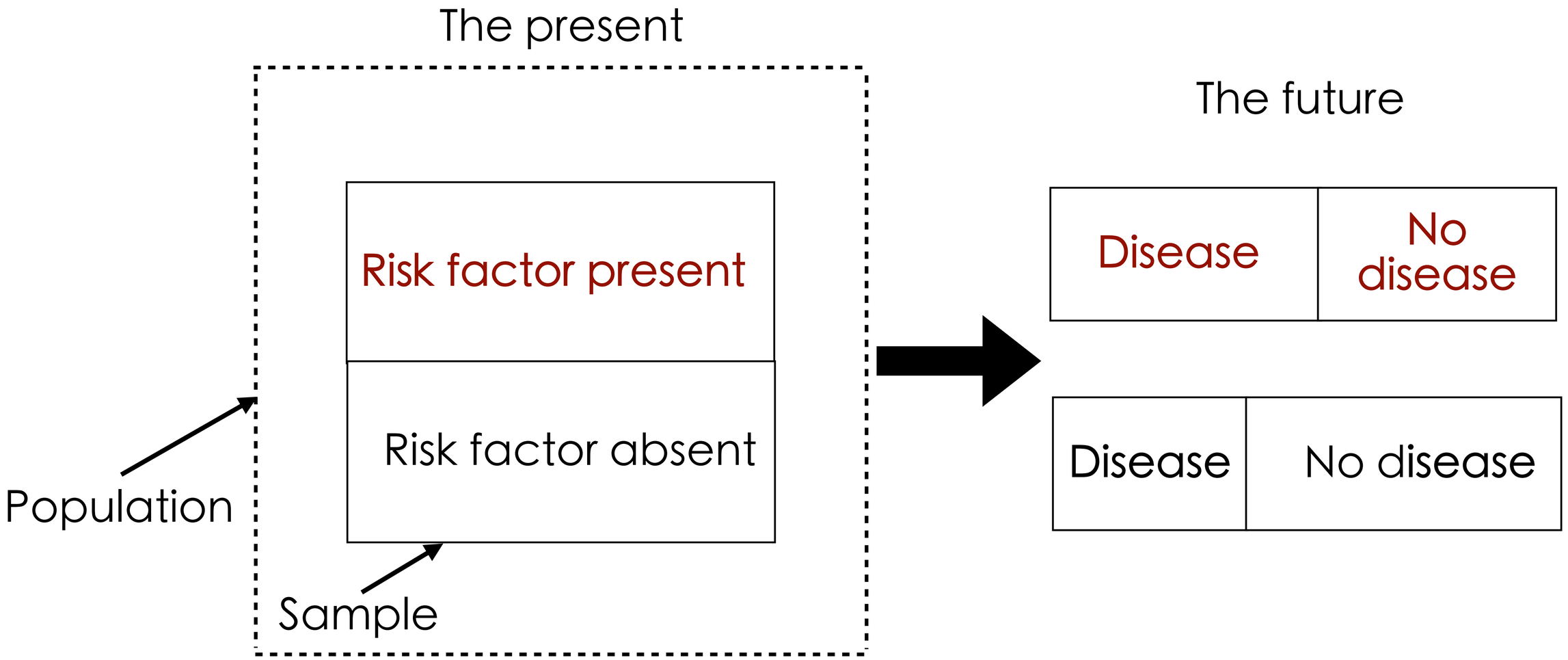
Cohort Study



Prospective Cohort Study

- Longitudinal study, Follow-up study
- Follow disease-free study population over a period of time
- Incidence in exposed > unexposed —> the exposure may be a cause of disease
- Pros: explain causal relationship, yields incidence
- Cons: expensive, take long time, need large sample size

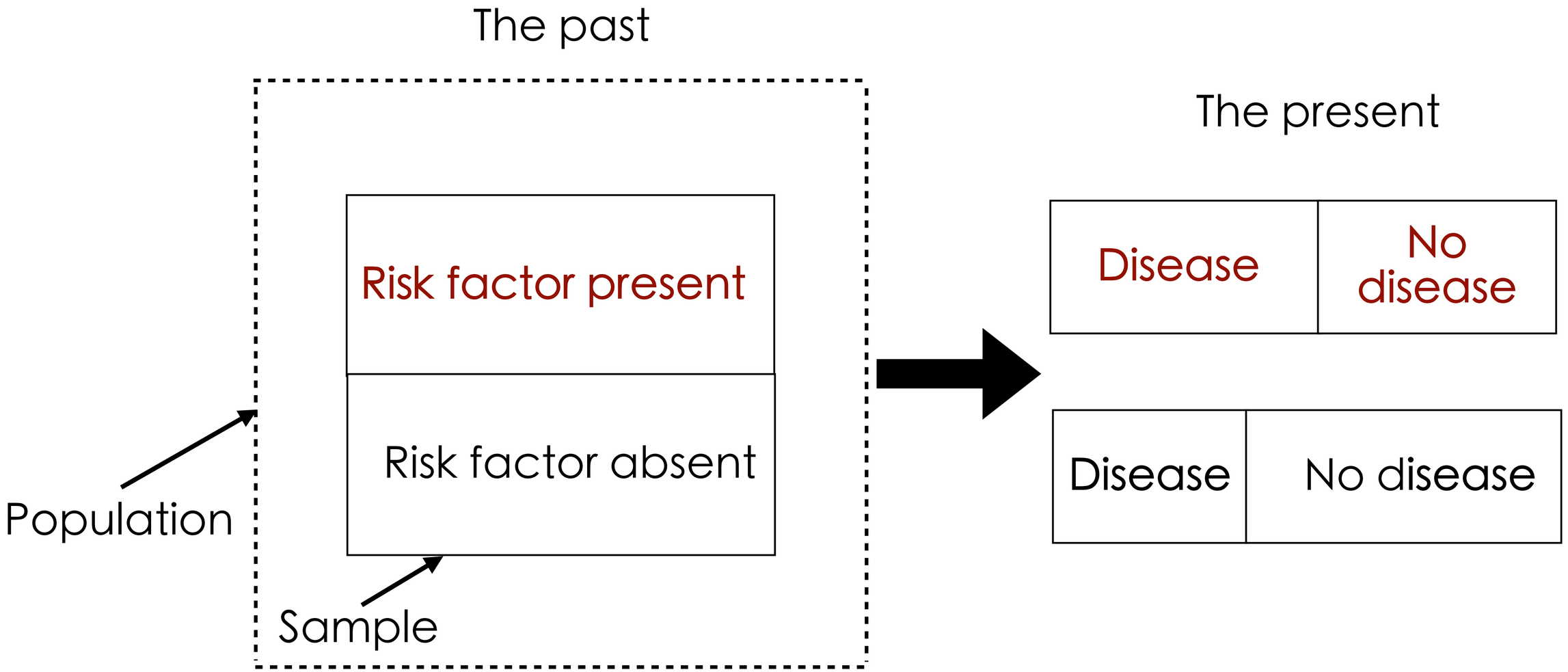
Prospective Cohort Study



Retrospective Cohort Study

- Historical cohort
- Researcher starts the study at the time follow-up has already been completed
- Pros: quick
- Cons: work with what has been measured in the past, often for another purpose

Retrospective Cohort Study



Risk Ratio

- Relative risk
- Risk = number of new cases divided by the total population-at-risk

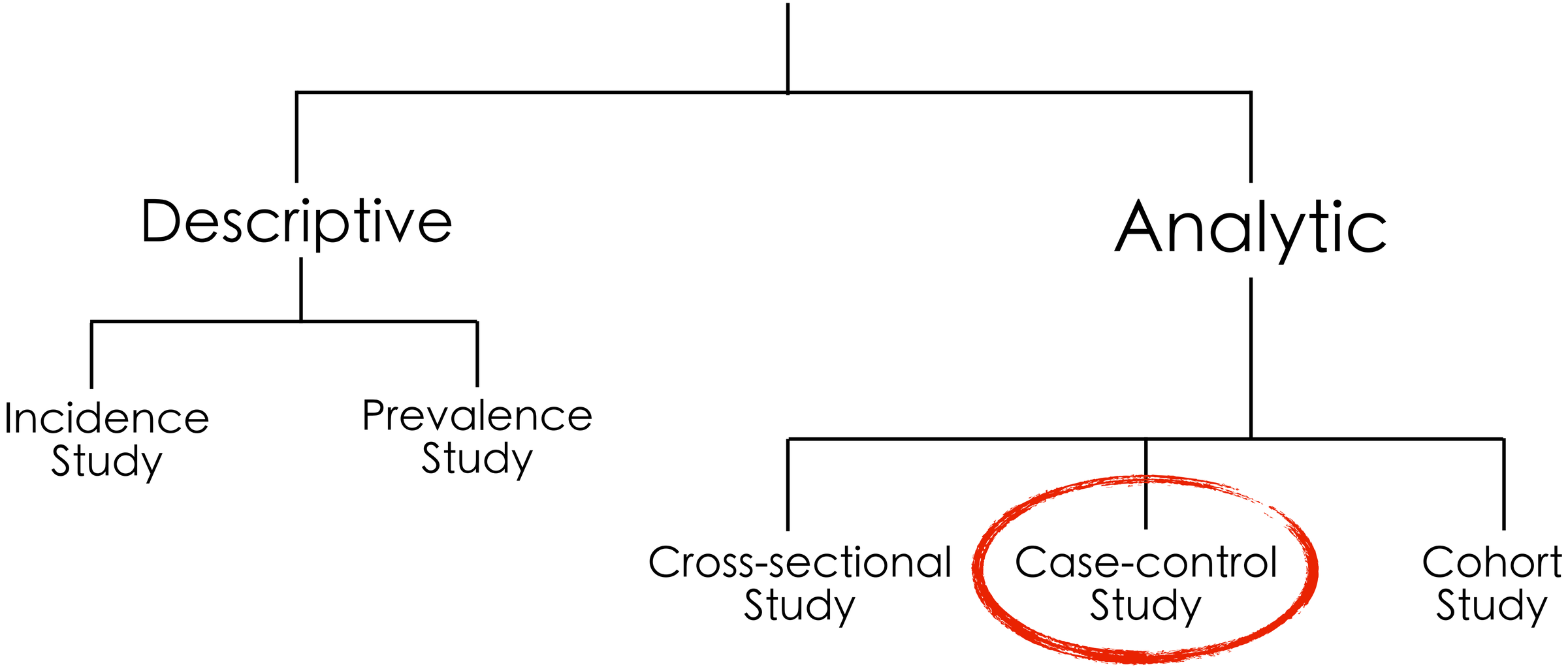
$$RR = \frac{\text{Risk of disease in exposed}}{\text{Risk of disease in unexposed}}$$

	Disease	No disease	
Exposed	a	b	a+b
Unexposed	c	d	c+d
	a+c	b+d	a+b+c+d

$$RR = \frac{\text{Risk of disease in exposed}}{\text{Risk of disease in unexposed}}$$

$$= \frac{a / (a+b)}{c / (c+d)}$$

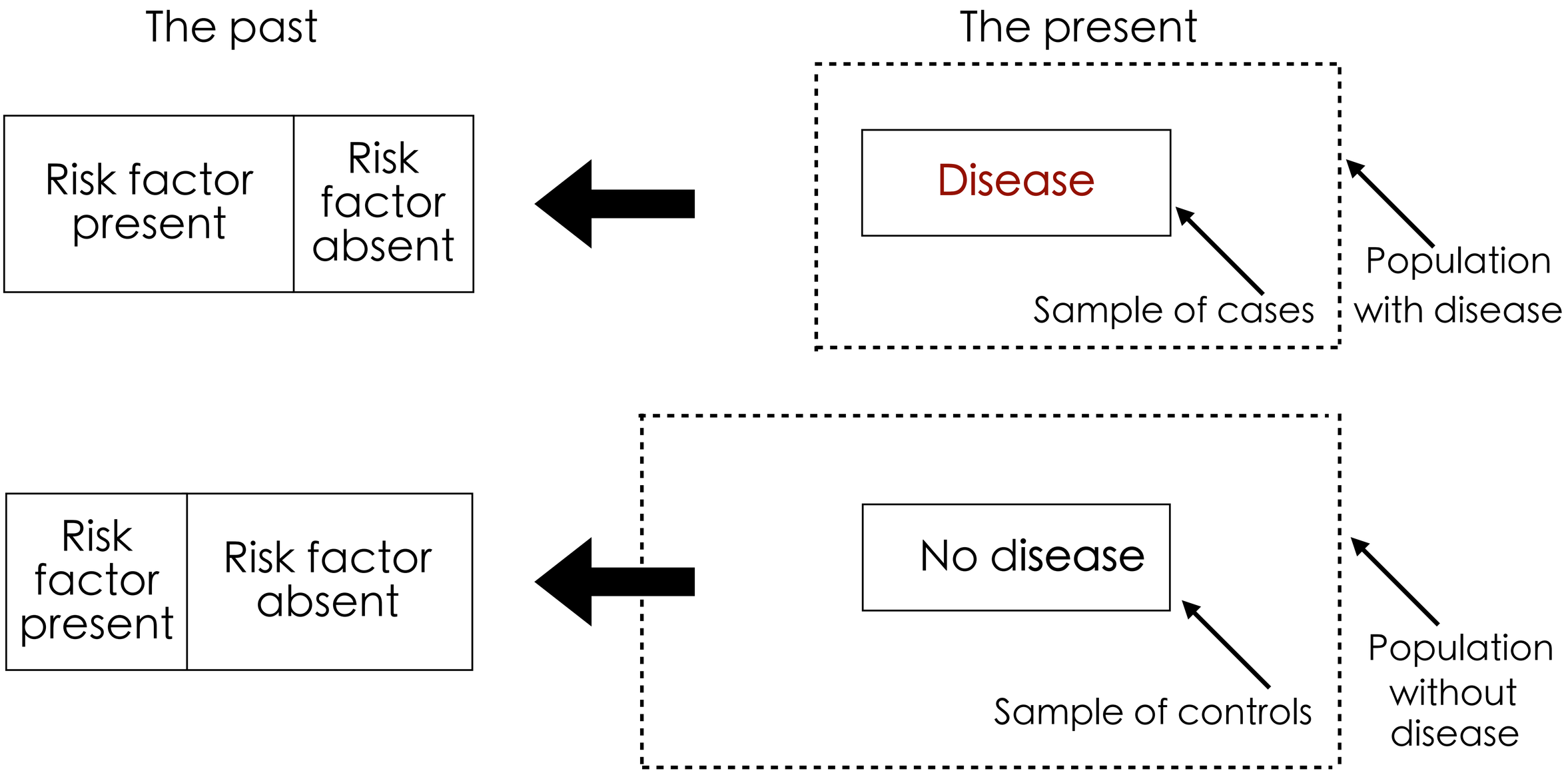
Observational Study



Case-control Study

- Identify the cases and controls (a group known to be free of the disease)
- Study the exposure in both groups
- If case has exposed > control —> the potential risk factor may be a cause of the disease
- Always retrospective
- Pros: efficient for rare diseases/ diseases with the long latency period
- Cons: prone to bias, no prevalence and incidence

Case-control Study



Probability

- Probabilities: proportion of chance of having interesting events out of all possibilities
- Throwing a dice: probability of getting “1” = 1/6

Odds

- Ratio of chance of having interesting events over chance of having non-interesting events
- Throwing a dice: Odds of getting “1” = ?

$$\text{Odds} = \frac{\text{Probability}}{1 - \text{Probability}} \qquad \text{Probability} = \frac{\text{Odds}}{1 + \text{Odds}}$$

Odds Ratio

- No prevalence or incidence in case-control study
- Not possible to calculate RR

$$OR = \frac{\text{Odds of exposed in case}}{\text{Odds of exposed in control}}$$

	Case	Control	
Exposed	a	b	a+b
Unexposed	c	d	c+d
	a+c	b+d	a+b+c+d

$$OR = \frac{\text{Odds of exposed in case}}{\text{Odds of exposed in control}}$$

$$= \frac{a / c}{b / d} = \frac{a*d}{b*c}$$

Exposure OR = Disease OR

	Cirrhosis	No cirrhosis	
Alcohol	80	20	100
No alcohol	10	50	60
	90	70	160

- In Case-control study, we calculate exposure OR

  Exposure OR = ?

- In Cohort study, we calculate disease OR

  Disease OR = ?

OR ~ RR

	Rare disease	No disease	
Expose	80	20	100
Un exposed	10	50	60
	90	70	160

- In other study design e.g. cross-sectional, cohort
- When disease is rare, OR is similar to RR

  OR = ?

  RR = ?

OR and RR interpretation

- No unit
- 0 - infinity

0 = No association

>1 = Positive association

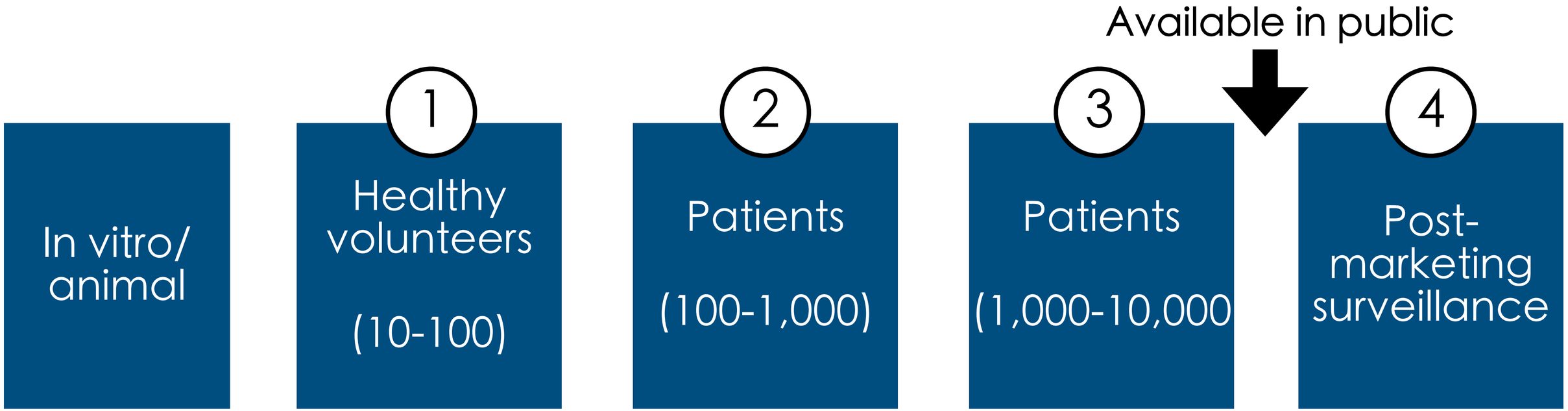
(Exposure is a risk factor)

<1 = Inverse association

(Exposure is a protective factor)

Experimental Study

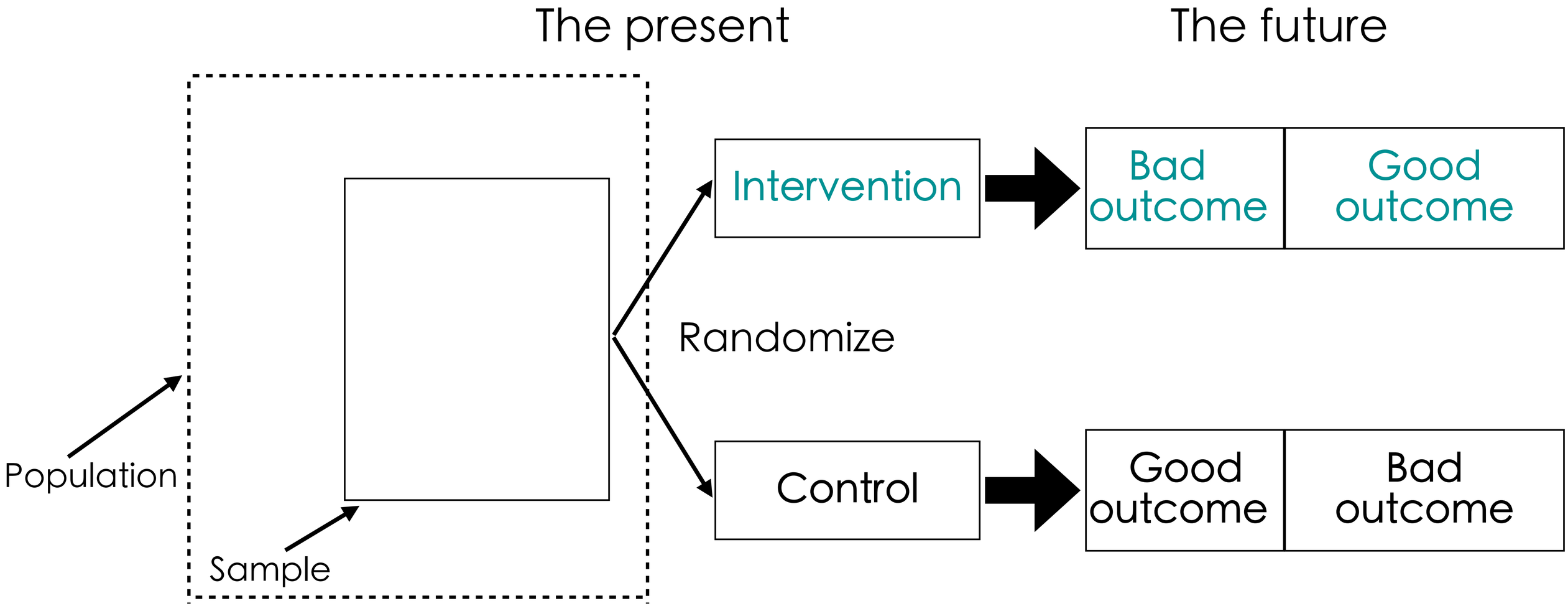
Phases of Clinical Trial



Randomized Controlled Trial (RCT)

- Provide strong evidence of a cause-effect relation
- Participants are randomly assigned to an experimental and a control group.
- Control group receives another treatment or a placebo.
- Blinding
  - Double blind: participants and investigators

Randomized Controlled Trial (RCT)



Other Designs

Crossover study

- Participants serve as their own control
- Randomly assign participants —> switch treatment
- Washout period
- Pros: reduce influence by confounders,
- Cons: carryover effects, period effects (resistance/disease progression)


Systematic reviews and meta-analyses of RCTs*
Randomized controlled trials
Cohort studies
Case-control studies
Cross-sectional studies, surveys
Case reports, case studies
Mechanistic studies
Editorials, expert opinion

Systematic Review

- Collects all possible studies related to a given topic and design
- Reviews and analyzes their results

Meta-analysis

- Statistical process of analyzing and combining results from several similar studies
- Publication bias