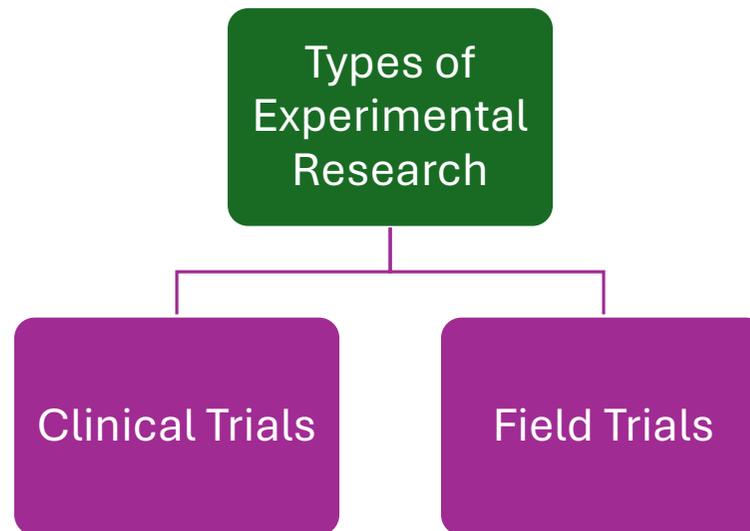


Week 10

Experimental (Interventional) Studies

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Types of Experimental Research



Clinical Trials

Aim:

It is the acquisition of all kinds of information about the efficacy and safety of the drug candidate product in patients and/or healthy volunteers selected by researchers who are competent in their field and subject, within the framework of a pre-designed and determined plan and program, under the supervision of competent and responsible researchers.

Clinical Trials

Clinical trials in humans have four phases, called "Phase".

Phase 1: Confidence Phase

It is the first time that a drug that has been studied in experimental animals is used on humans for the first time.

Few individuals (20-80 people)

Phase 2: Efficiency and Reliability Phase

It is based on the results of phase 1 studies and to examine whether the treatment should be used in large-scale randomized trials, the optimal dose of the drug is determined, whether its efficacy is high enough to proceed to the next phase, and the side-effect profile is examined.

Performed in approximately 200 individuals

Clinical Trials

Phase 3: Comparison Phase

When the drug has a reasonable effect, the benefit/risk ratio is determined by comparing it with placebo or standard treatment.

"Is the new drug better than the standard drug?" search for an answer to the question.

It is planned in a double-blind, randomized controlled and multicenter way on a large number of patients.

Forms the basis for registration of drugs

Phase 4: Inspection / Licensing Phase

The clinical trial process does not end with the obtaining of a license.

Phase IV drug studies are also carried out during the license phase, called post-marketing control.

The efficacy and safety characteristics of the drug, which is used in a large number of people in the community, determined in studies are mostly evaluated with observational studies.

Field Trials

It is carried out on healthy individuals

It is performed in the field rather than in hospitals or clinics.

Purpose: To determine whether a process, application or a measure reduces the risk of disease development in healthy individuals.