

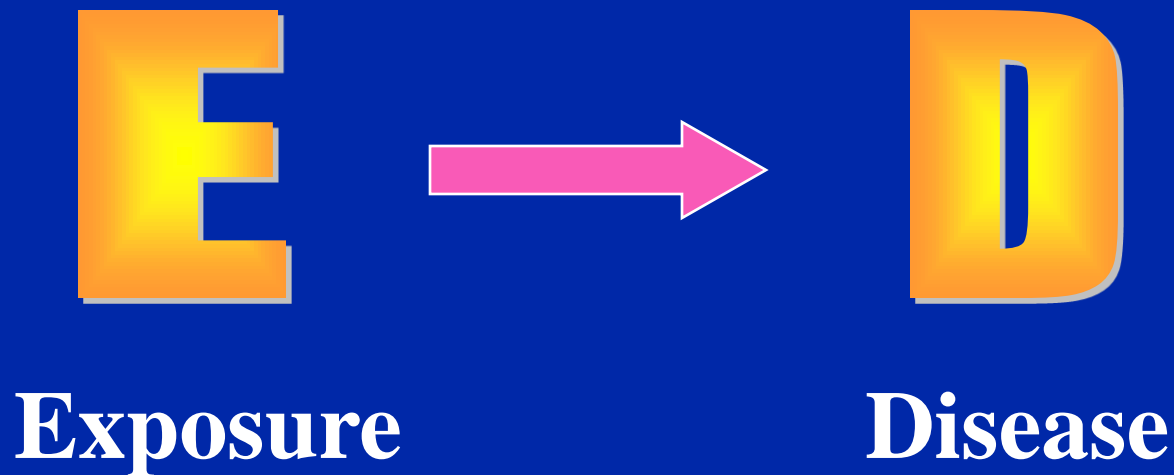
# Study Designs

# Types of primary studies

- **Descriptive studies**
  - describe occurrence of outcome
- **Analytic studies**
  - describe **association** between exposure and outcome

# Basic Question in Analytic Epidemiology

- Are exposure and disease linked?



# Study Designs

## Descriptive

Case report

Case series

Descriptive  
Epidemiology

## Analytic

RCT

Cohort study

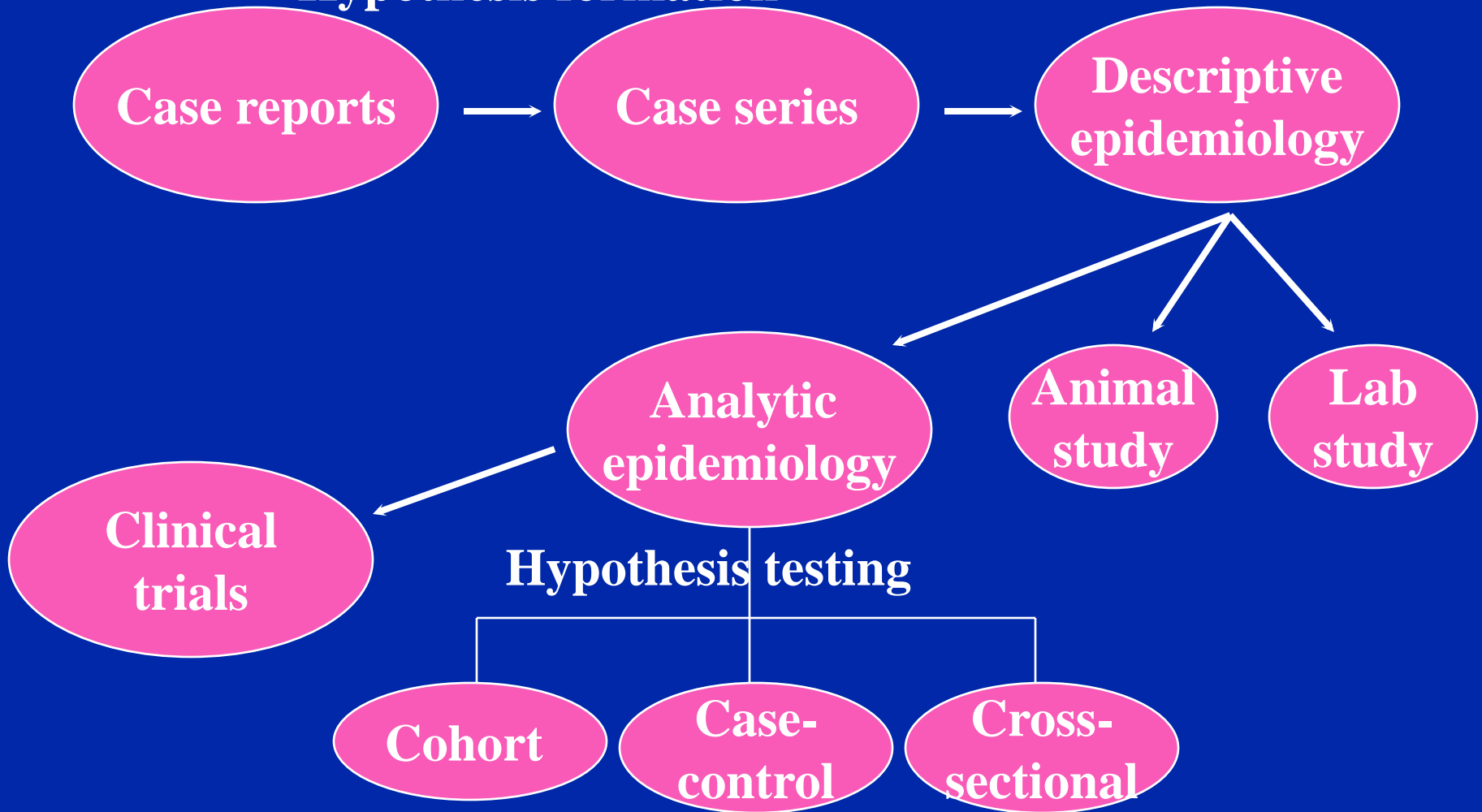
Case-Control  
study

Cross-sectional  
study

Ecologic study

# Study Design Sequence

## Hypothesis formation



**Increasing Knowledge of  
Disease/Exposure**



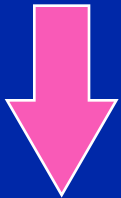
**Descriptive Studies**



**Case-control Studies**



**Cohort Studies**



**Clinical trials**

**Develop  
hypothesis**

**Investigate it's  
relationship to  
outcomes**

**Define it's meaning  
with exposures**

**Test link  
experimentally**

# Descriptive Studies

# Analytical Studies

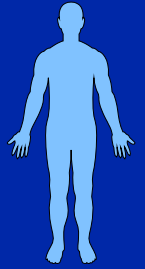
# Observational Studies

- **non-experimental**
- **observational because there is no individual intervention**
- **treatment and exposures occur in a “non-controlled” environment**
- **individuals can be observed prospectively, retrospectively, or currently**

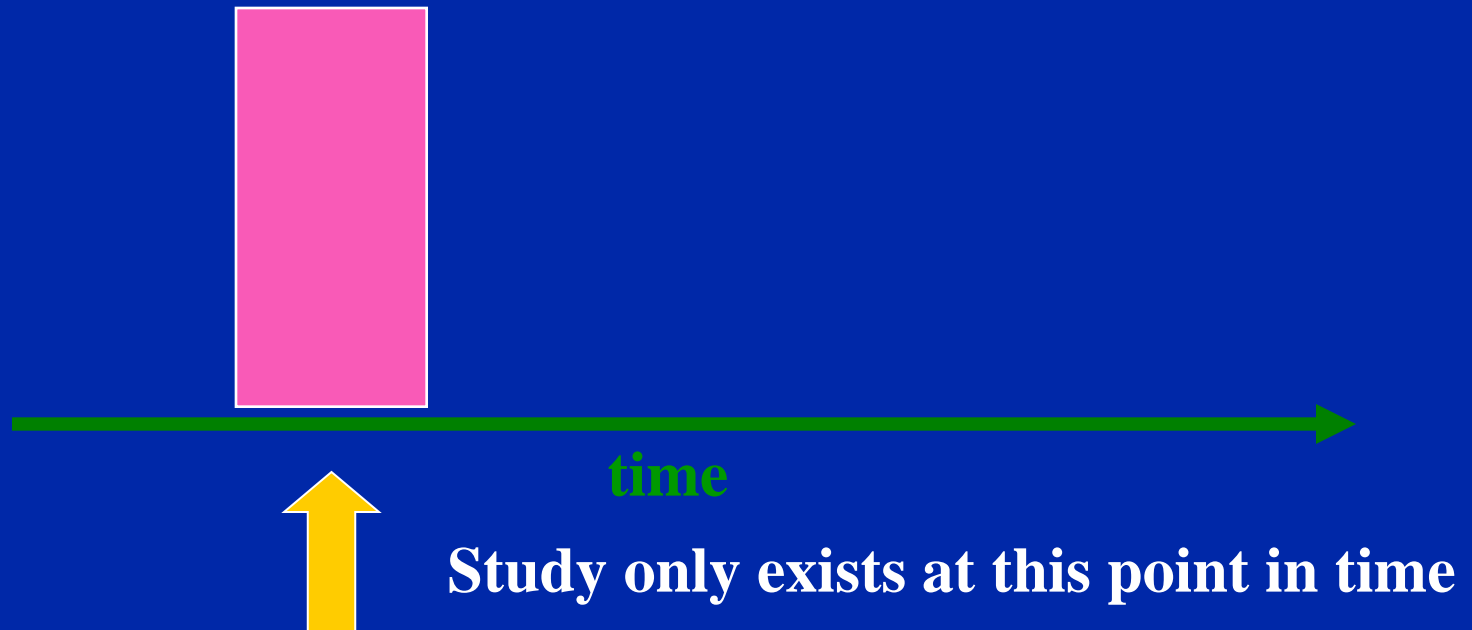
# Experimental Studies

- **treatment and exposures occur in a “controlled” environment**
- **planned research designs**
- **clinical trials are the most well known experimental design. Clinical trials use randomly assigned data.**
- **Community trials use nonrandom data**

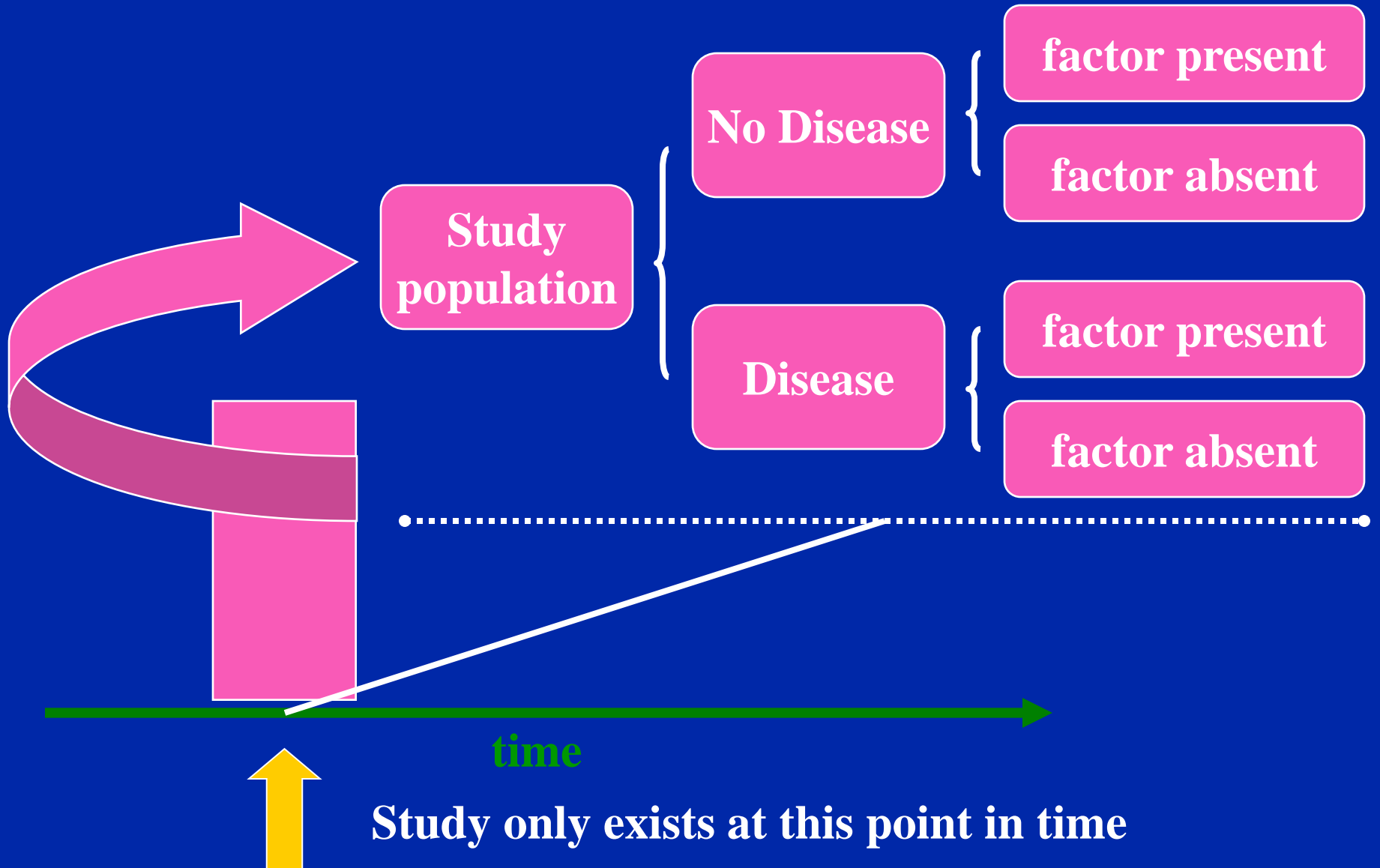
# Cross-sectional studies



- An “observational” design that surveys exposures and disease status at a single point in time (a cross-section of the population)



# Cross-sectional Design



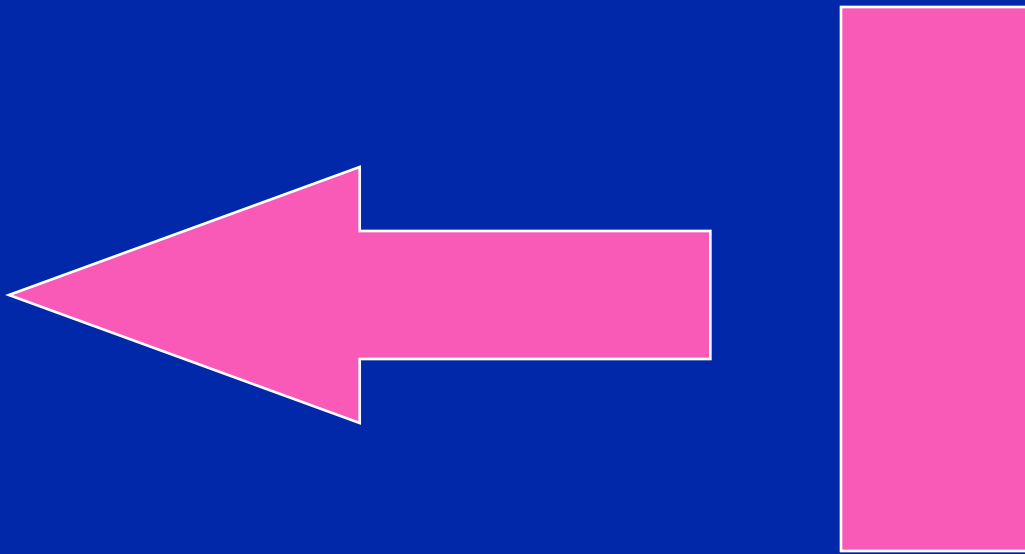
# Epidemiologic Study Designs

- **Case-Control Studies**
  - an “observational” design comparing exposures in disease cases vs. healthy controls from same population
  - exposure data collected retrospectively
  - most feasible design where disease outcomes are rare

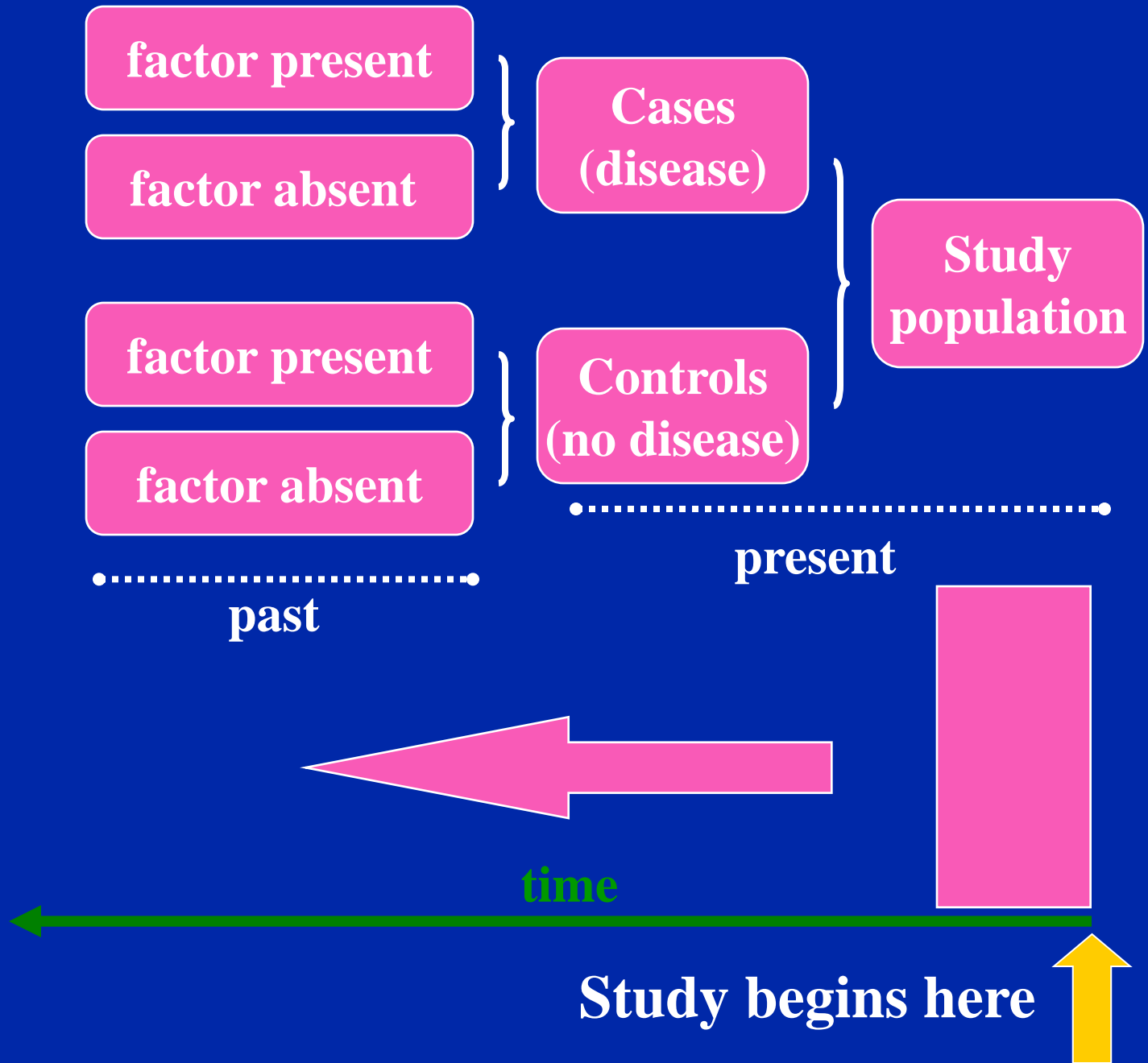
# Case-Control Studies

**Cases: Disease**

**Controls: No disease**



# Case-Control Design



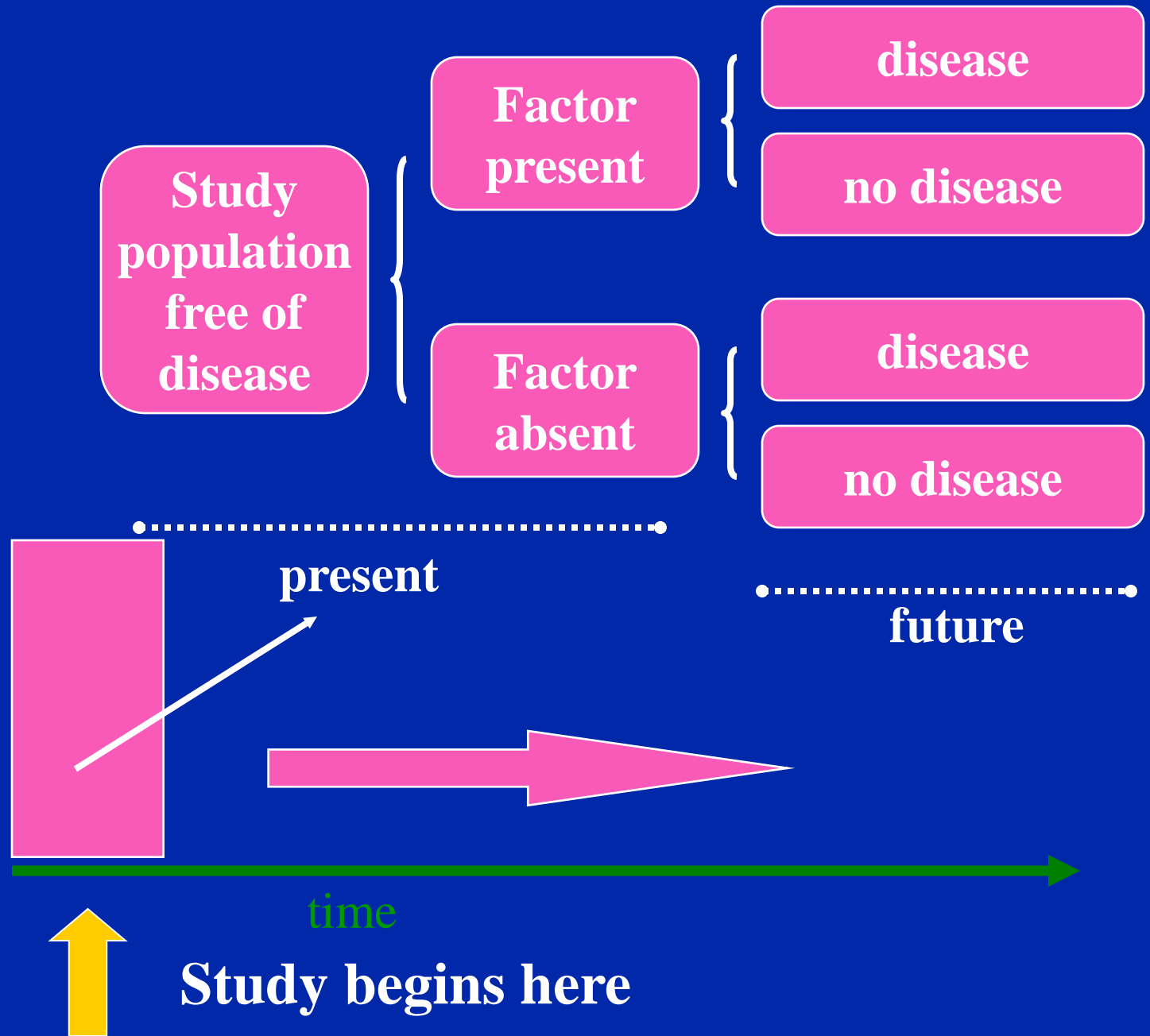
# Case-Control Study

- **Strengths**
  - **Less expensive and time consuming**
  - **Efficient for studying rare diseases**
- **Limitations**
  - **Inappropriate when disease outcome for a specific exposure is not known at start of study**
  - **Exposure measurements taken after disease occurrence**
  - **Disease status can influence selection of subjects**

# Epidemiologic Study Designs

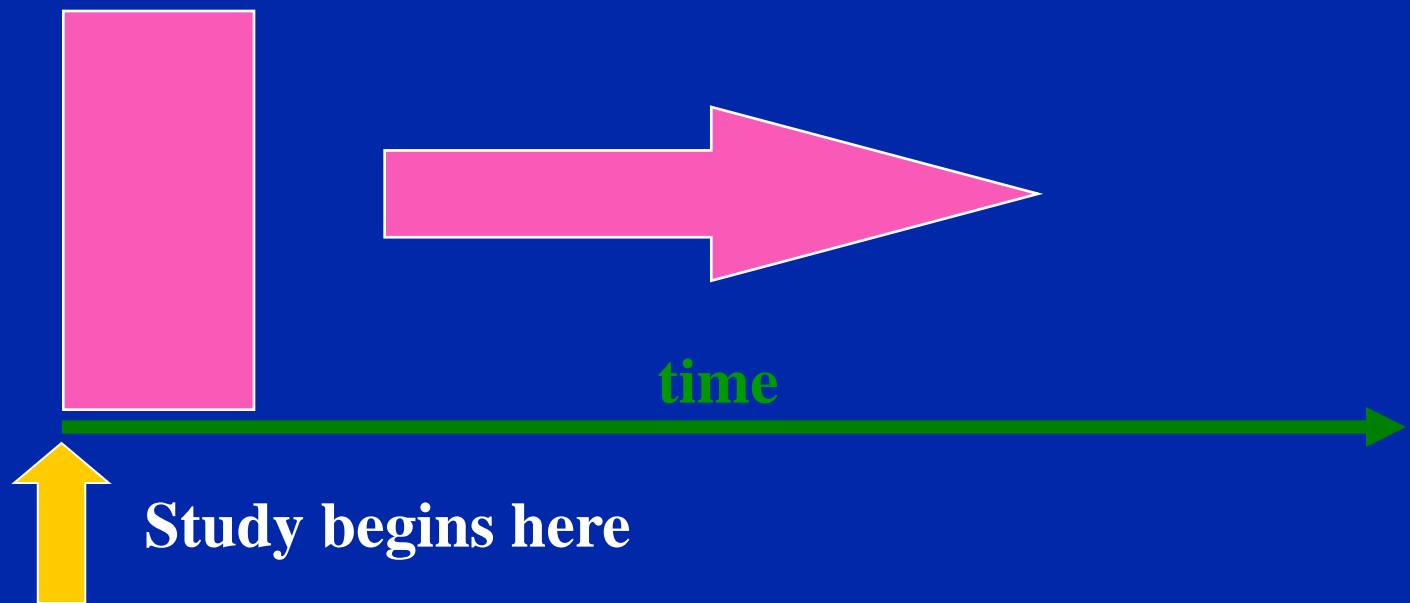
- **Cohort Studies**
  - an “observational” design comparing individuals with a known risk factor or exposure with others without the risk factor or exposure
  - looking for a difference in the risk (incidence) of a disease over time
  - best observational design
  - data usually collected prospectively (some retrospective)

# Cohort Design

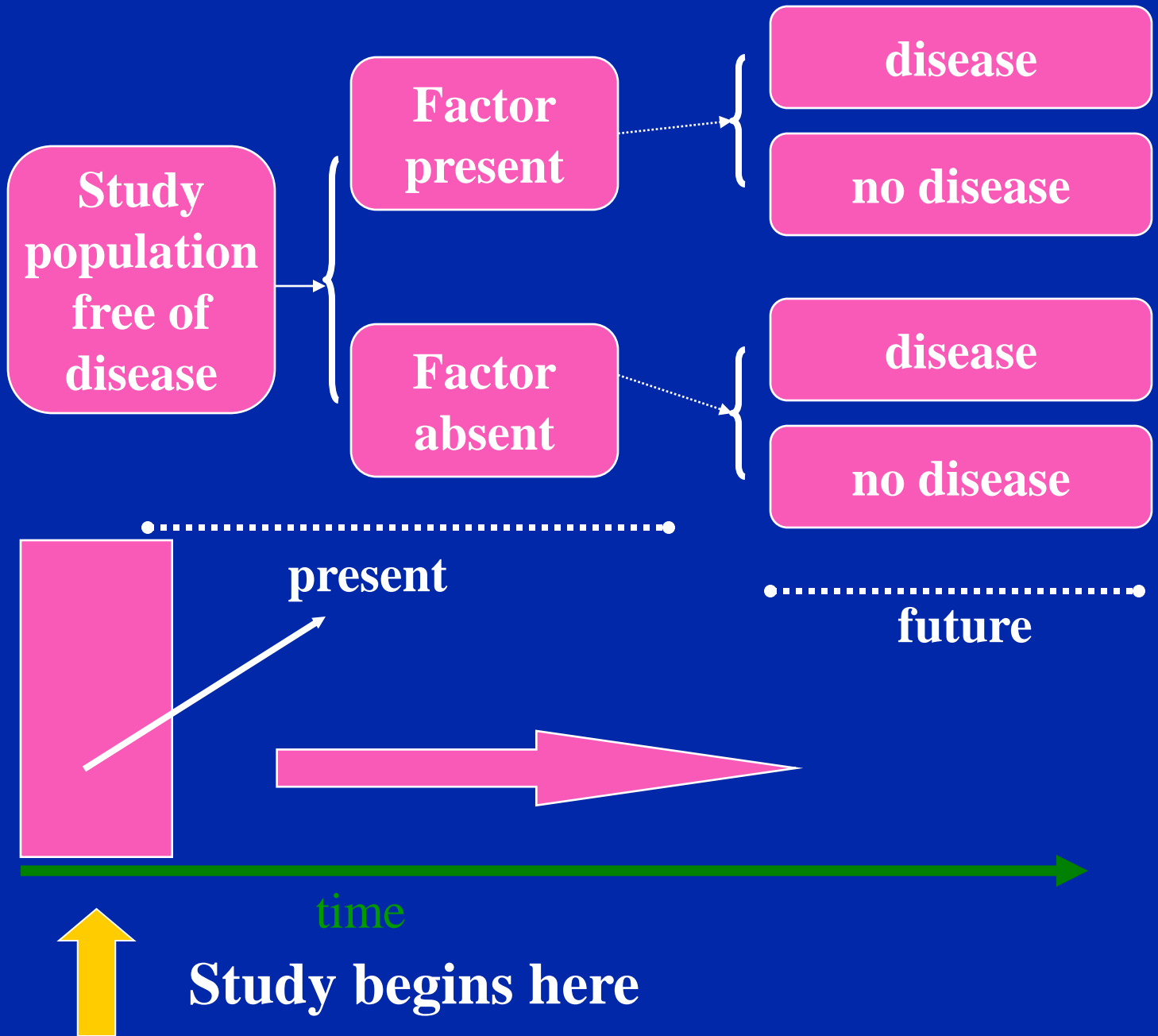


# Timeframe of Studies

- **Prospective Study** - looks forward, looks to the future, examines future events, follows a condition, concern or disease into the future



# Cohort Design



# Cohort Study

- **Strengths**

- **Exposure status determined before disease detection**
- **Subjects selected before disease detection**
- **Can study several outcomes for each exposure**

- **Limitations**

- **Expensive and time-consuming**
- **Inefficient for rare diseases or diseases with long latency**
- **Loss to follow-up**

# Experimental Studies

- investigator can “control” the exposure
- akin to laboratory experiments except living populations are the subjects
- generally involves random assignment to groups
- clinical trials are the most well known experimental design
- the ultimate step in testing causal hypotheses

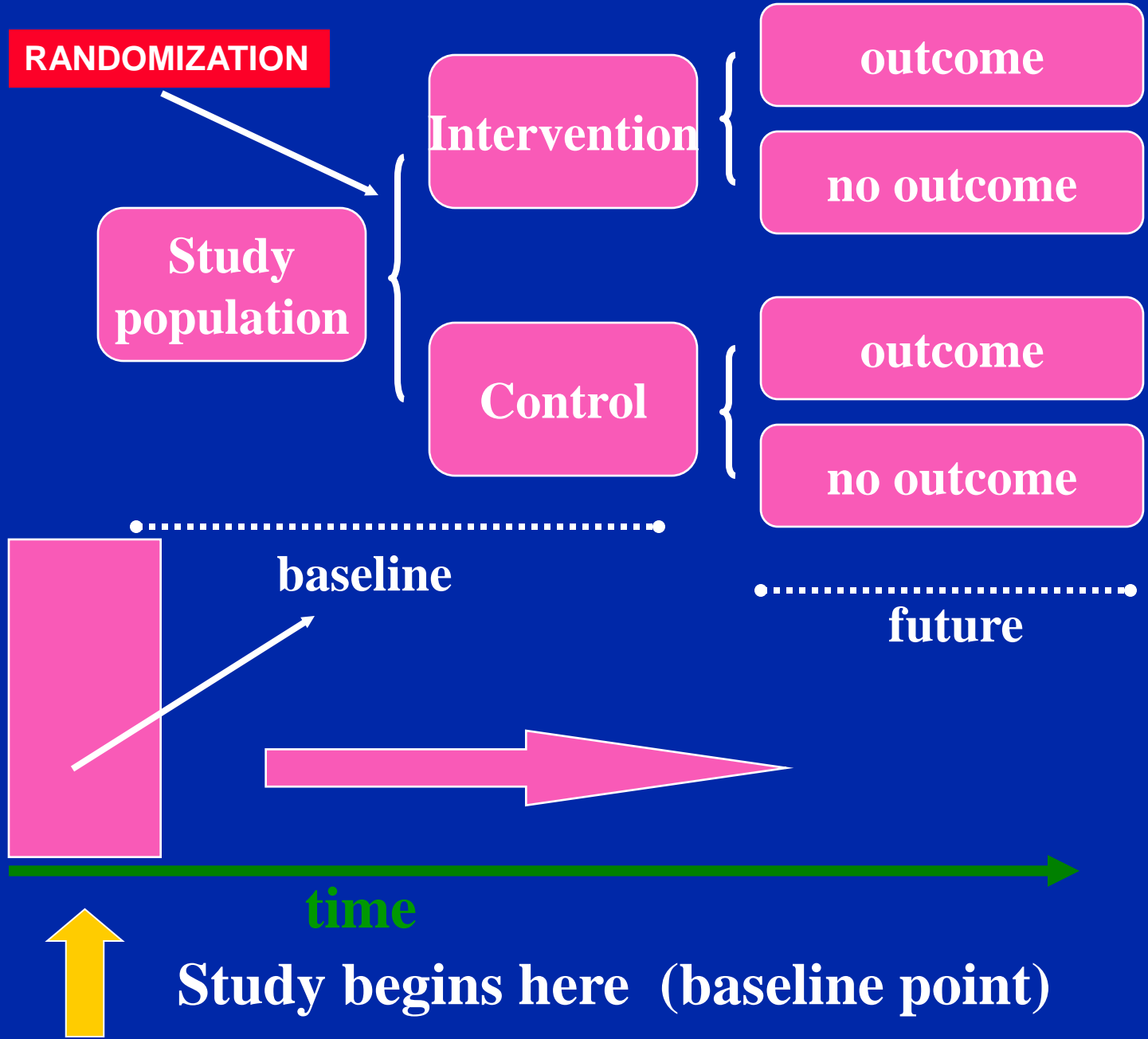
# Experimental Studies

- In an experiment, we are interested in the consequences of some treatment on some outcome.
- The subjects in the study who actually receive the treatment of interest are called the **treatment group**.
- The subjects in the study who receive no treatment or a different treatment are called the **comparison group**.

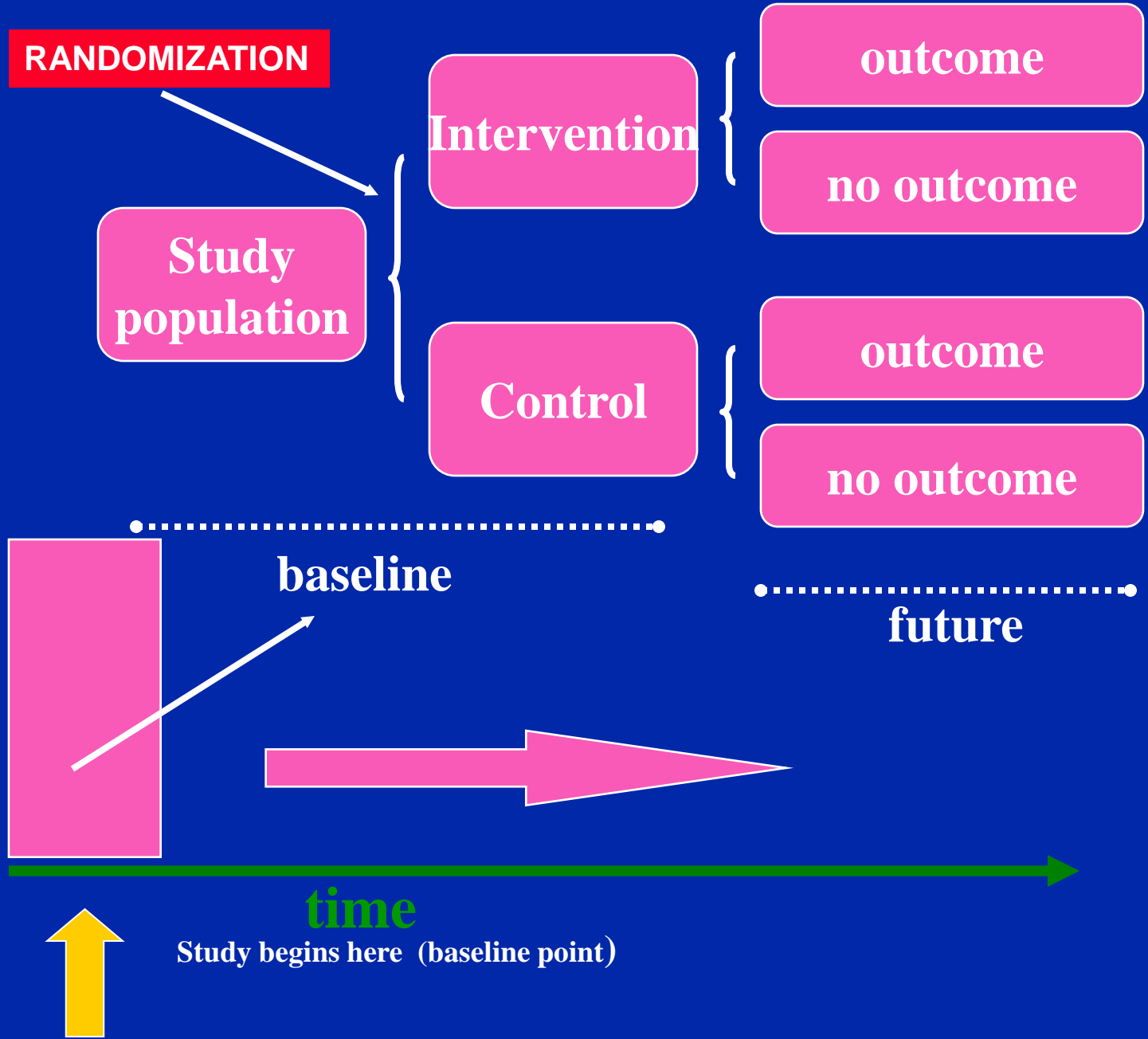
# Epidemiologic Study Designs

- **Randomized Controlled Trials (RCTs)**
  - a design with subjects randomly assigned to “treatment” and “comparison” groups
  - provides most convincing evidence of relationship between exposure and effect
  - not possible to use RCTs to test effects of exposures that are expected to be harmful, for ethical reasons

# Experimental Design



# Experimental Design





# Epidemiologic Study Designs

- **Randomized Controlled Trials (RCTs)**
  - the “gold standard” of research designs
  - provides most convincing evidence of relationship between exposure and effect
- *trials of hormone replacement therapy in menopausal women found no protection for heart disease, contradicting findings of prior observational studies*

# Randomized Controlled Trials

- **Disadvantages**
  - **Very expensive**
  - **Not appropriate to answer certain types of questions**
    - **it may be unethical, for example, to assign persons to certain treatment or comparison groups**