Study Types
Experimental

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Observational Study

- A non-interventional study is a study in the context of which knowledge from the treatment of person with drug in accordance with instruction for use specified in their registries is analyzed using epidemiological methods. The diagnosis, treatment and monitoring are not performed according to a previously specified study protocol, but exclusively according to medical practice.
- Source: Medicinal Products Act (The Drug Law) Federal Republic of Germany

Clinical Trial

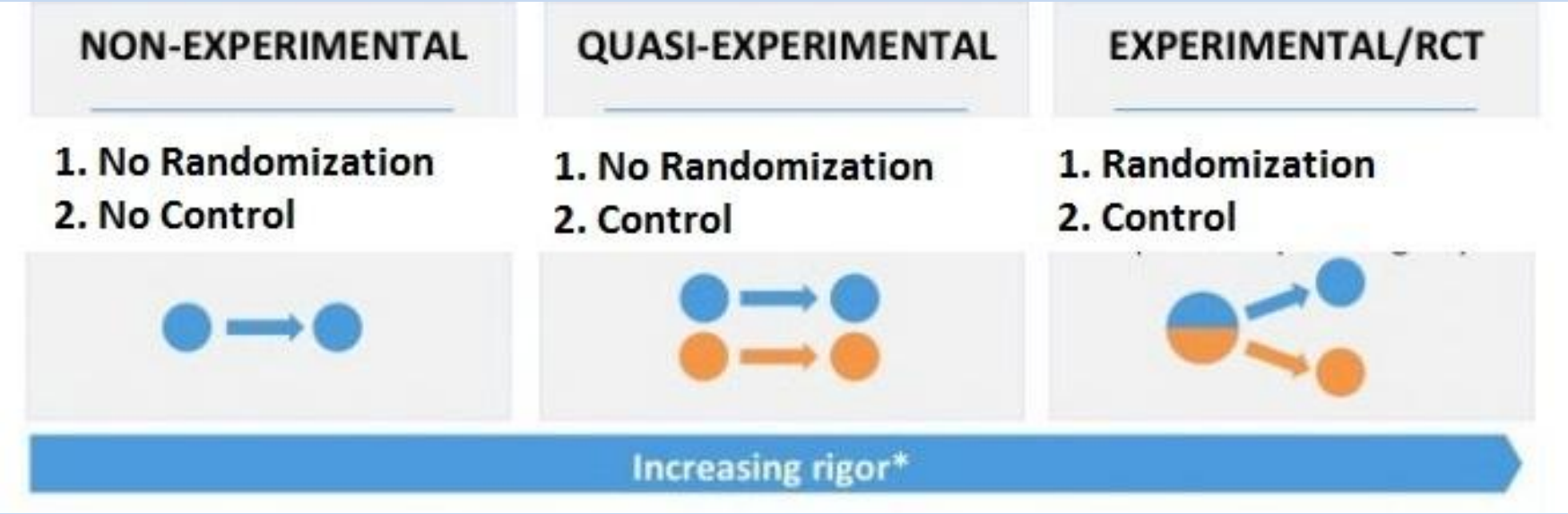
- “Any study performed on human with purpose of studying or demonstrating the clinical or pharmacological effects of drugs, to establish side effects, or to investigate absorption, distribution, metabolism or elimination with the aim of providing clear evidence of the efficacy or safety of the drug.”
- Source: Medicinal Products Act (The Drug Law)
  Federal Republic of Germany

Clinical Trial - Objectives

- To provide scientific proof of etiological (or risk) factors which may permit the modification or control of disease.
- To provide a method of measuring the effectiveness and efficacy of health product or services for the prevention, control and treatment of diseases and improve the health of the community.

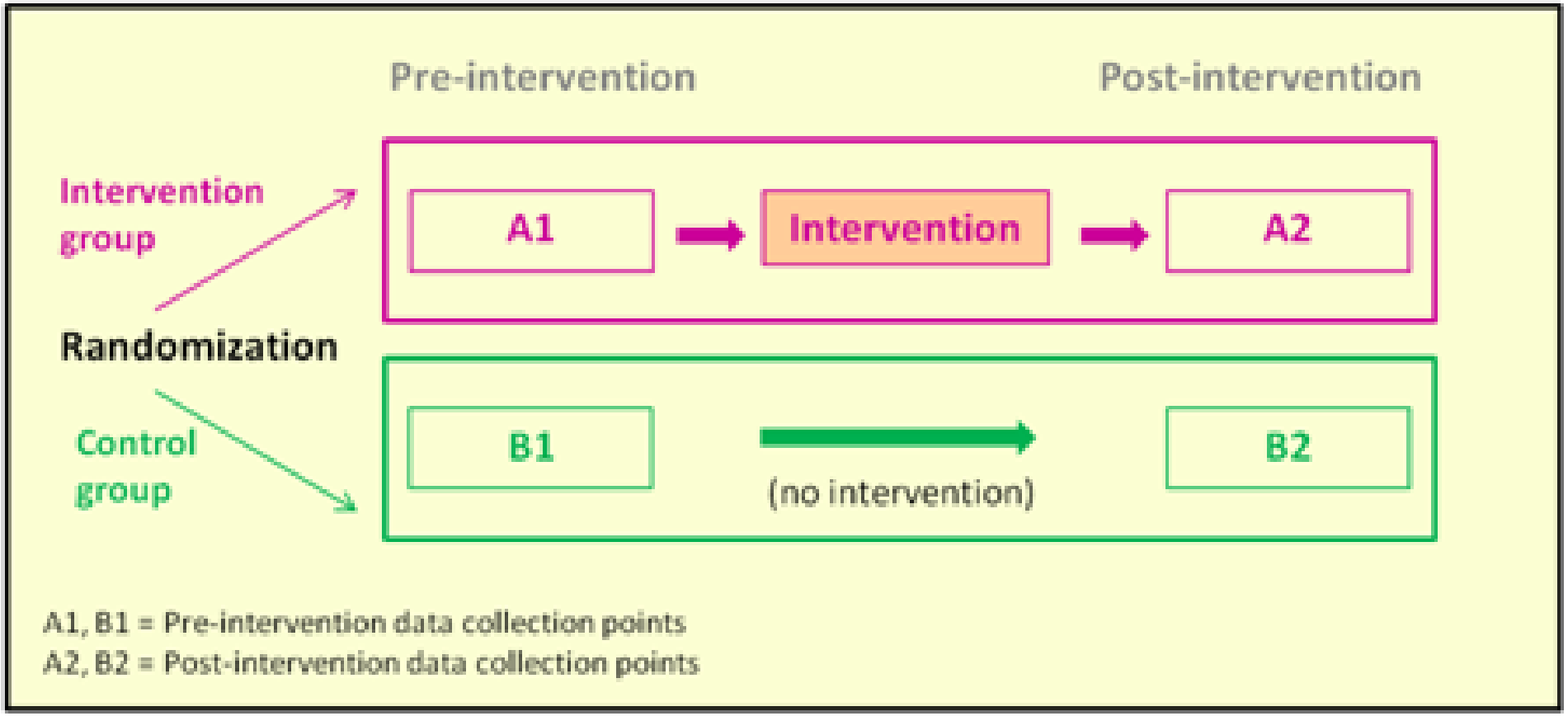
Experimental Study Design

- Randomization
- Control



Randomized Control Trial

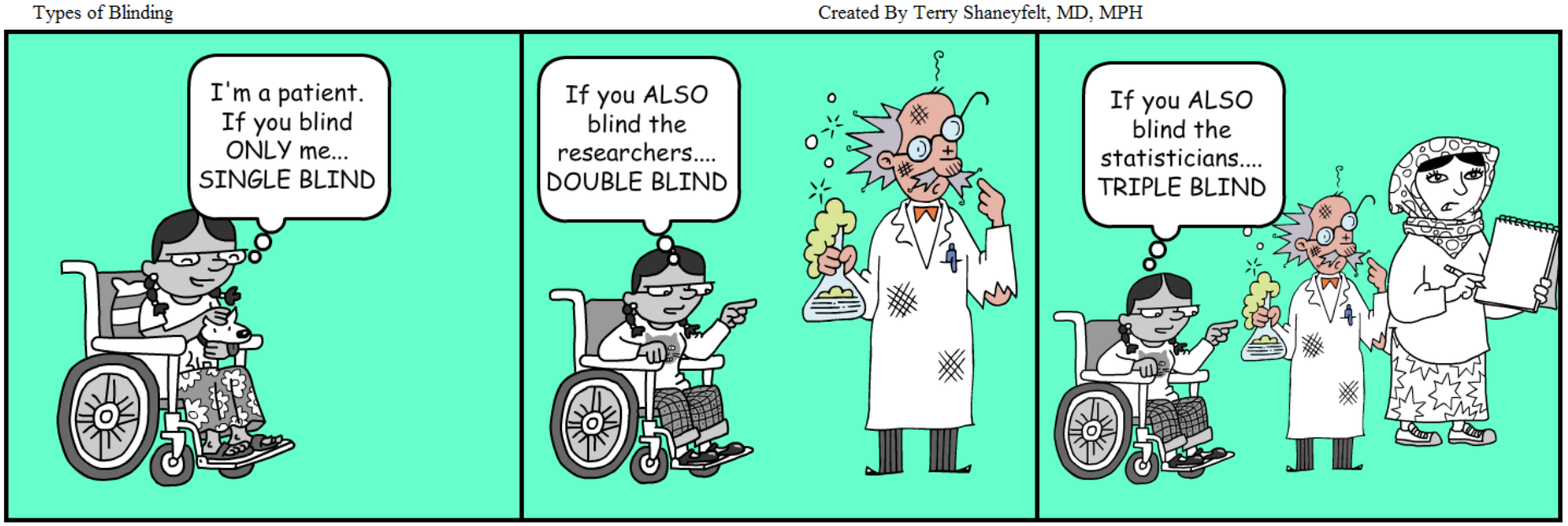
Classical Design of Randomized Experiments



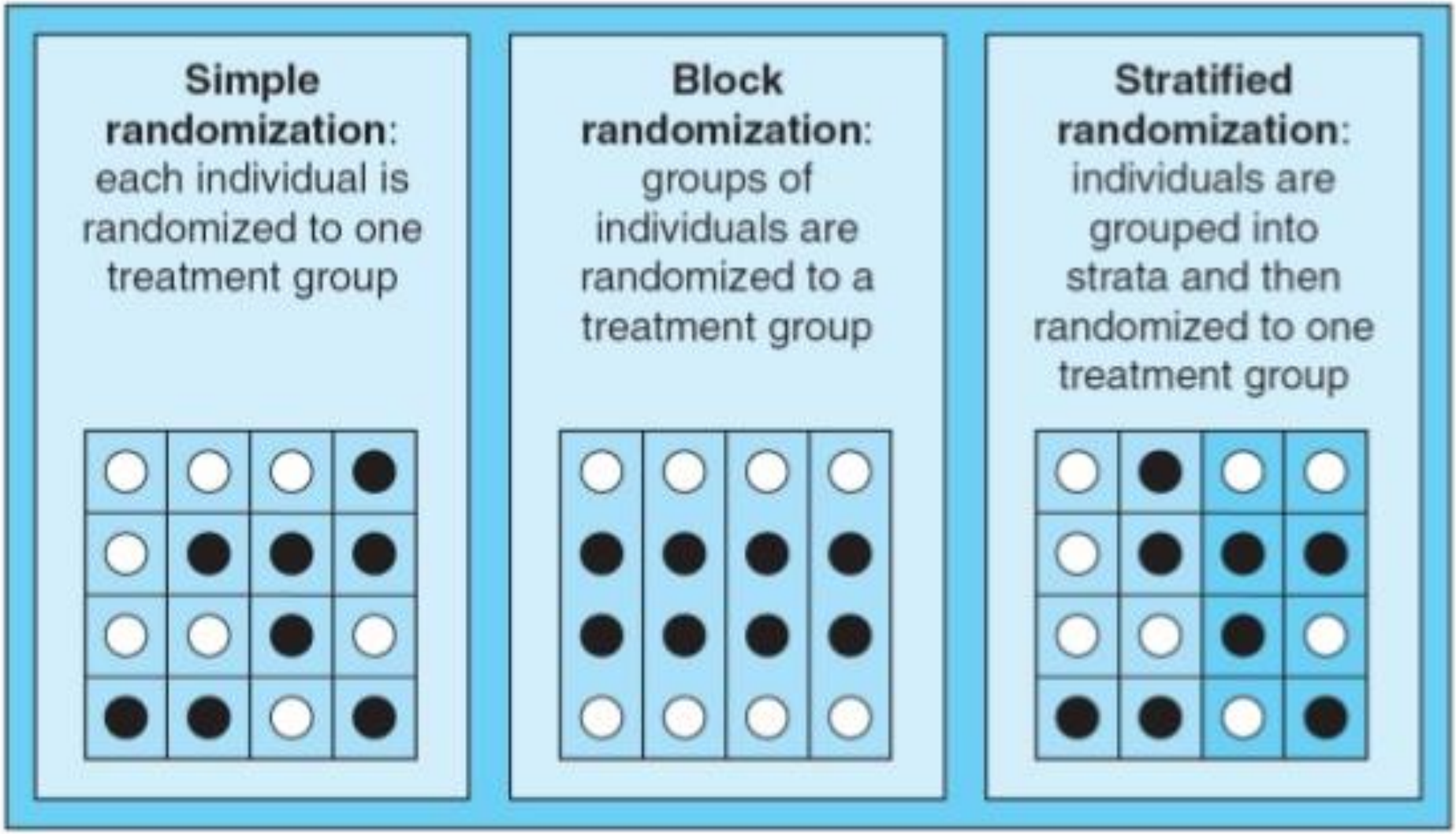
Clinical Trial - Types

Purpose	Study Design	Control	Interest	Hypothesis	Blinding
Pre-clinical	Parallel Arm	Controlled	Efficacy	Superiority	Open
Clinical	Crossover	Uncontrolled	Effectiveness	Non-inferiority	Blind
Field	Factorial			Equivalence	

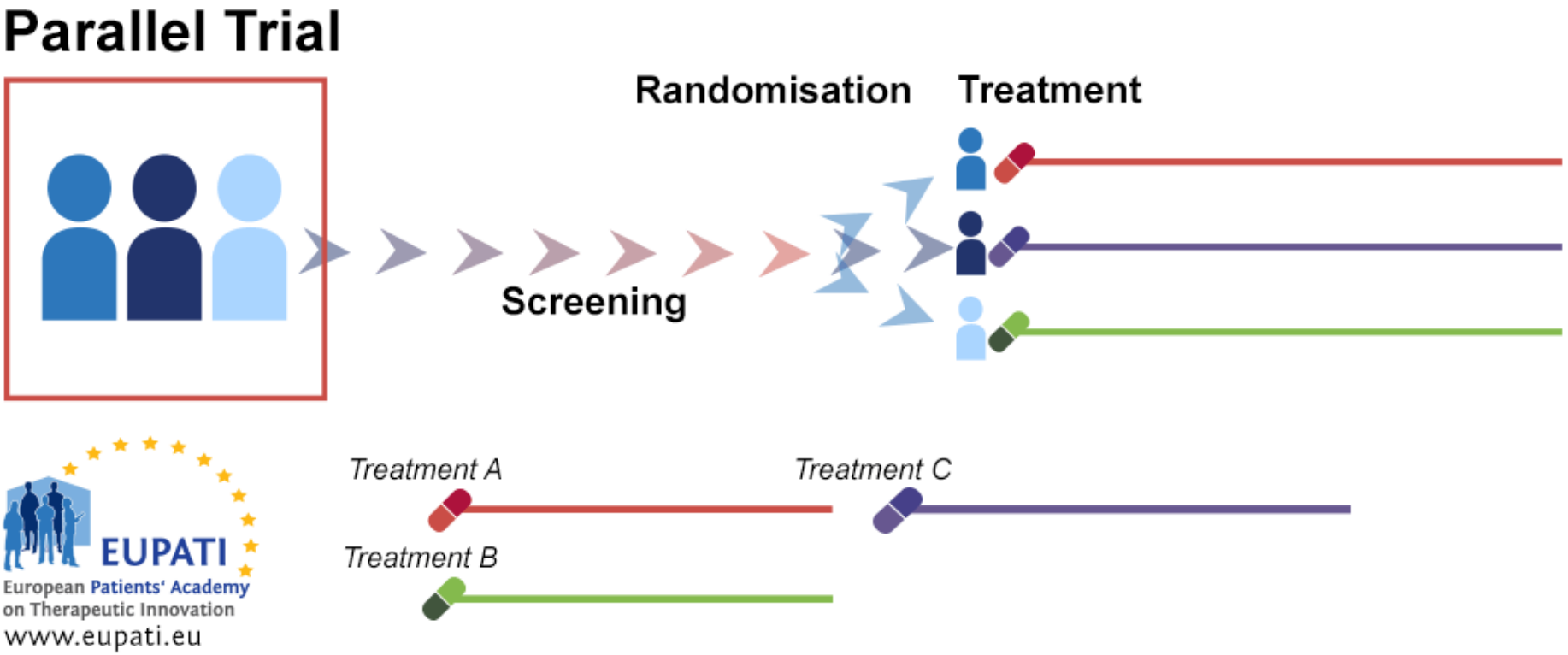
Clinical Trial - Blinding



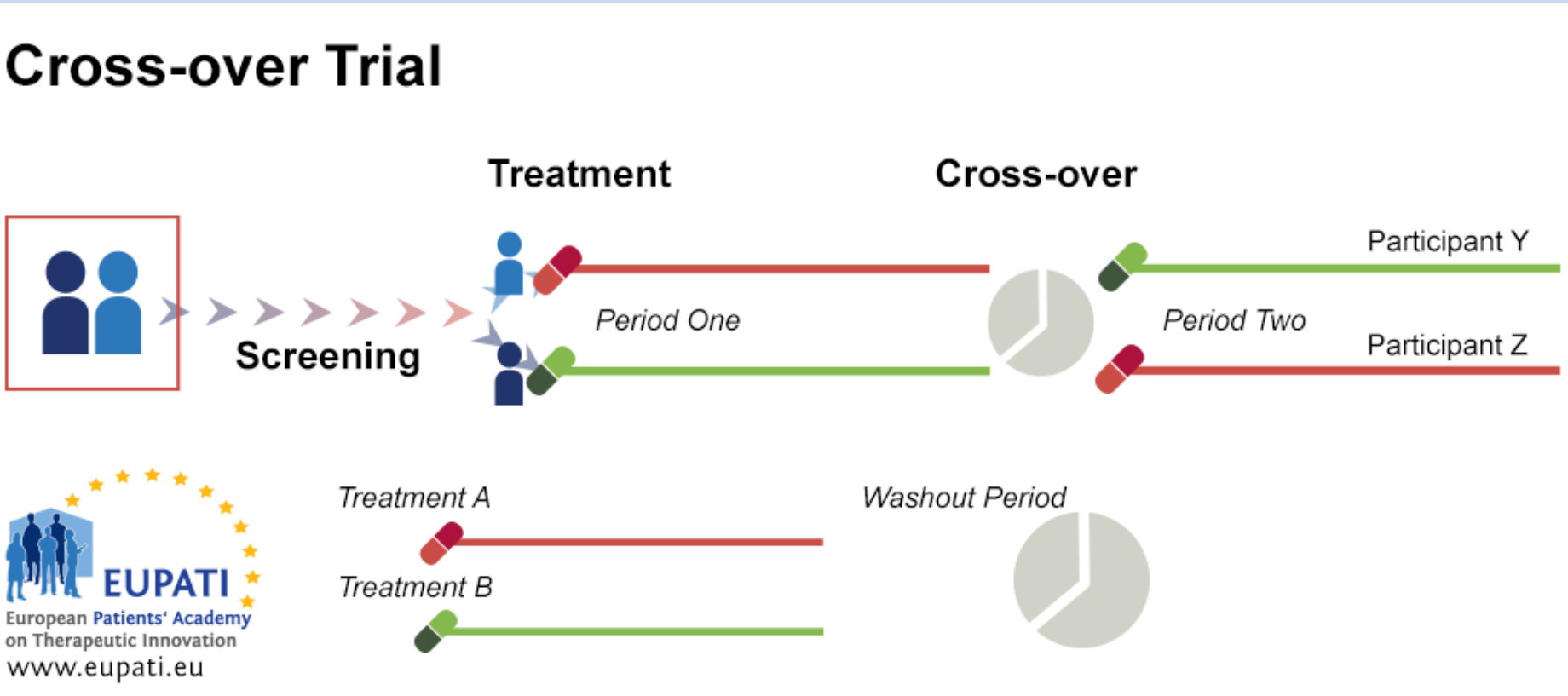
Randomization



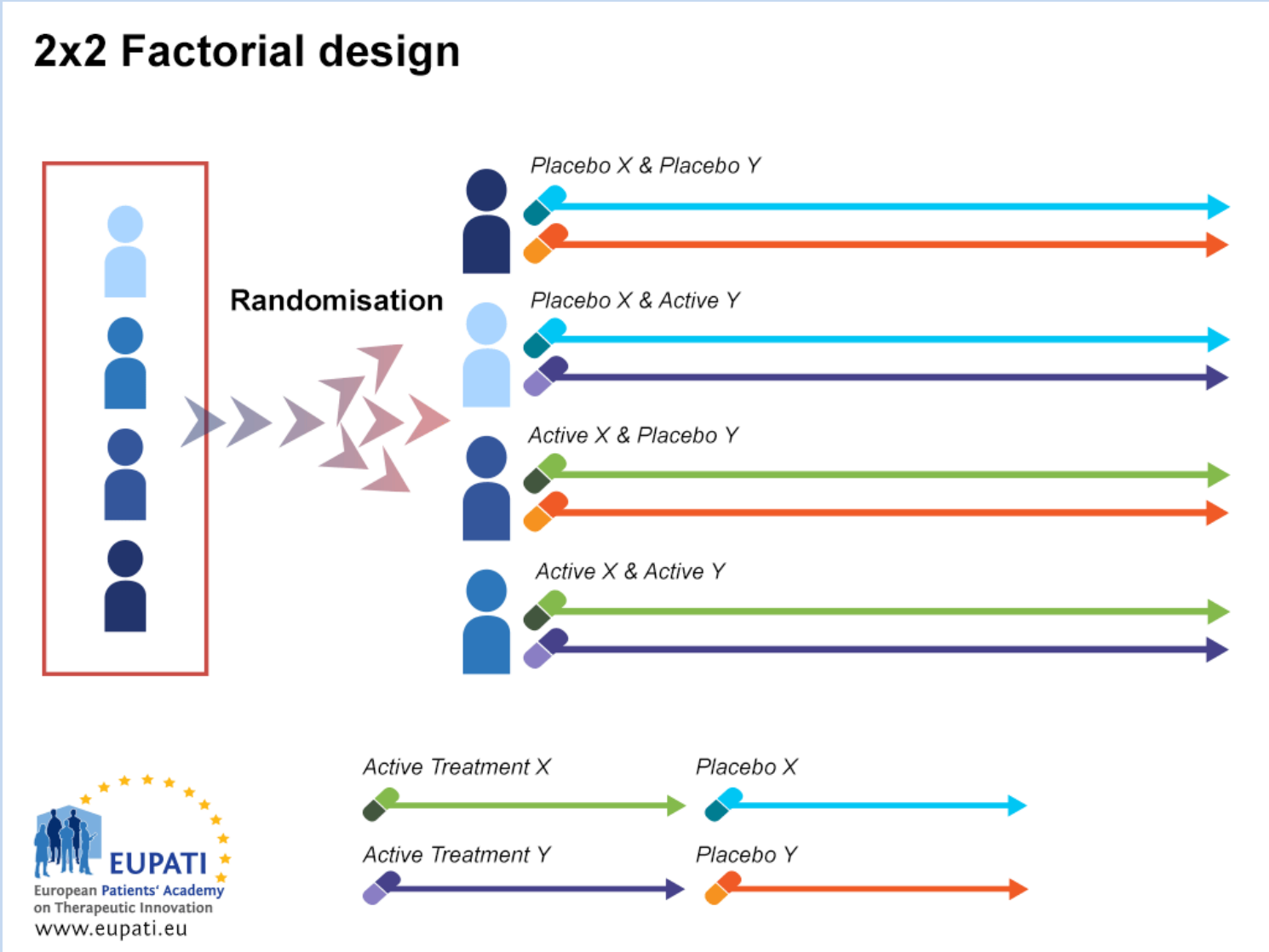
Parallel Trial



Cross-over Trial



Factorial Design

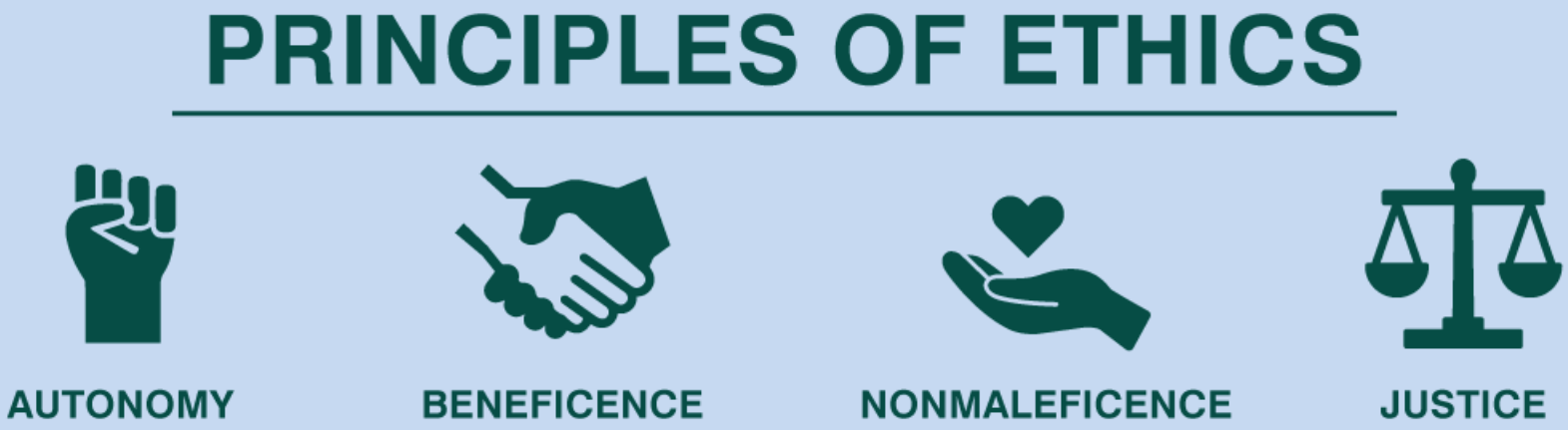


Clinical Trial - Phases

Advantages & Disadvantages

Advantages	Disadvantages
Assess Causality	Volunteer Bias
Control Bias	Ethical Considerations
Control Variables	Patient Recruitment
Robust Statistical Analysis	Costly & Time Consuming
	Hawthorne Effect

Medical Ethics



Hawthorne Effect

People will act differently if they know they are being Observed. Its also known as ***Observer effect***.

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- **Registration of clinical trials:**
- “Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Regulated vs Non-Regulated Clinical Trials / Interventions

- **Regulated**:
- Drugs
- Biologics
- Devices.

- **Non-Regulated**
- Diets
- Exercise programmes
- Physiotherapy
- Surgical procedures
- Behavioural interventions,
- Complementary medicine.

Non-Regulated Drugs

- Unregulated products do not claim to cure any particular disease or ailment
- They are not subjected to the rigorous clinical processes to prove their effectiveness and safety.
- Their labels will not make any specific claim of benefit, but instead use general terms like 'may be helpful in', health aid, or 'has been used in', and may list a number of general health conditions.

Clinical Research