

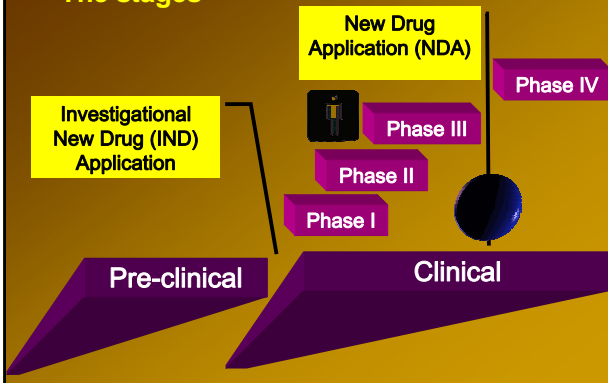
Module II: The Trial Landscape

Contents

- Why clinical trials?
- Main features of clinical trial design
- The history of clinical trials
- The drug development process
- **Phases of clinical trials**
- Clinical trial players
- Trial guidelines - GMP, GLP and GCP
- Quality assurance – audits and inspections
- Research ethics
- Risk and benefits of trial participations

Phases of Clinical Trials

The stages



Phases of Clinical Trials

Pre-clinical stage

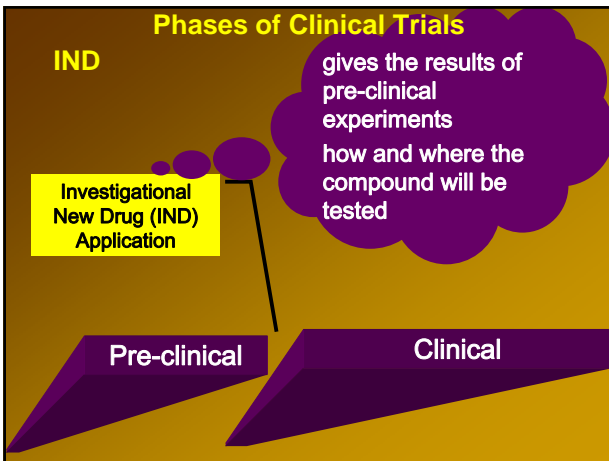
- develop a pharmacological profile of the drug;
- determine the acute toxicity of the drug in at least two species of animals;
- conduct short-term toxicity studies ranging from 2 weeks to 3 months.

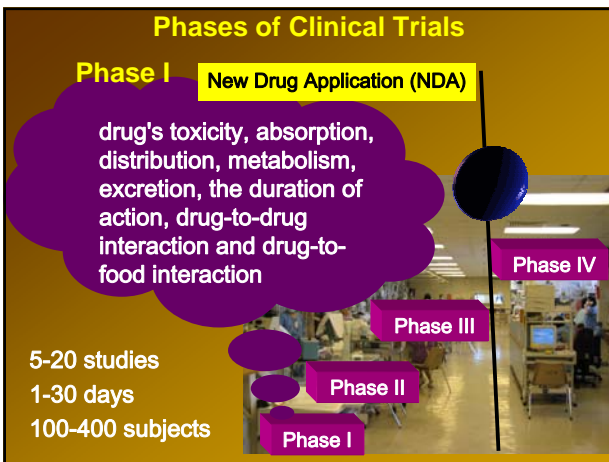
Pre-clinical Stage

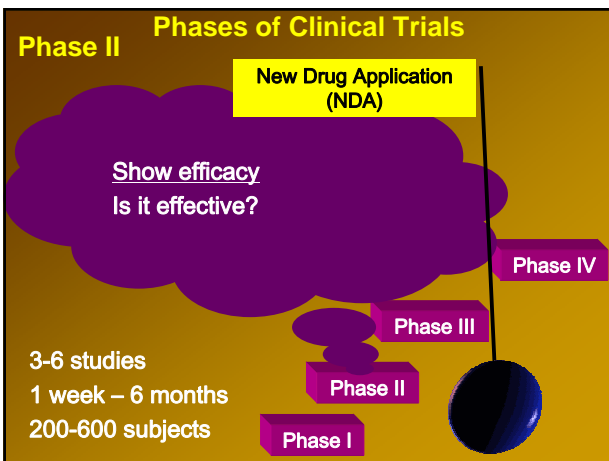
Lab Tests
Animal Studies

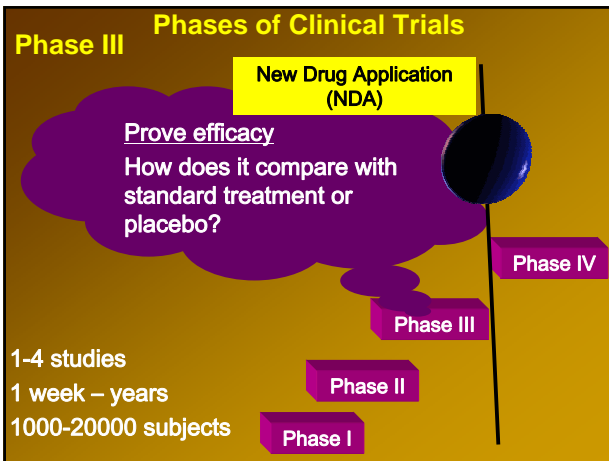
Clinical Stage

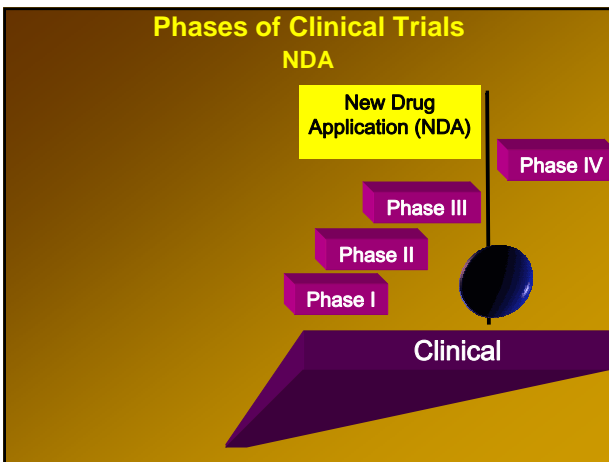
Human Trials

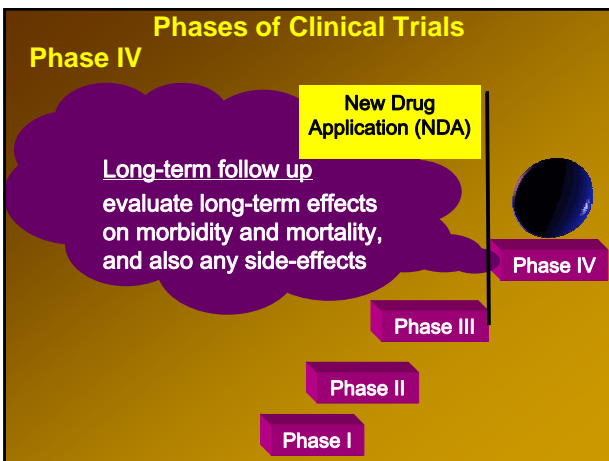


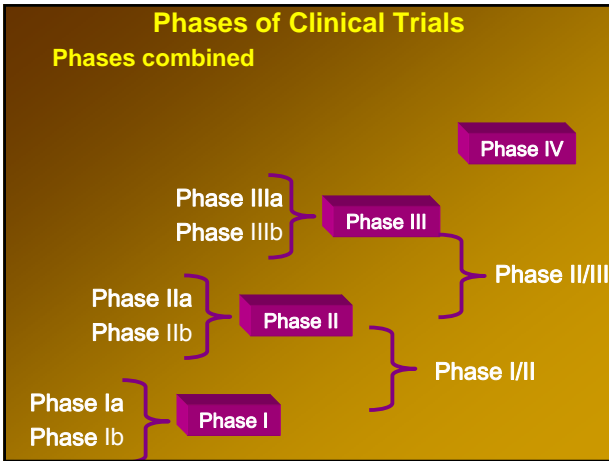


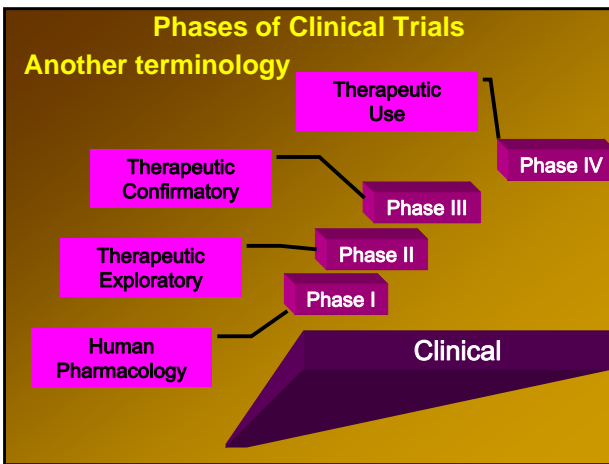


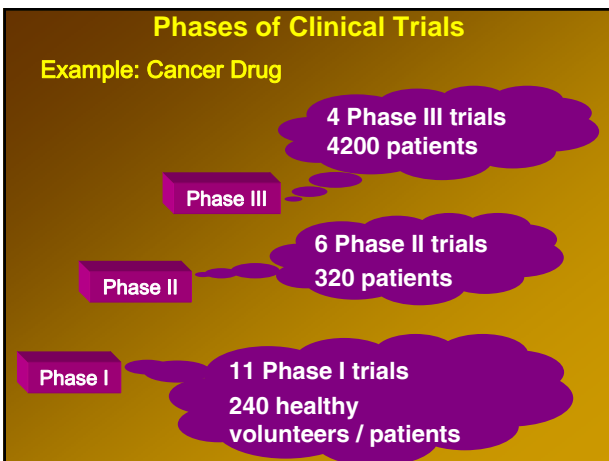












Phases of Clinical Trials

Example: Diabetes Drug

Phase III

3 Phase III trials:
0.5-2 years
3900 patients

Phase II

3 Phase II trials:
1 – 6 months
430 patients

Phase I

20 Phase I trials:
1 – 14 days
450 subjects

Phases of Clinical Trials

IB contents

CONTENTS OF INVESTIGATOR'S BROCHURE *(Example)*

- Introduction
- Physical, Chemical, and Pharmaceutical Properties
- Formulation
- Nonclinical Studies
 - Nonclinical Pharmacology
 - Pharmacokinetics and Product Metabolism in Animals
 - Toxicology
- Effects in Humans
 - Pharmacokinetics and Product Metabolism in Humans
 - Safety and Efficacy
 - Marketing Experience
- Summary of Data and Guidance for the Investigator
- References on Publications and Reports

Conclusion

Phases of Clinical Trials

- There are four phases of clinical trials:
 - Phase I - Human Pharmacology
 - Phase II - Therapeutic Explorative
 - Phase III - Therapeutic Confirmatory
 - Phase IV - Therapeutic Use.
