Randomized Controlled Trial (RCT)

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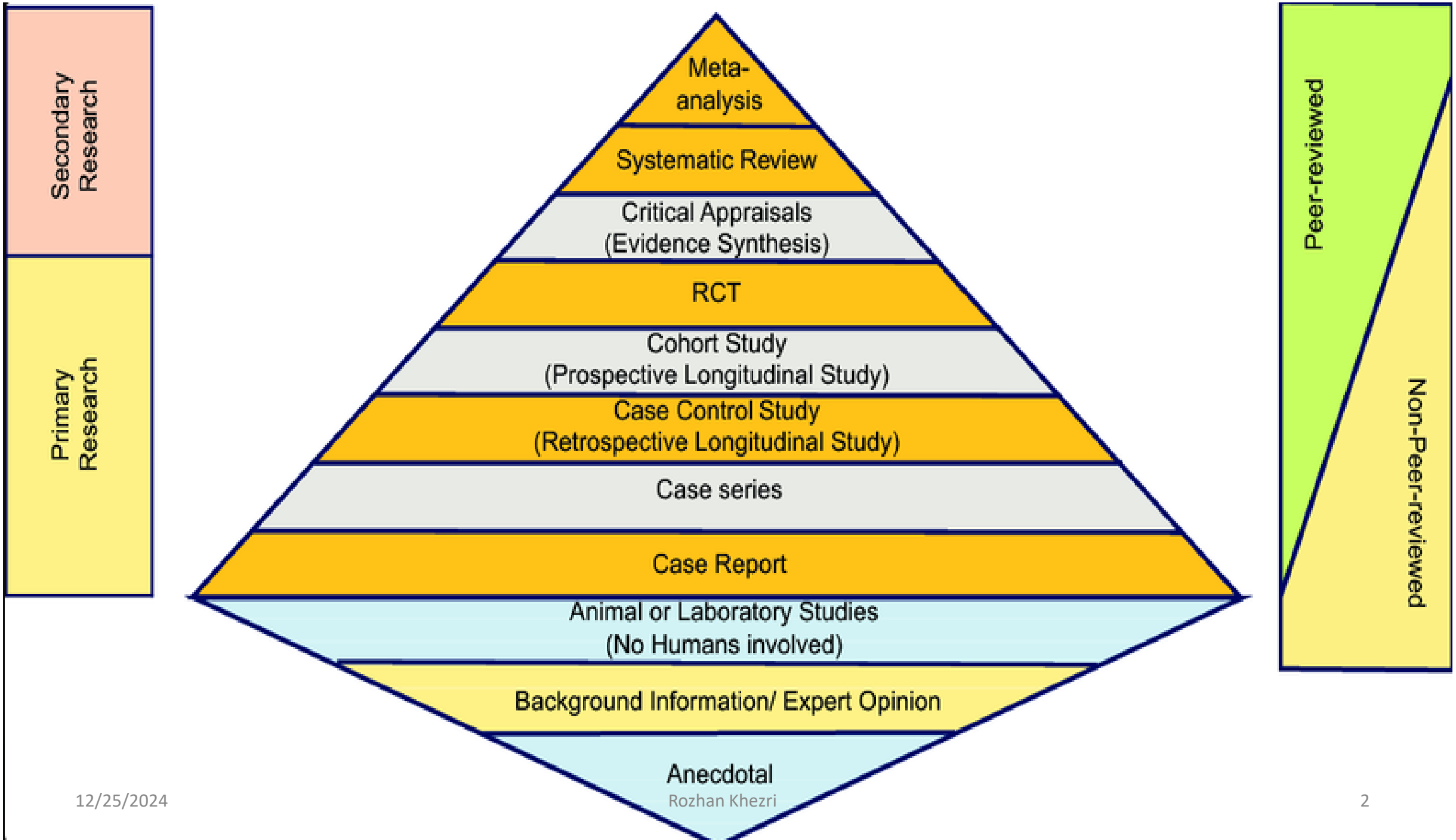

Secondary Research
Primary Research
Meta-analysis
Systematic Review
Critical Appraisals (Evidence Synthesis)
RCT
Cohort Study (Prospective Longitudinal Study)
Case Control Study (Retrospective Longitudinal Study)
Case series
Case Report
Animal or Laboratory Studies (No Humans involved)
Background Information/ Expert Opinion
Anecdotal
Peer-reviewed
Non-Peer-reviewed

Trials

- Randomised Control Studies
- Non-randomised concurrent control studies
- Historical control / databases
- Crossover designs
- Withdrawal studies
- Factorial designs
- Group Allocation designs
- Hybrid designs
- Large Simple Clinical Trials

What is a clinical trial

- **Prospective**
- **Intervention**
- **Control**
- **Studies on human beings**

Clinical Equipoise

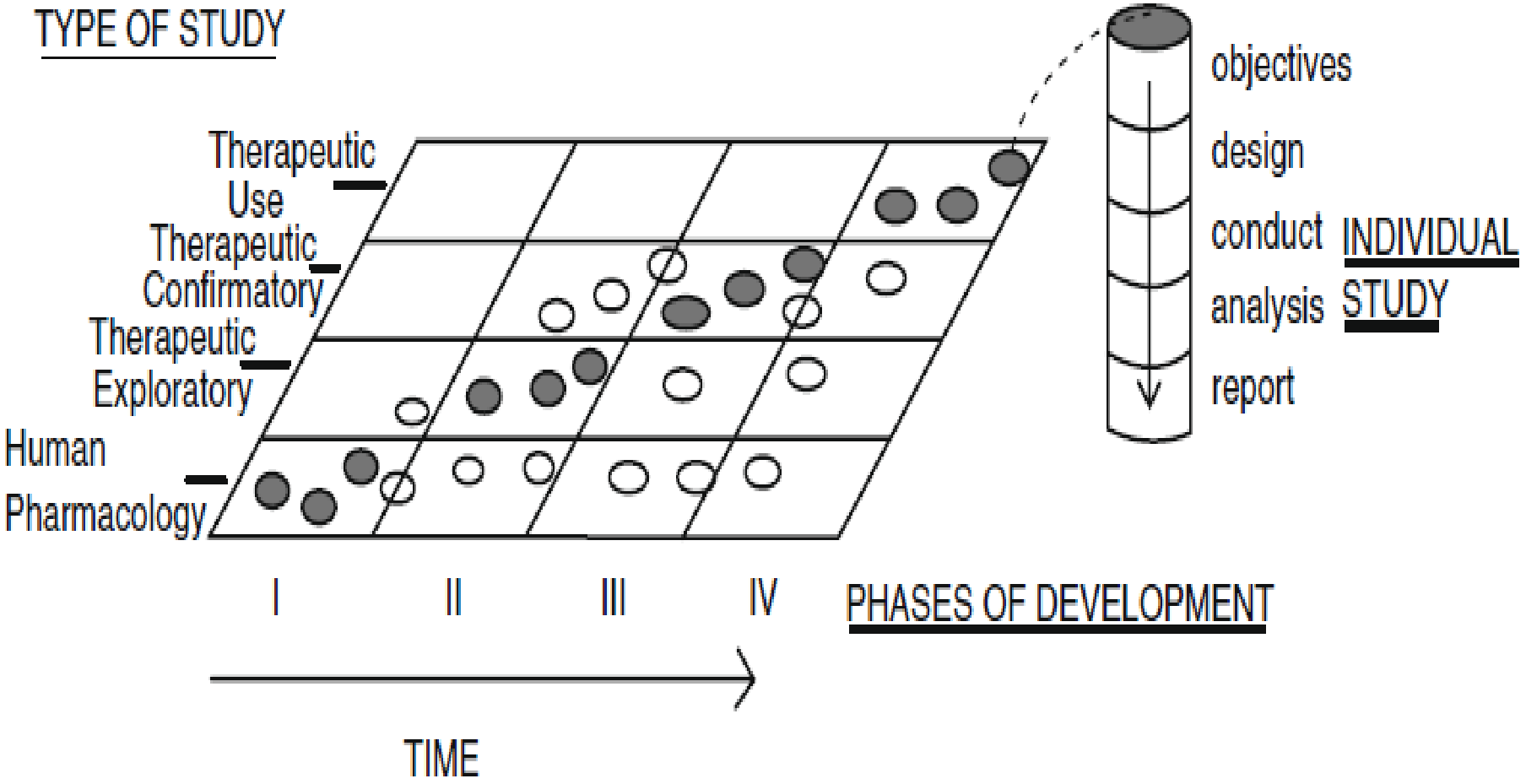
What is a clinical trial

Early phase studies may be controlled or uncontrolled. Although common terminology refers to phase I and phase II trials, because they are sometimes uncontrolled, we will refer to them as clinical studies.

What is a clinical trial

These may be single or combinations of diagnostic, preventive, or therapeutic drugs, biologics, devices, regimens, procedures, or educational approaches.

PHASES OF DEVELOPMENT

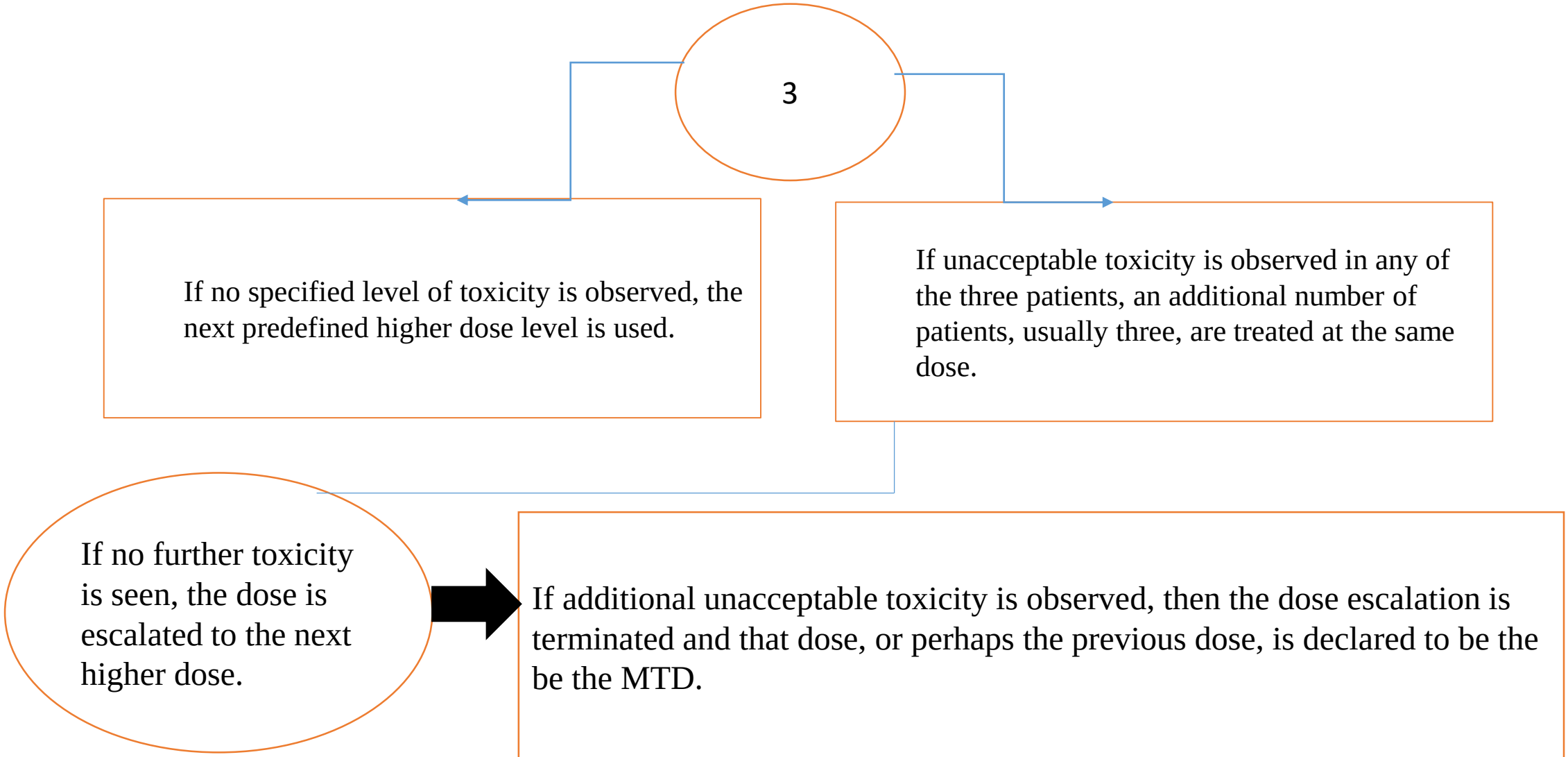


Phase I trial

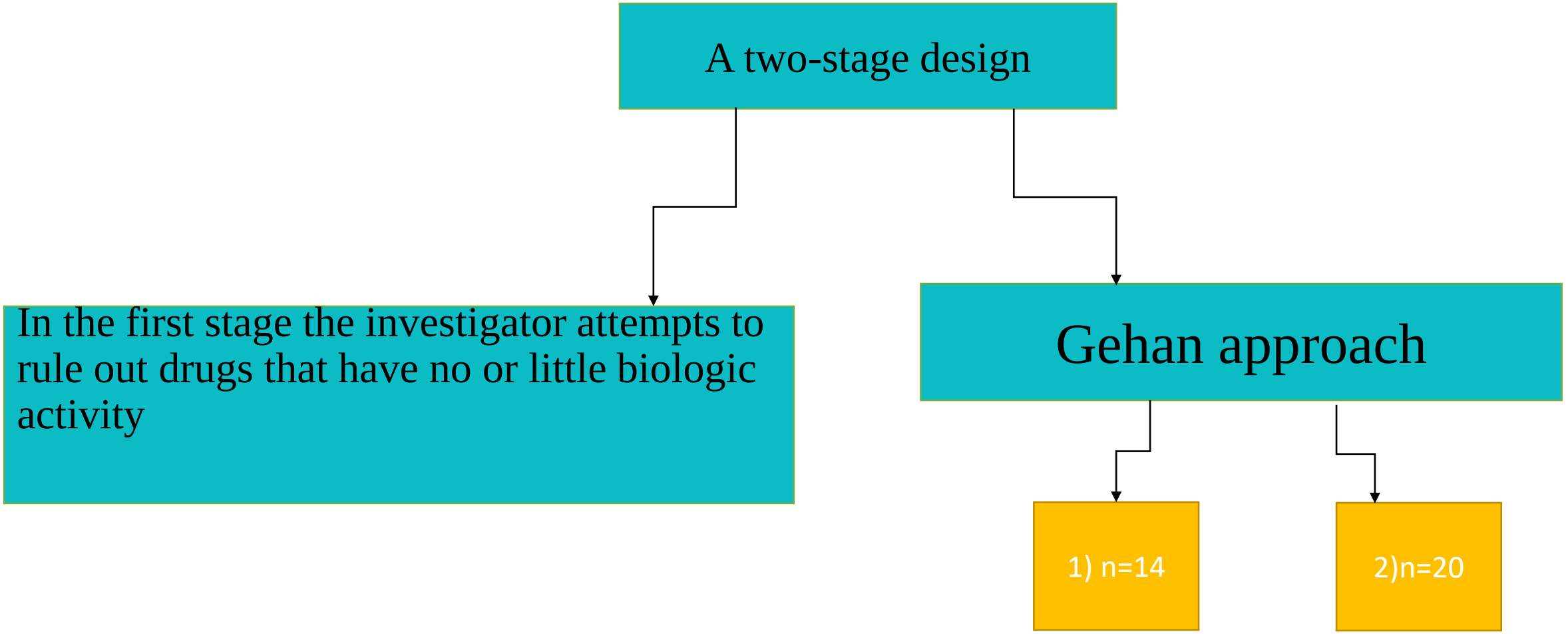
Maximally Tolerated Dose, **(MTD):** how large a dose can be given before unacceptable toxicity is experienced by patients

DLT (Dose Limiting Toxicity)=1/3 unacceptable toxicity

Phase I trial



Phase II trials



Phase III trials

- Safety
- Efficacy
- Therapeutic confirmatory

Phase IV

- Chronic Conditions
- Long-term Safety

Phase III trials= RCT

Enrollment of participants

- Informed consent
- Assessment of eligibility
- Baseline examination
- Intervention allocation (e.g., Randomization method)

Randomisation

Fixed Allocation Randomisation

- Simple randomisation
- Blocked randomisation
- Stratified randomisation

Simple Randomisation

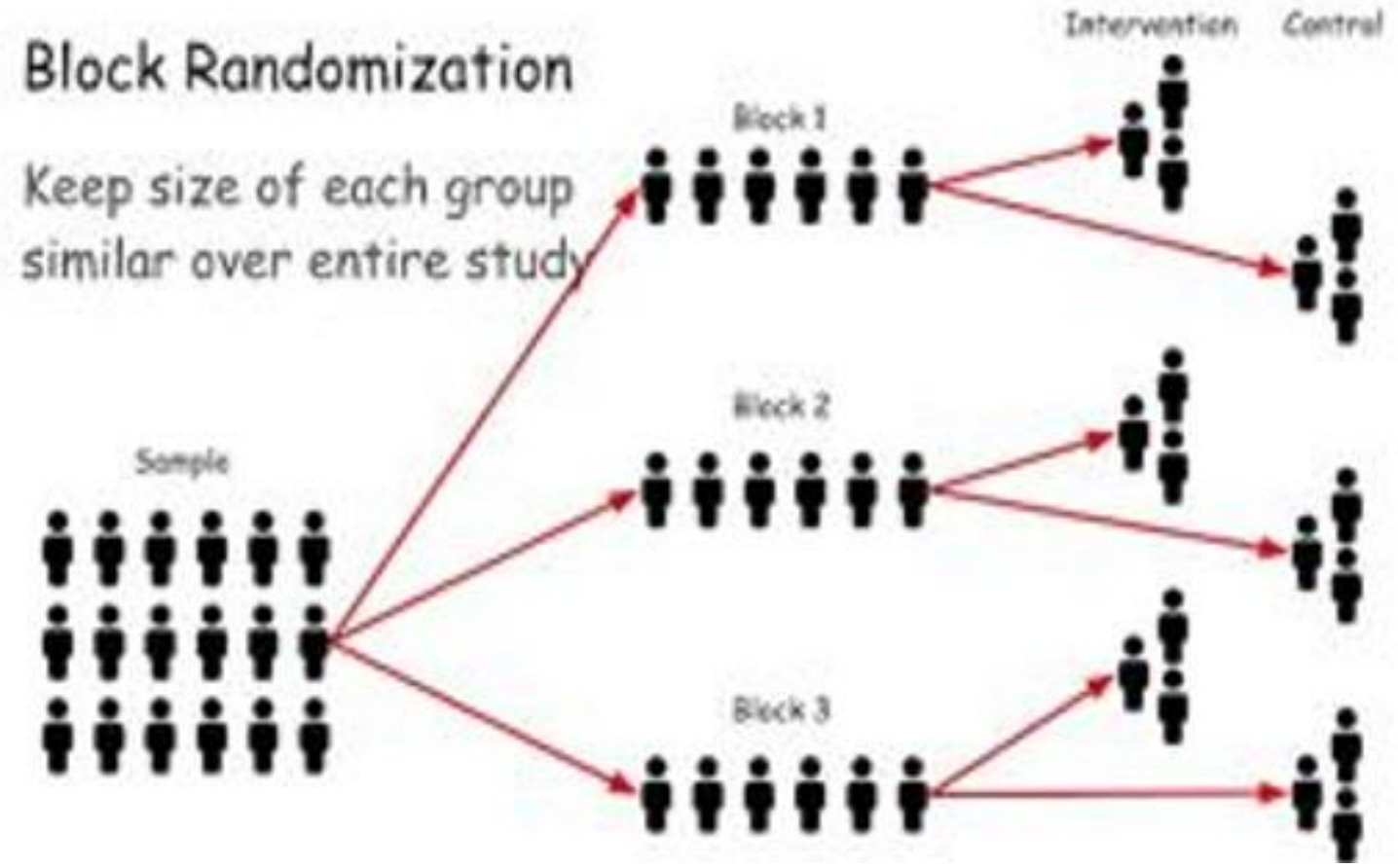
Each participant has the same chance of being assigned to either intervention or control.

Blocked Randomisation

Creating a balance in the number of samples allocated to each of the study groups.

Blocked Randomisation

- Fixed
- Variable



Stratified Randomisation

Stratified block randomization adds another layer by considering specific characteristics (strata) of participants, such as age or gender.

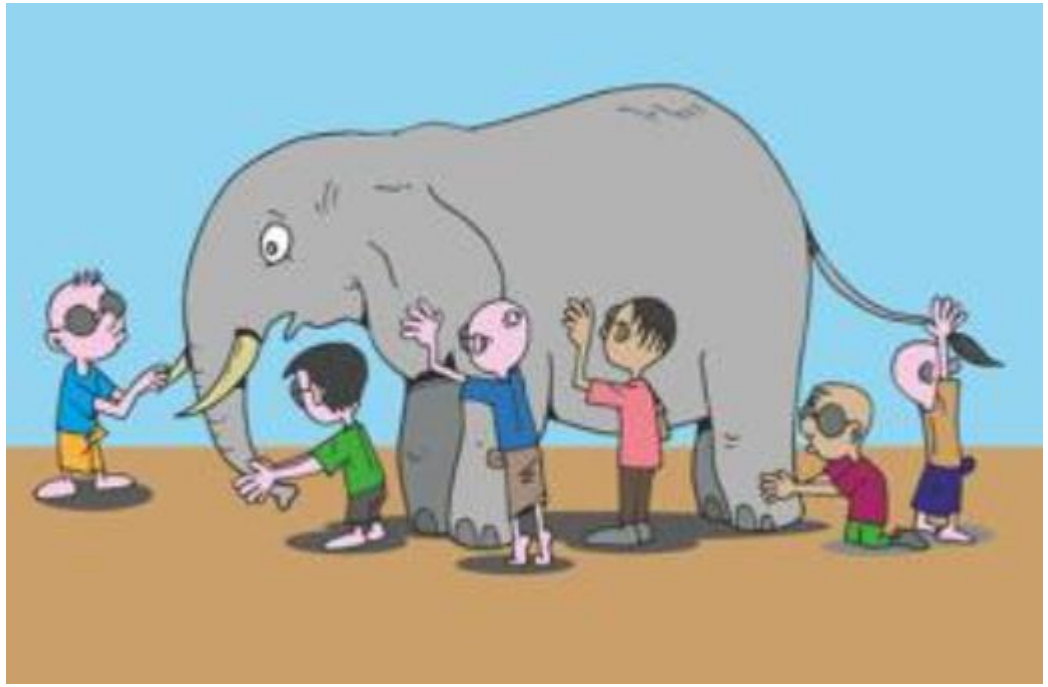
The Benefits Of Randomization

- Produce study groups comparable with respect to known and unknown risk factors
- Avoid bias(1. Selection bias . 2. Accidental bias)

Blinding?

Blinding

- Unblinded trials
- Single blind trials
- Double blind trials
- Triple blind trials



RCT

- Primary question
- Secondary questions
- Adverse effects
- Ancillary questions, substudies

RCT

Main Methods of Analysis

Analysis Type	Inclusion Criteria	Advantages	Disadvantages
Intention-to-Treat (ITT)	All randomized participants regardless of adherence	Reduces bias, preserves sample size	May underestimate treatment effect
Per Protocol (PP)	Only those who completed treatment as assigned	Clearer efficacy estimates	Potential for bias, loss of statistical power
As Treated (AT)	Participants based on actual treatment received	Reflects real-world adherence	Complicated interpretations, potential bias


THANK
YOU