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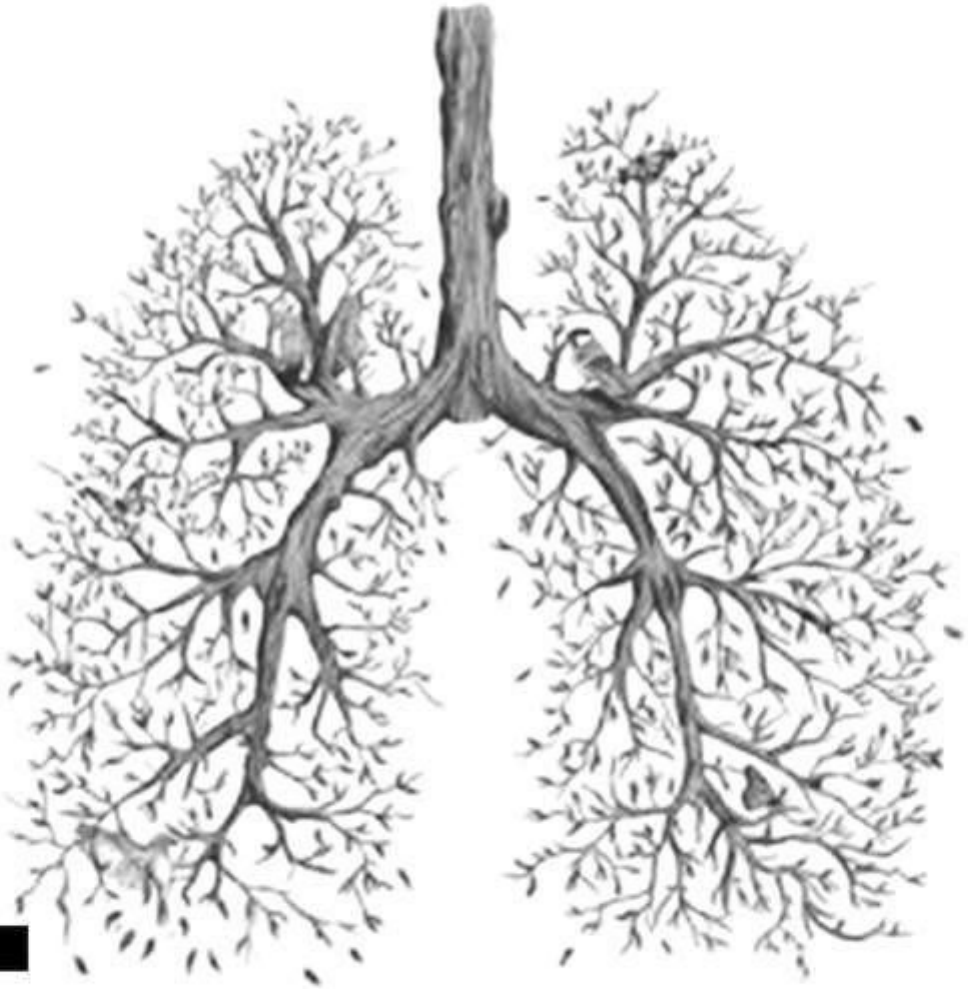
Medical Committee
The University of Jordan

Community Medicine



Slides ■
Sheet □

Slide #: **22** Doctor: **Dr. Ahmad**

Date:

Basic Epidemiology

Study Designs in Epidemiologic Research

Epidemiology = A branch of medical science

- **Definition**: **Epidemiology** :is defined as the study of the distribution and determinants of health, disease and injuries in human population

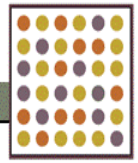
- Derived from Greek **epi (upon), demos (people), logos (knowledge) =** the knowledge of what happens to people

Definitions

1. **Epidemic: A disease that clearly exceeds normal or expected frequency in a community or region.**
2. **Pandemic: Epidemic with worldwide distribution (for e.g. plague or AIDS)**
   - **In England alone, approximately one fourth of the population died from the plague.**
3. **Endemic: Continuing presence of a disease or infectious agent in a given geographic area means the disease is endemic to that area.**

The Five Ws of Epidemiologic Studies

The Five Ws of Epidemiology Studies



- What = Clinical
- Who = Person
- Where = Place
- When = Time

} Descriptive Epidemiology

- Why / How = Causes
  Risk factors
  Modes of transmission

} Analytic Epidemiology

Fundamental Assumption in Epidemiology

- Disease doesn't occur in a vacuum

  * Disease is not randomly distributed throughout a population
  - Epidemiology uses systematic approach to study the differences in disease distribution in subgroups
  - Allows for study of causal and preventive factors

Components of Epidemiology

- **Measure disease frequency**
  - **Quantify disease**
- **Assess distribution of disease**
  - **Who is getting disease?**
  - **Where is disease occurring?**
  - **When is disease occurring?**

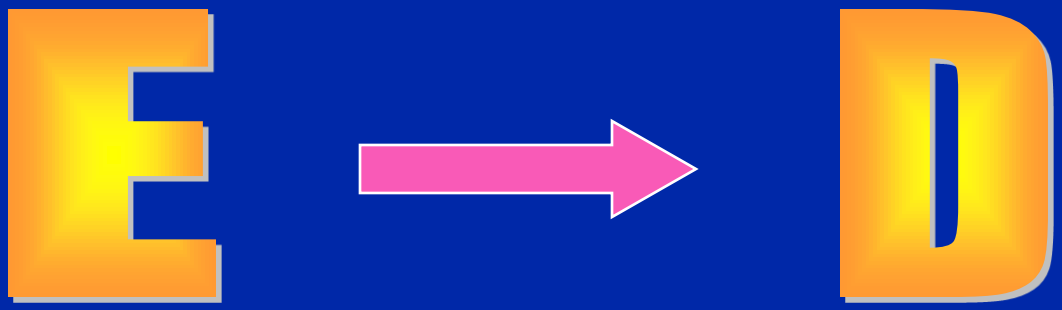
  ➔Formulation of hypotheses concerning causal and preventive factors
- **Identify determinants of disease**
  - **Hypotheses are tested using epidemiologic studies**

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?



Exposure **Disease**

Basic Questions in Analytic Epidemiology

- Look to link exposure and disease
  - **What is the exposure?**
  - **Who are the exposed?**
  - **What are the potential health effects?**
  - **What approach will you take to study the relationship between exposure and effect?**

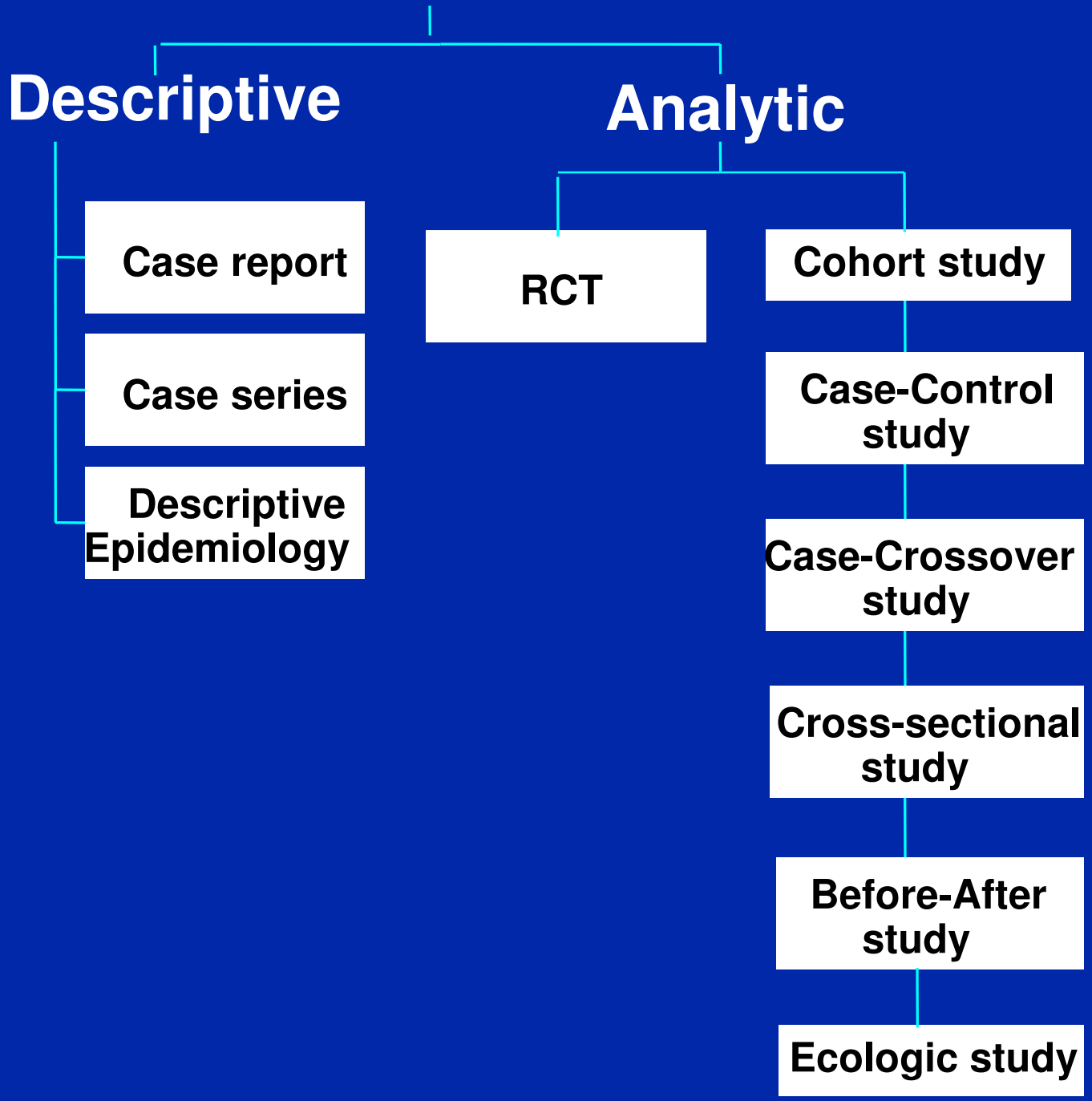
Basic Research Study Designs and their Application to Epidemiology

Big Picture

- To prevent and control disease
- In a coordinated plan, look to
  - identify hypotheses on what is related to disease and may be causing it
  - formally test these hypotheses
    - Study designs direct how the investigation is conducted

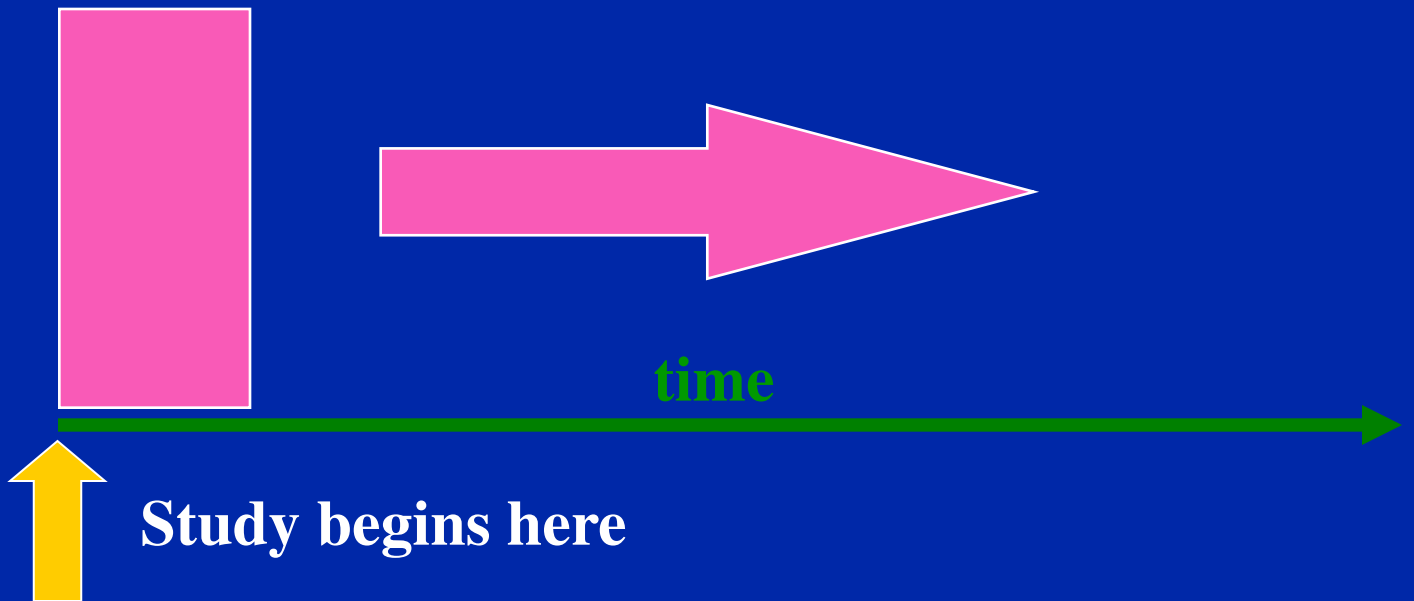
What designs exist to identify and investigate factors in disease?

Study Designs



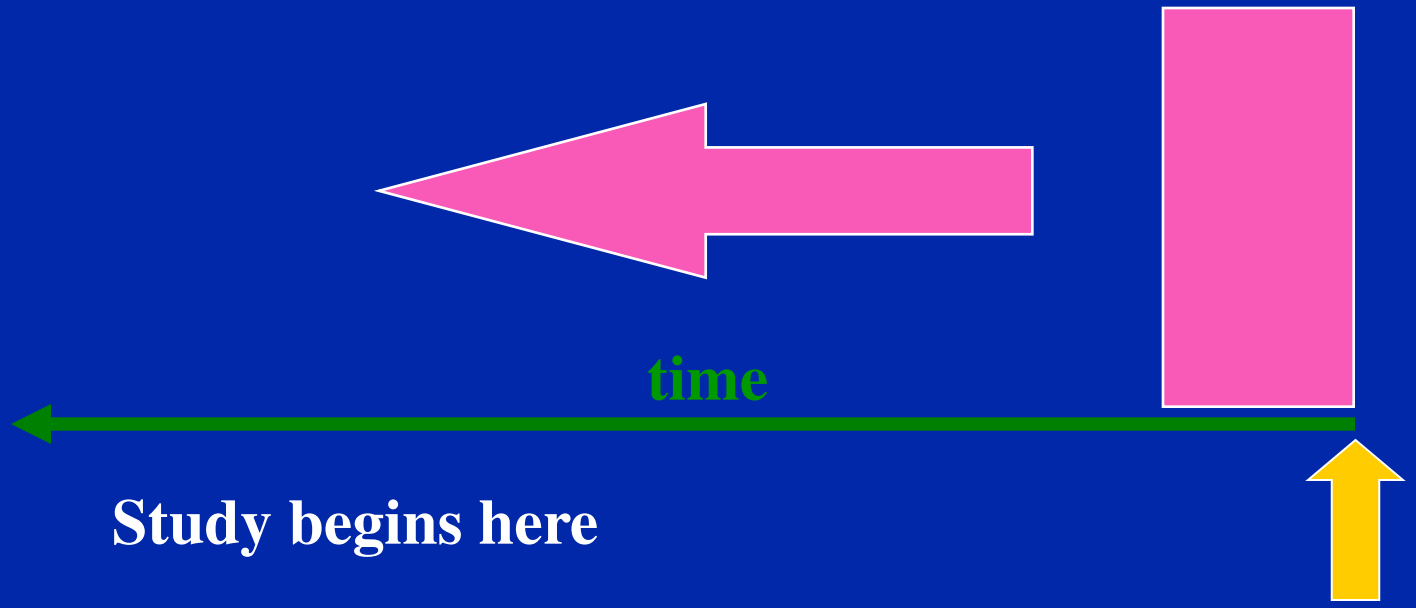
Timeframe of Studies

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

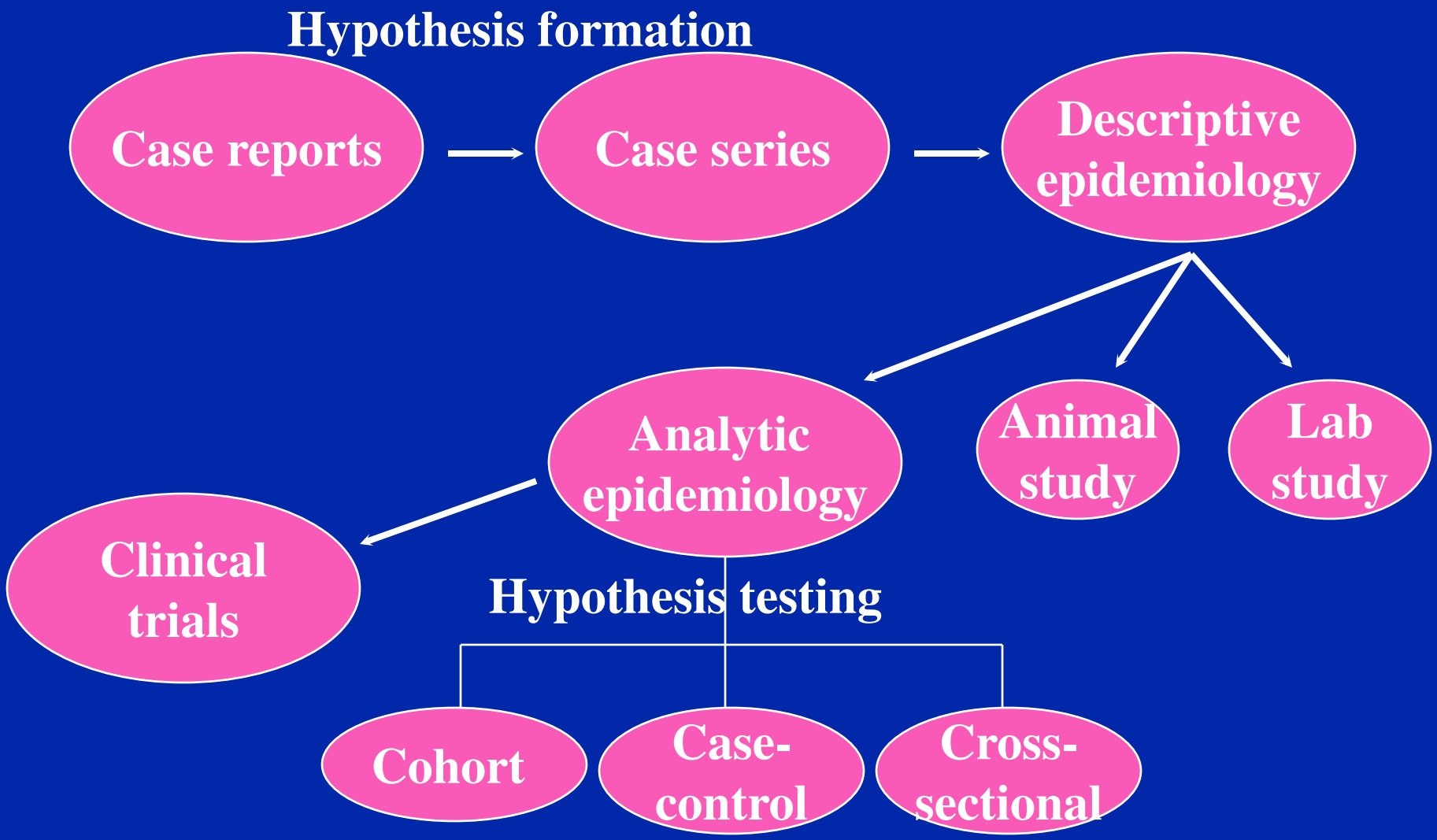


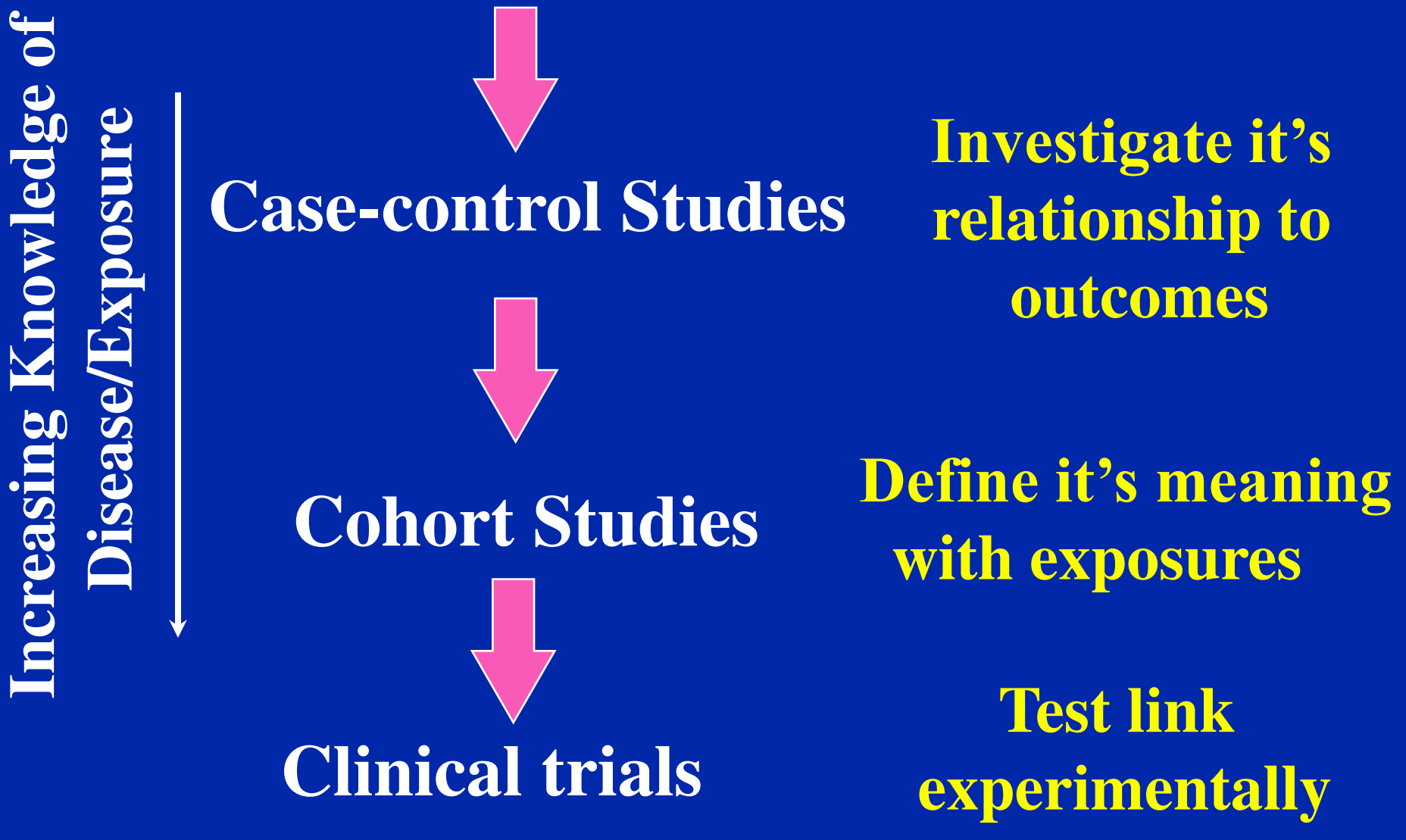
Timeframe of Studies

- **Retrospective Study** - **"to look back", looks back in time to study events that have already occurred**



Study Design Sequence




Descriptive Studies
Develop hypothesis
Increasing Knowledge of Disease/Exposure
Case-control Studies
Investigate it's relationship to outcomes
Cohort Studies
Define it's meaning with exposures
Clinical trials
Test link experimentally

Descriptive Studies

Case Reports

- Detailed presentation of a single case or handful of cases
- Generally report a new or unique finding
    - e.g. previous undescribed disease
    - e.g. unexpected link between diseases
    - e.g. unexpected new therapeutic effect
    - e.g. adverse events

Case Series

- Experience of a group of patients with a similar diagnosis
- Assesses prevalent disease
- Cases may be identified from a single or multiple sources
- Generally report on new/unique condition
- May be only realistic design for rare disorders

Case Series

- **Advantages**
  - **Useful for hypothesis generation**
  - **Informative for very rare disease with few established risk factors**
  - **Characterizes averages for disorder**
- **Disadvantages**
  - **Cannot study cause and effect relationships**
  - **Cannot assess disease frequency**

Case Report → **One case of unusual findings**

Case Series → **Multiple cases of findings**

Descriptive Epidemiology Study → **Population-based cases with denominator**

Analytical Studies

Study Designs - Analytic Epidemiology

- Experimental Studies
  - Randomized controlled clinical trials
  - Community trials
- Observational Studies
  - Group data
    - Ecologic
  - Individual data
    - Cross-sectional
    - Cohort
    - Case-control
    - Case-crossover

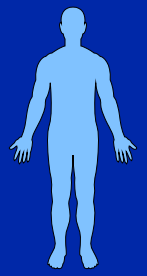
Experimental Studies

- 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

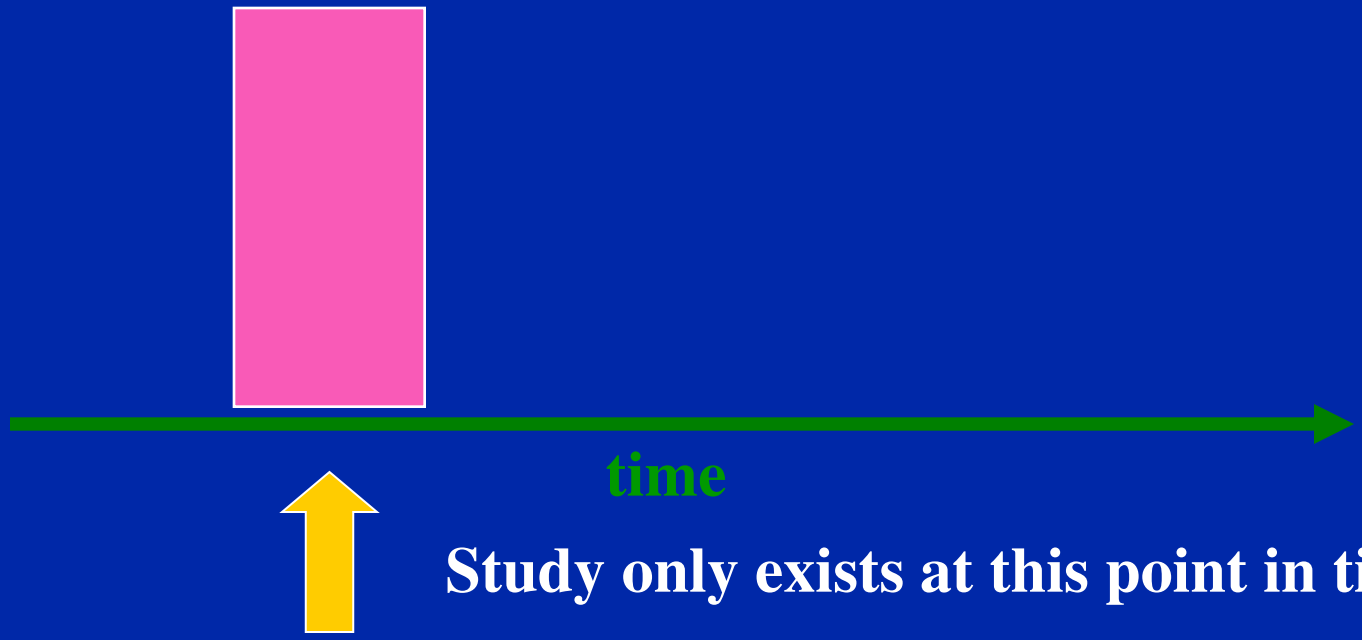
Observational Studies

- 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

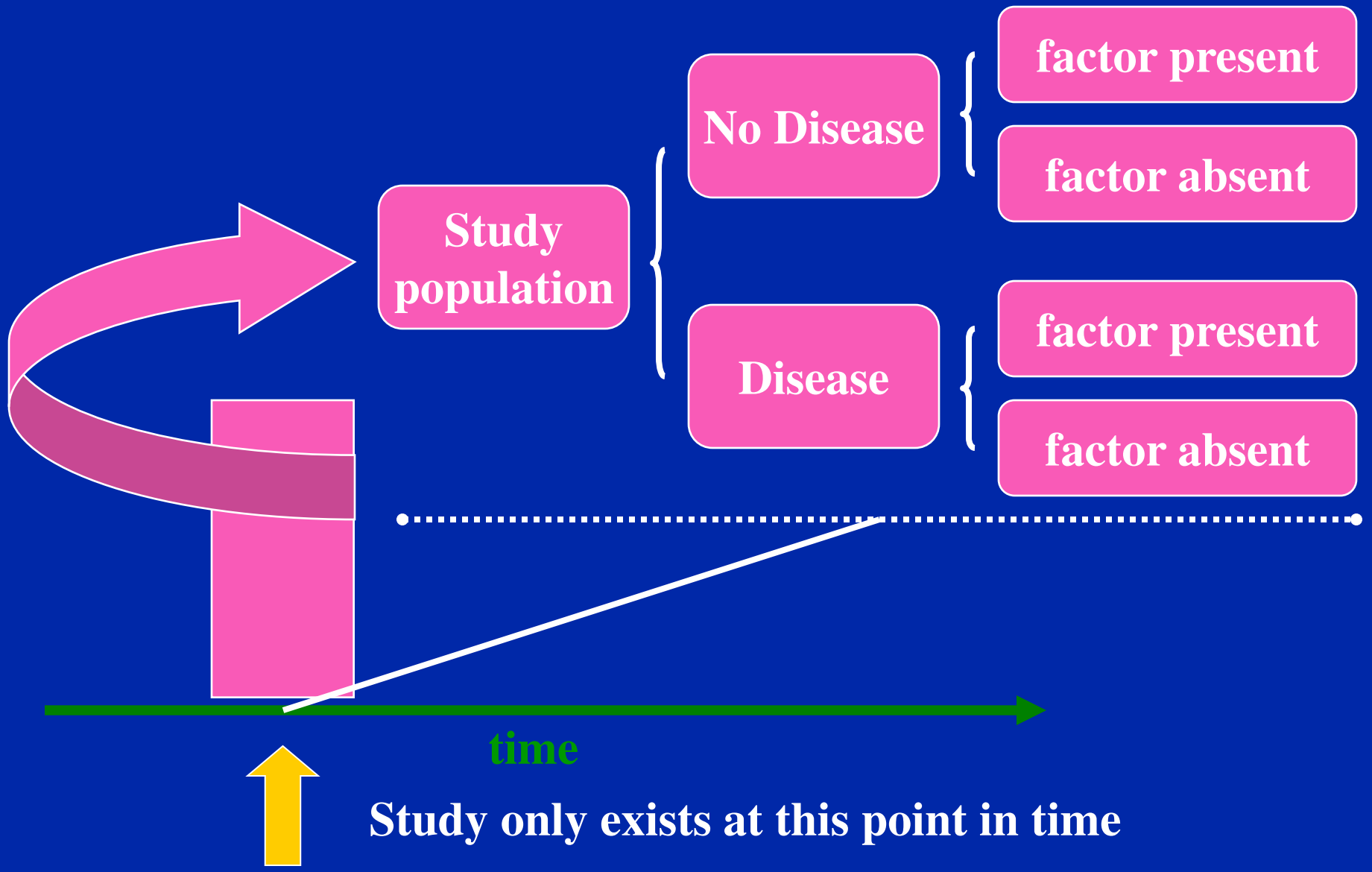
Cross-sectional studies



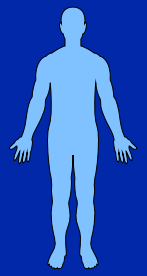
- An "observational" design that surveys exposures and disease status at a single point in time (a cross-section of the population)



Cross-sectional Design

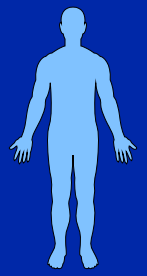


Cross-sectional Studies



- Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)
- It measures prevalence, not incidence of disease
- Example: community surveys
- Not suitable for studying rare or highly fatal diseases or a disease with short duration of expression

Cross-sectional studies



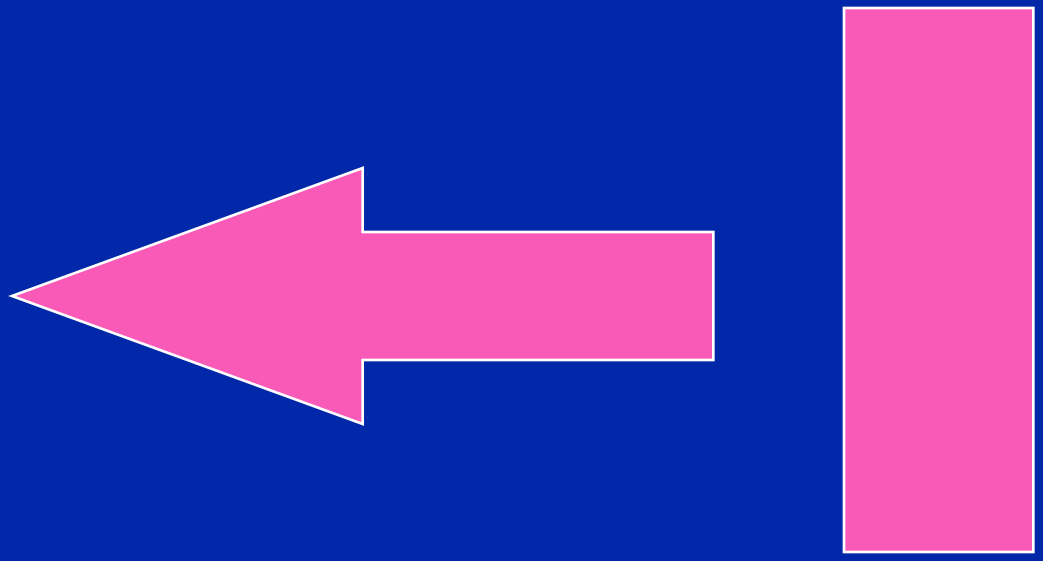
- **Disadvantages**
  - **Weakest observational design, (it measures prevalence, not incidence of disease). Prevalent cases are survivors**
  - **The temporal sequence of exposure and effect may be difficult or impossible to determine**
  - **Usually don't know when disease occurred**
  - **Rare events a problem. Quickly emerging diseases a problem**

Epidemiologic Study Designs

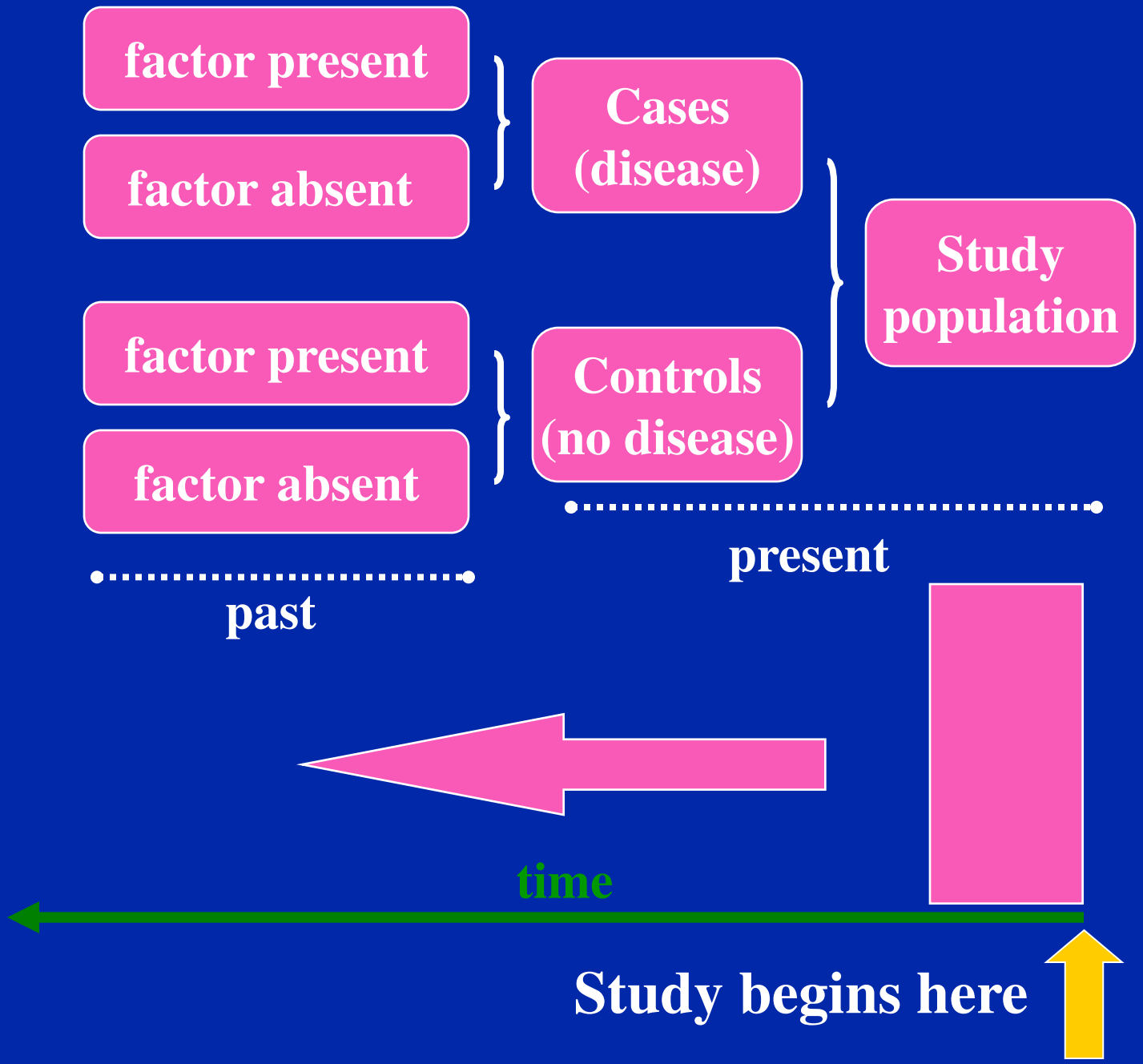
- Case-Control Studies
  - an "observational" design comparing exposures in disease cases vs. healthy controls from same population
  - exposure data collected retrospectively
  - most feasible design where disease outcomes are rare

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**

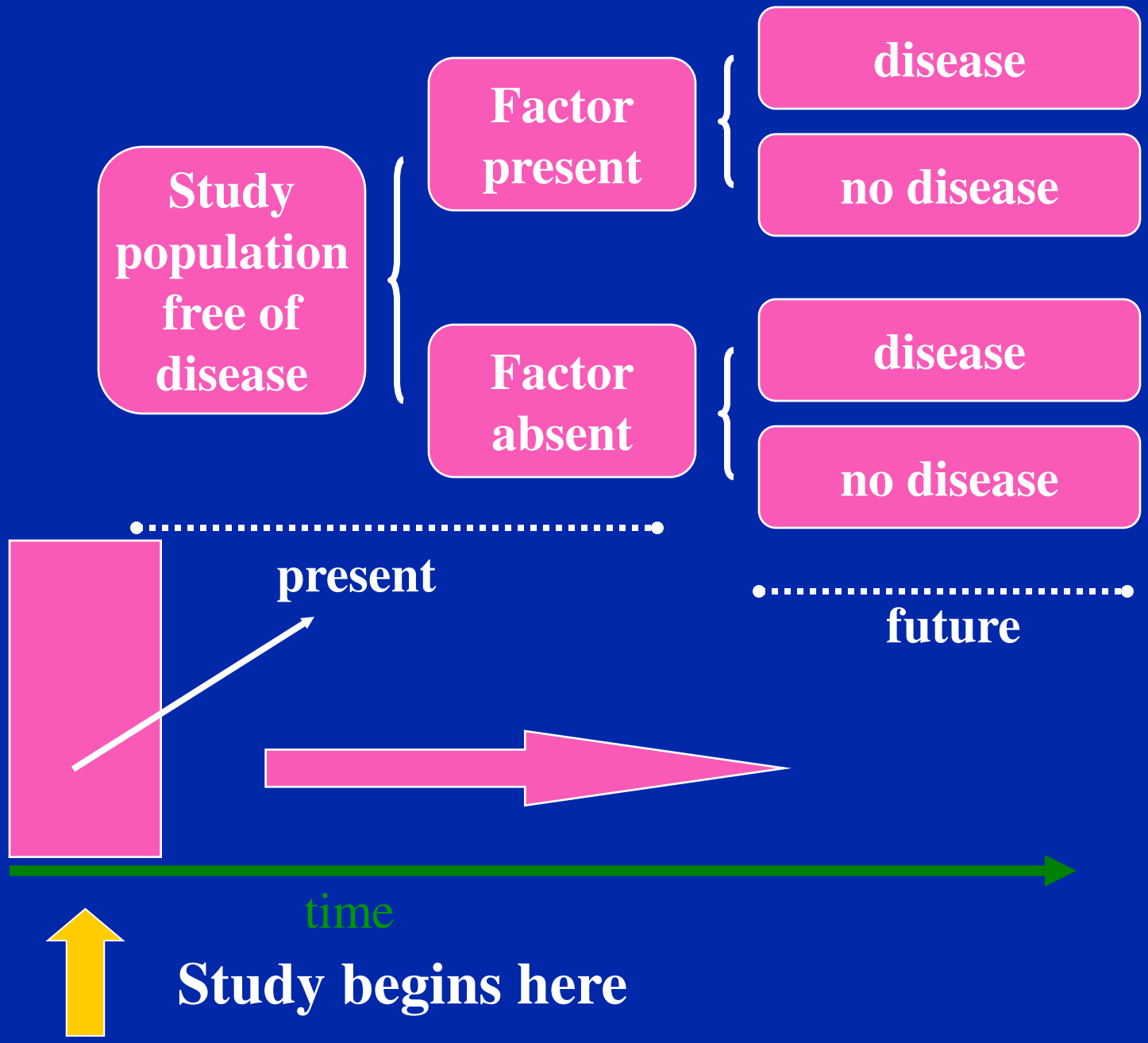
Hypothesis Testing: Case-Crossover Studies

- Study of “triggers” within an individual
- ”Case" and "control" component, but information of both components will come from the same individual
- ”Case component" = hazard period which is the time period right before the disease or event onset
- ”Control component" = control period which is a specified time interval other than the hazard period

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



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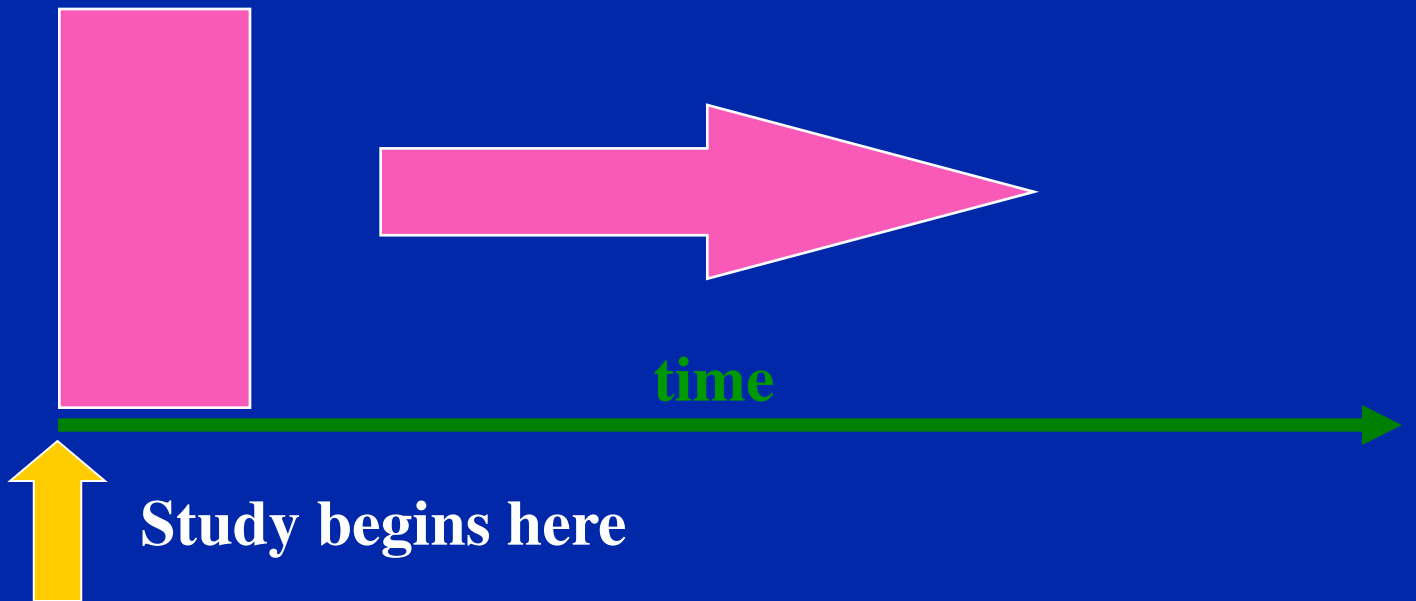
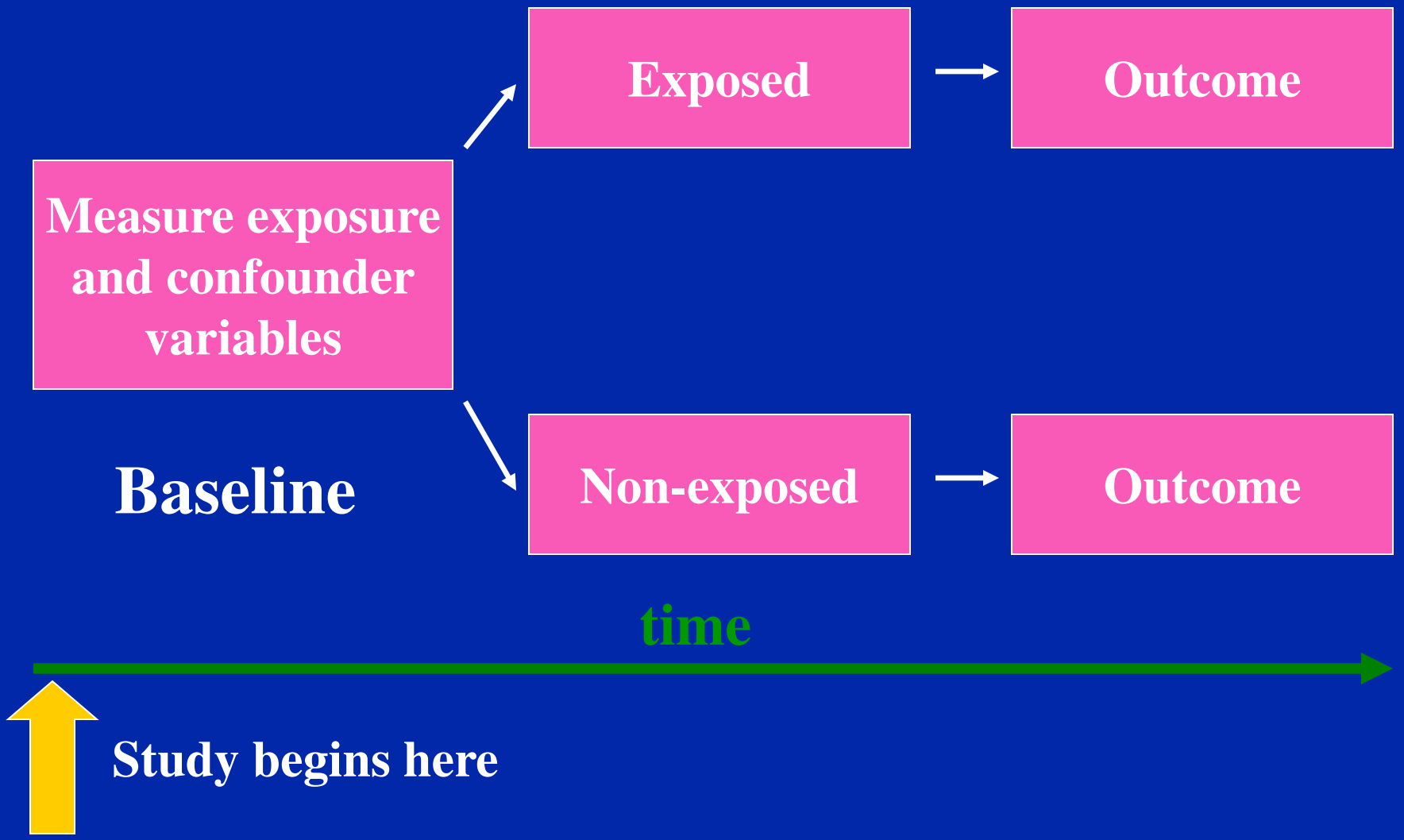


Prospective Cohort study



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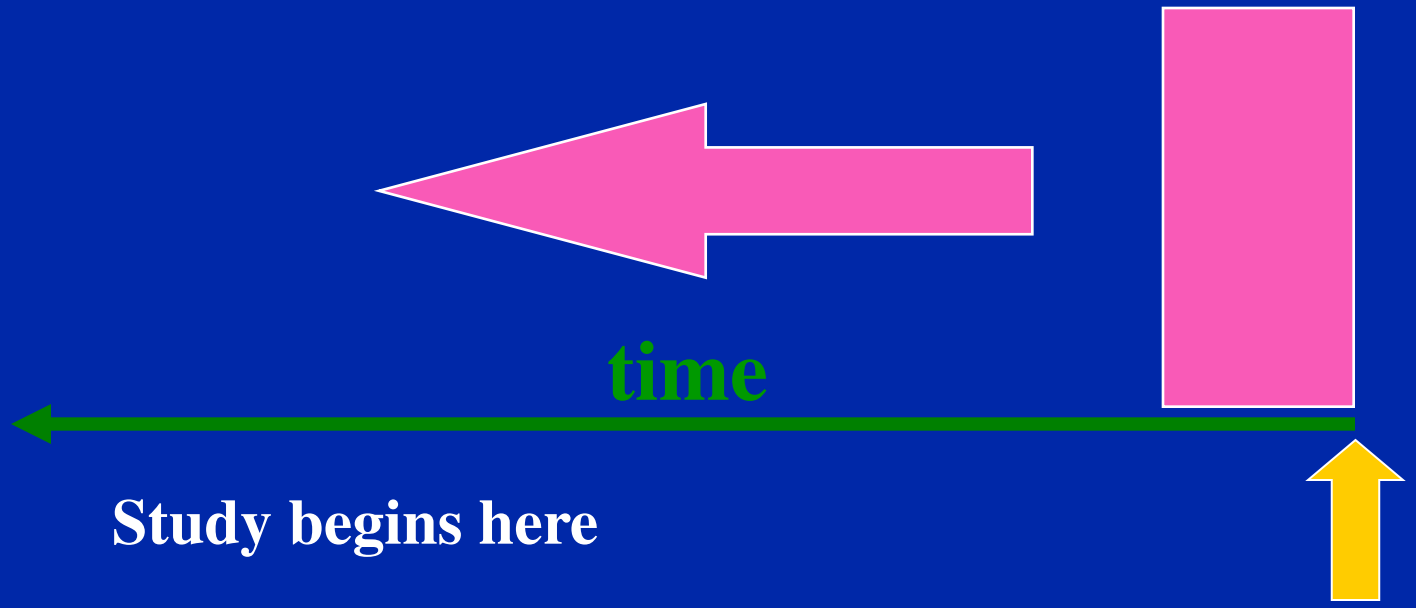
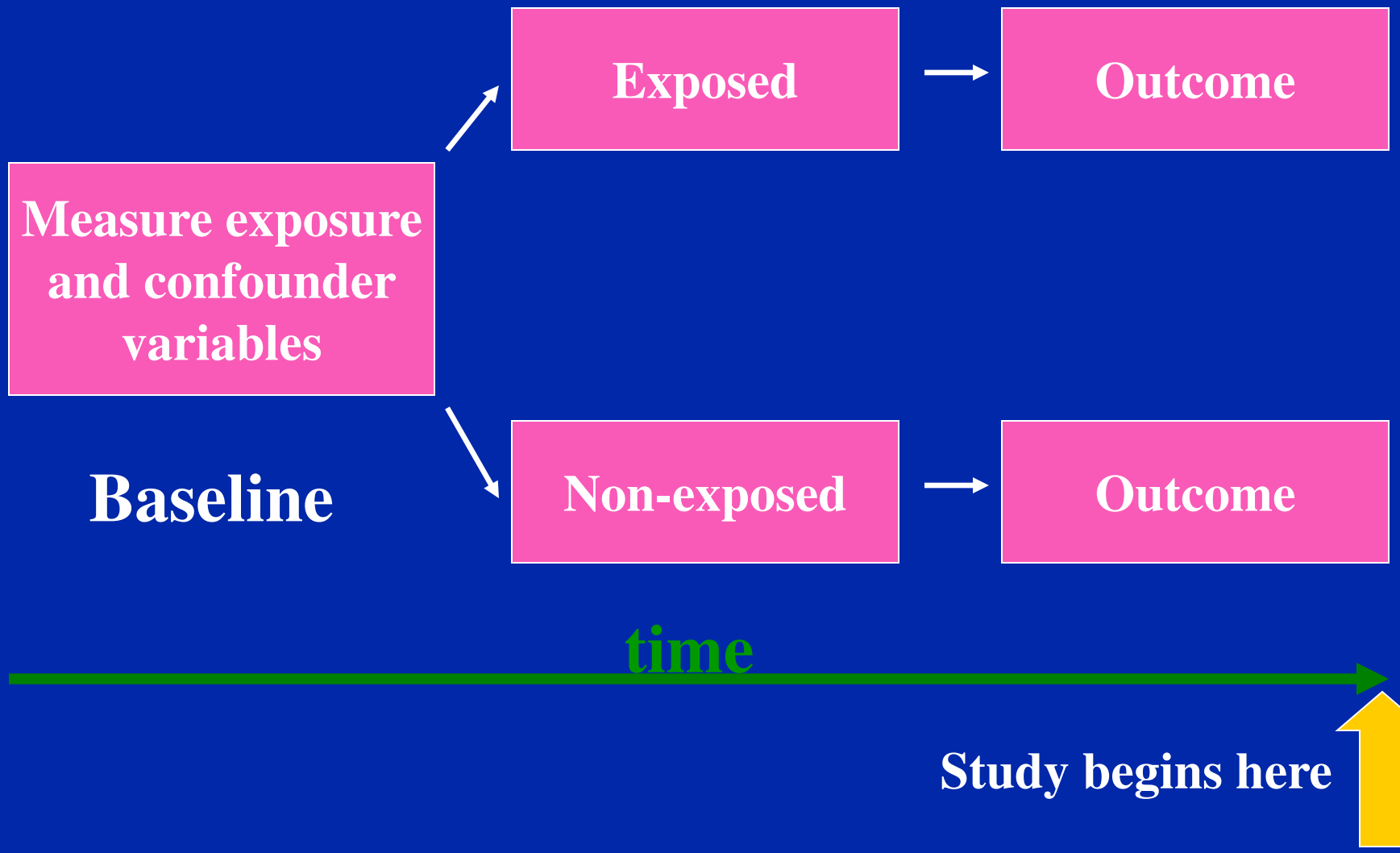


Retrospective Cohort study



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

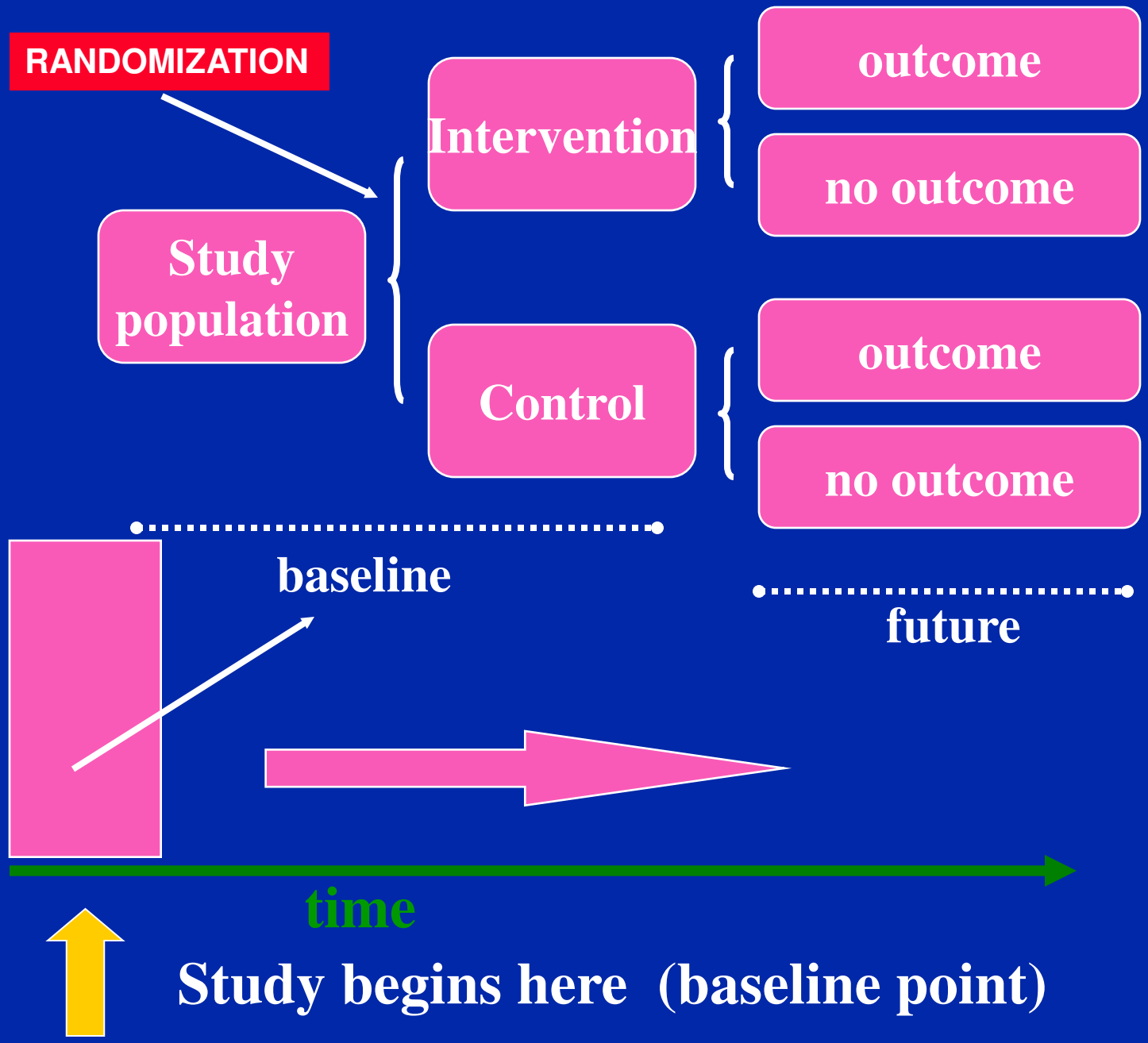
Experimental Studies

- 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



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**

Host, agent and environment model

1. **Host is:** A susceptible **human or animal** who harbors and nourishes a disease-causing agent

- Hosts' resistance depends on:
  - Age
  - Sex
  - Race
  - Genetic influence
  - People's response to stress
  - Lifestyle: diet, exercise, sleep patterns, healthy and unhealthy habits
- Concept of resistance is important in CHN practice مقاومة which can be promoted through preventive measures

Host, agent and environment model (continued)

2. **Agent is**: A factor that causes or contributes to a health problem or condition.

- Five types of agents:
  1. Biologic: Bacteria, viruses, fungi, protozoa, worms and insects. Infectious biologic agents such as influenza and HIV
  2. Chemical agents: liquids, solids, gases, dusts, fumes. Examples: poisonous sprays on garden pests, industrial wastes
  3. Nutrient agents: Too much or too little
  4. Physical agents: anything mechanical such as autmobile, rockslide, atm,ospheric ultraviolet radiation, geologic earthquakes, or genetically transmitted

Host, agent and environment model (continued)

- Agents can be classified as infectious or non-infectious
- Infectious agents cause **communicable** diseases (can spread from one person to another) such as TB or AIDS
- Characteristics of infectious agents important to understand for CHN
  1. Extent of exposure to the agent درجة التعرض
  2. The agent's pathogenicity (disease-causing ability) القدرة على احداث المرض
  3. Infectivity (invasive ability) القدرة على الانتشار
  4. Virulence (severity of disease) درجة الايذاء
  5. The infectious agent structure and chemical

Host, agent and environment model (continued)

- **Environment**: All external factors surrounding the host that might influence resistance.
- Physical environment:
  - Geography
  - Climate
  - Weather
  - Safety of buildings
  - Water and food supply
  - Presence of animals
  - Plants
  - Insects
  - Microorganisms (serve as reservoirs = storage

Host, agent and environment interact with each other to cause a disease or health condition

- **Concept of causality means trying to find a cause and effect relationship in epidemiology**
- **Chain of causation:**

1. **Identify reservoir: (where the causal agent can live and multiply)**
2. **Identify portal of exit from reservoir and mode of transmission**
3. **Identify agent itself**
4. **Identify portal of entry**

- **Multiple causation = web of causation includes the concept of association (smoking and cancer)**