Phases of Clinical Trials

Presentation · March 2022

DOI: 10.13140/RG.2.2.32963.78882

CITATIONS
0

READS
16

1 author:

Rasha Abdelsalam Elshenawy
University of Hertfordshire
143 PUBLICATIONS **151** CITATIONS

SEE PROFILE

FADIC

First Arabian Drug Information Center

Clinical Trial Phases

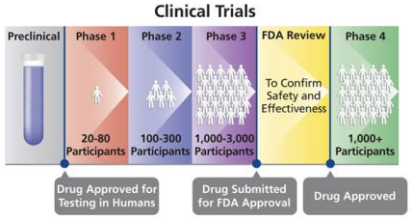
Dr. Rasha Abdelsalam

BCPS - AQ (ID) , CPHQ, TQM (AUC),
Master & Diploma of clinical pharmacy
Quantitative Research Certification
Antimicrobial Stewardship Certification/SIDP
tem Writing American Board Infectious Disease
Reviewer for PSAP ID 2018 Series

FADIC

What clinical trial phases are ?

Clinical trials are divided into different stages, called phases. The earliest phase trials may look at whether a drug is safe or the side effects it causes.



FADIC

What trial phases are ?

There are 3 main phases of clinical trials – phases 1 to 3. But some trials have an **earlier stage called phase 0,** and there are some **phase 4 trials done after a drug has been licensed**.

Pre-Clinical Phase

Before pharmaceutical companies start clinical trials on a drug, they conduct extensive pre-clinical studies.

These involve in vitro (test tube or cell culture) and in vivo (animal) experiments using wide-ranging doses of the study drug to obtain preliminary efficacy, toxicity and pharmacokinetic information.

Such tests assist pharmaceutical companies to decide whether a drug candidate has developed as an investigational new drug.

Phase 0

Phase 0 trials known as human micro dosing studies and designed to speed up development of promising drugs.

Phase 0 trials include administration of single subtherapeutic doses of the study drug to a small number of subjects (10 to 15) to gather preliminary data on the agent's pharmacokinetics (what the body does to drugs).

A Phase 0 study gives **no data on safety or efficacy**.

Phase 1

Phase I trials were formerly referred to as **"first-in-man studies"** Normally, a small group of **2–100 healthy volunteers** will be recruited.

These trials are often conducted in a clinical trial clinic, where the subject can be **observed by full-time staff.**

Phase 1

This phase is designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. Phase I trials normally include dose-ranging, also called dose escalation studies, to discover the point at which a compound is too poisonous.

Before beginning a phase I trial, the sponsor must submit an Investigational New Drug application to the FDA detailing the preliminary data on the drug.

Phase 1

1- Single Ascending Dose "Phase 1A"
To asses the side effects

2- Multiple Ascending Dose "Phase 1B"
To assess PK, PD - looking at safety and tolerability

3- Food Effect
To investigate any differences in absorption of the drug by the body, caused by eating before the drug is given

Phase 2

Go to the next goal is to evaluate whether the drug has any **biological activity or effect.**

Phase II trials are **performed on larger groups (100–300)** and are designed to assess how well the drug works. Also to continue Phase I safety assessments in a **larger group** of volunteers and patients.

Phase 2

There is no formal definition for these **2 sub-categories, but generally:**

- **Phase IIA studies** are usually pilot studies designed to demonstrate clinical efficacy or biological activity ('proof of concept' studies)

- **Phase IIB studies** look to find the optimum dose at which the drug shows biological activity with minimal side-effects ('definite dose-finding' studies).

Phase 3

Phase III studies are randomized controlled multicenter trials on large patient groups **(300–3,000 or more)** and aimed at being the definitive assessment of how effective the drug in comparison with current 'gold standard' treatment.

Phase III trials are the **most expensive, time-consuming and difficult trials to design and run,** especially in therapies for chronic medical conditions.

Phase 3

Phase III trials, demonstrating a **drug's safety and efficacy,** in order to obtain approval from the appropriate regulatory agencies such as FDA (USA), or the EMA (European Union).

Most drugs undergoing Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines through a New Drug Application (NDA) containing all manufacturing, pre-clinical, and clinical data.

In case of any adverse effects being reported anywhere, the drugs need to be recalled immediately from the market.

Phase II studies may cost as much as $20 million, and Phase III as much as $53 million