Strengthening the Occupational Health Expertise and Scientific Performance of Public Health Institution of Turkey

Study protocol Workshop 3 : Methods
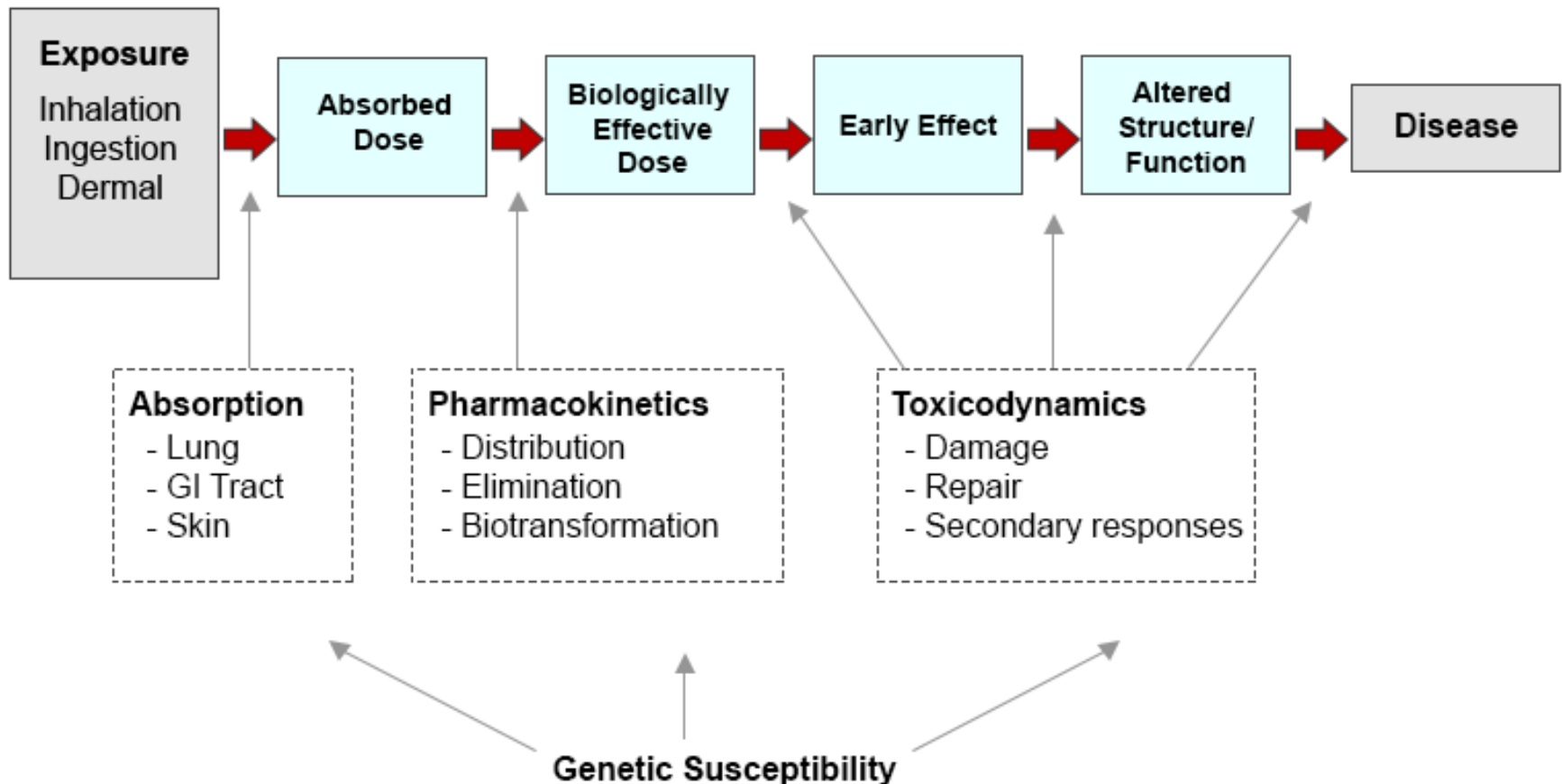
B 2.3.2 ppt Design of surveillance

Learning Objectives

1. You are able to select an appropriate study design
2. You are able to define your target population and study population
3. You can describe the different steps in the chain from exposure towards developing of disease and the appropriate monitoring methods

From Exposure towards Disease

Conceptual Model for Exposure-related Disease: Considerations for Biological Monitoring

Exposure
Inhalation
Ingestion
Dermal

➡ **Absorbed Dose** ➡ **Biologically Effective Dose** ➡ **Early Effect** ➡ **Altered Structure/ Function** ➡ **Disease**

Absorption
- Lung
- GI Tract
- Skin

Pharmacokinetics
- Distribution
- Elimination
- Biotransformation

Toxicodynamics
- Damage
- Repair
- Secondary responses

Genetic Susceptibility

From Exposure towards Disease

In Occupational Disease surveillance one usually looks back from disease to exposure. Difficulties in exposure characterisation

An alternative option is to follow exposed workers and look at their future health effects (cohort studies: expensive/ time consuming)

In the scheme the chain of events from exposure towards disease is shown and possibilities for biomonitoring and biologic effect monotoring methods can be demonstrated

# Example: Medical surveillance of (nano-) workers at risk

– Early detection of possible workplace-related adverse health effects.   'early warning system'

Provide a basis for later targeted evaluation of findings on group basis (epidemiology).

Complementory to toxicological risk assessment of substances

Identification a cohort of workers with relevant exposure to MNP problematic

Form of Post-marketing Surveilance as requested in pharmacovigilance
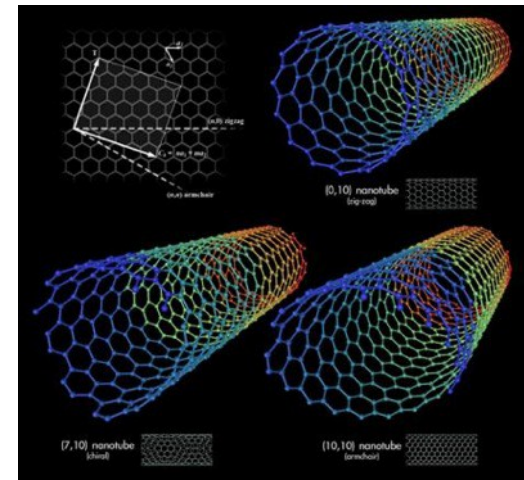
What is epidemiology?

Epidemiology is the science and practice that analyses the occurrence of **diseases** in different **groups** of persons and the **why**.

Epidemiologists are the detectives of the diseases

Epidemiology
-Formal definition-

Epidemiologists study

- Factors that have an influence on **health:**
  - The start of a **disease**
  - The diagnosis
  - The prognosis (course)
  - The consequences
- **Prevention and treatment** e.g. effectiveness of interventions

Two types of epidemiological studies

Observational study

e.g. risk on ebola for health care workers in a region in a certain period of time

Intervention study

e.g. evaluation of effectiveness of specific guidelines (plus PPE, instruction and supervision).

Designs of a descriptive study

Cross-sectional study

Case-control study

Cohort study

Case study

Qualitative study

Can you give a definition and an example?

Cross-sectional study

- Not taking into account *time course*
- Exposure and prevalence of disease measured at same time
- Useful
  - first information about **association** between exposure and disease
  - for development of surveillance programs
- Not permitted to conclude that the exposure preceded the disease or vice versa. What came first : the egg or the chicken?
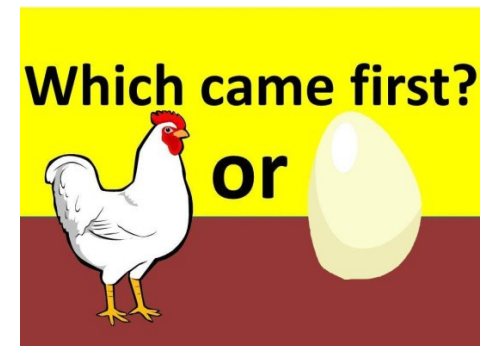
Cross-sectional study: advantages

- Easy to complete
- Quick, cheap („a bargain")
- First impression of the problem
- You can study various diseases/health complaints and exposure at once
- Adequate for chronic diseases that are not fatal such as allergies, asthma, COPD, chronic low back pain, chronic stress complaints

Cross-sectional study: advantages

- Not useful for rare diseases

- Not useful for diseases with a short duration

- Not appropriate for causal investigations

- But you can find an association and check this in a new or existing other studies

- Take care of information bias and selection bias

Methods for Tracing New Occupational Diseases (Signal Detection)

- Reports from physicians (cases, clusters)

- Notification by Workers

- Periodic literature screening

- Data mining in relevant data-bases

- Linking data-bases

- Active medical surveillance (synthetic nano particles)

- Secundary analysis of patient data
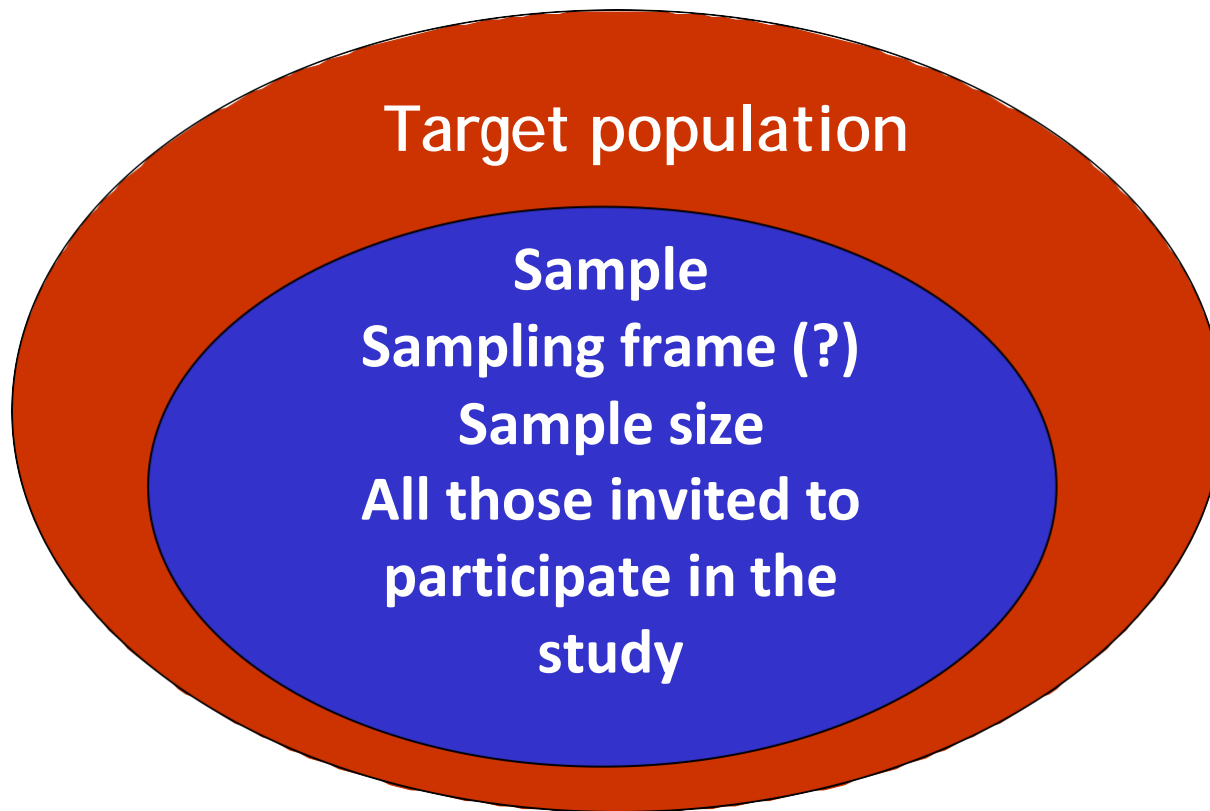
Studies should reflect the real situation

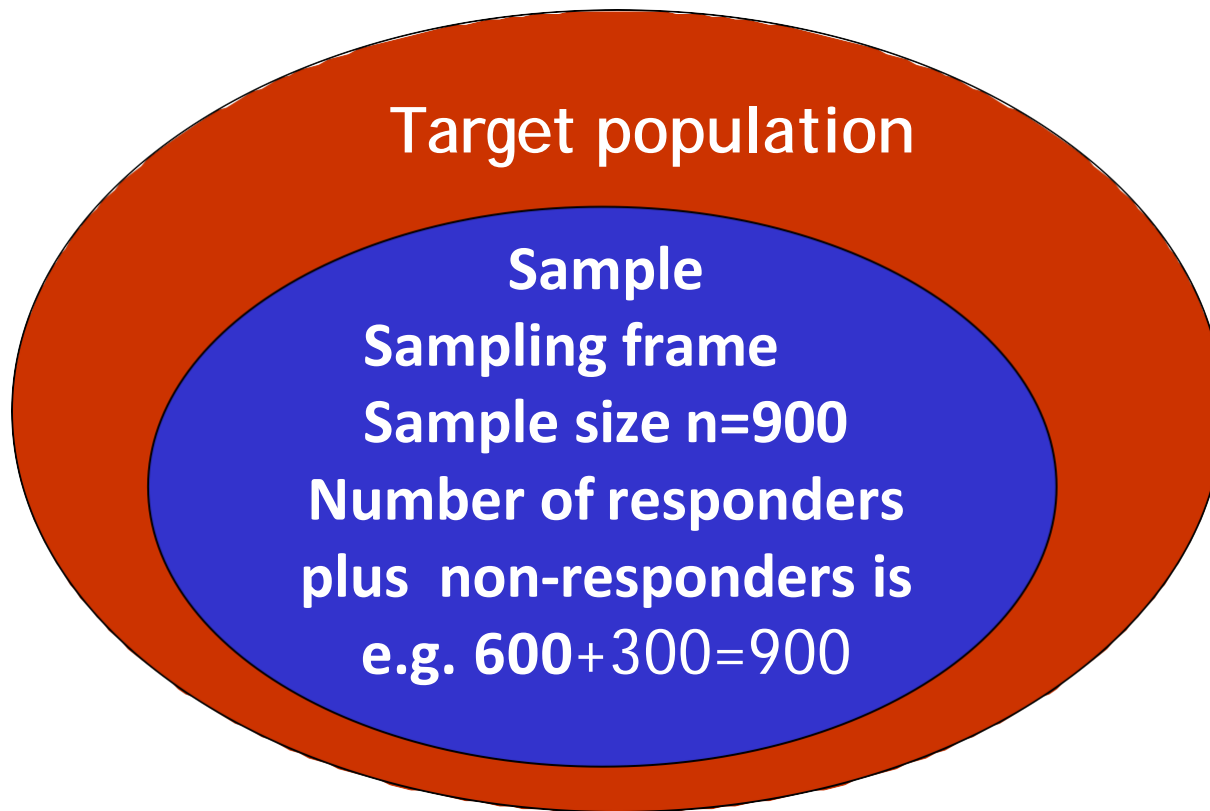# Target population and Study population

Target population

Population that is the study object

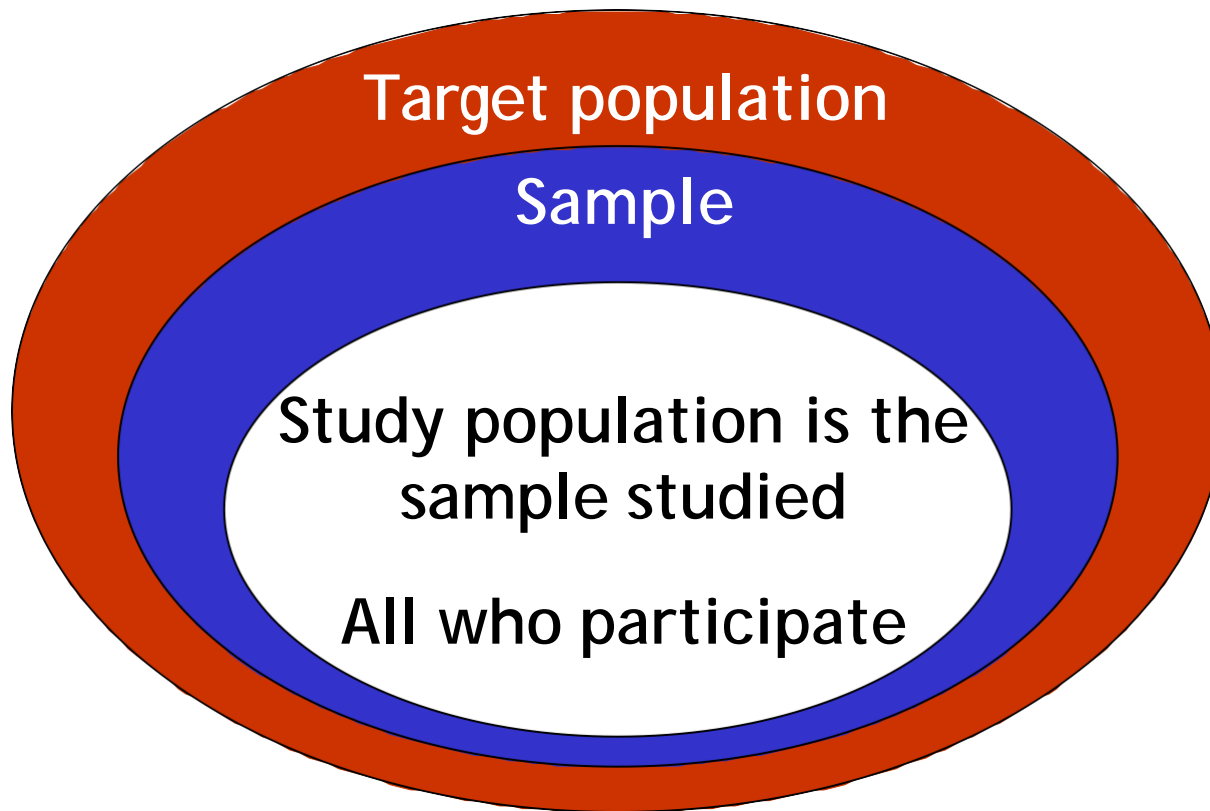All workers/patients that the researcher is interested in

Target population and Study population

Target population

Sample
Sampling frame (?)
Sample size
All those invited to participate in the study

Target population and Study population

Target population

Sample
Sampling frame
Sample size n=900
Number of responders
plus non-responders is
e.g. 600+300=900

Target population and Study population

Target population

Sample

Study population is the sample studied

All who participate

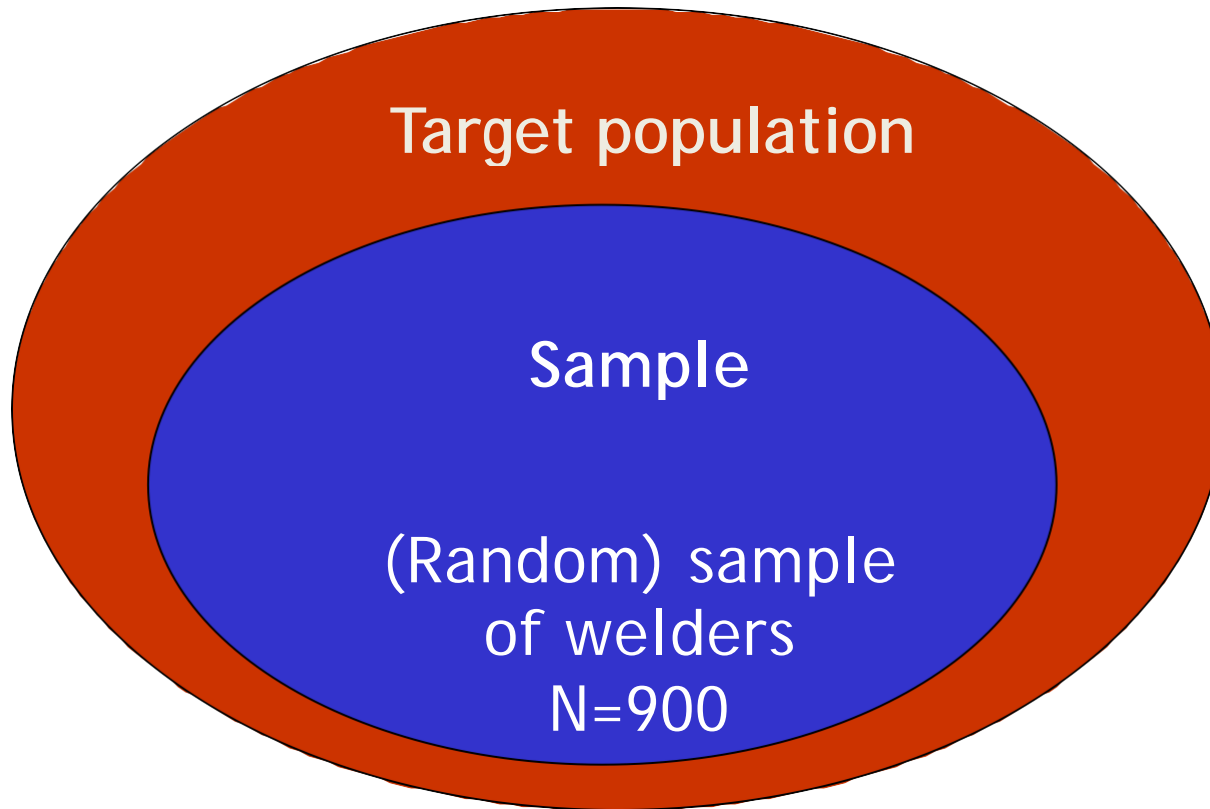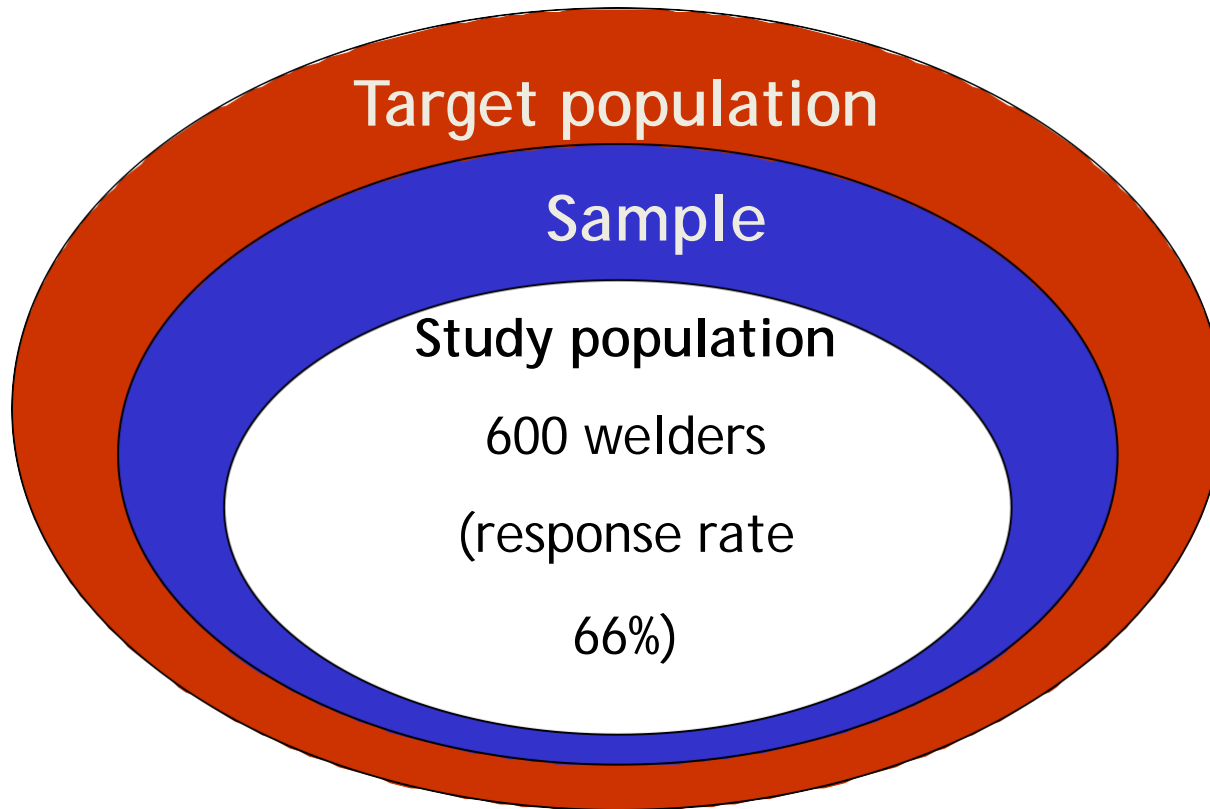# Example:
Health effects in welders in Turkish metal industry

Target population

All welders in Turkish metal industry:
formal and informal workers

Target population and Study population

Target population

Sample

(Random) sample
of welders
N=900

Target population and Study population

Validity of a study

Internal validity

      The association found reflects in a reliable way the association between exposure and disease in the study population

      Sources for errrors (bias):

            Selection bias, information bias, confounder bias

External validity

      The association found is correct for the target population. A related term is representativeness. It is important to select an appropriate sample!

Your target population
- Examples -

- All workers in the informal sector, working for hotels and restaurants in Antalya.

- All outsourced (subcontractor) workers in a large company.

- All patients at the respiratory diseases department in the main hospital in one city in 2017.

- All patients diagnosed with mesothelioma in a Occupational Diseases hospital or included in a national mesothemioma register in 2007-2016.

Your protocol

- Describe briefly (½ -1 page) your
    - Methods
    - Target population,
    - Your sample,
    - Your study population.
- Explain why you have decided to study this target population.
- Explain why you decided to select this sample, how to approach the population, what to do to increase the response.

For more details: see the Manual.

Workshop 3

Work in small groups:

- Develop a study strategy
- Define the methods, target and study population