

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai

Approved by Pharmacy Council of India, New Delhi.

Coimbatore -641035

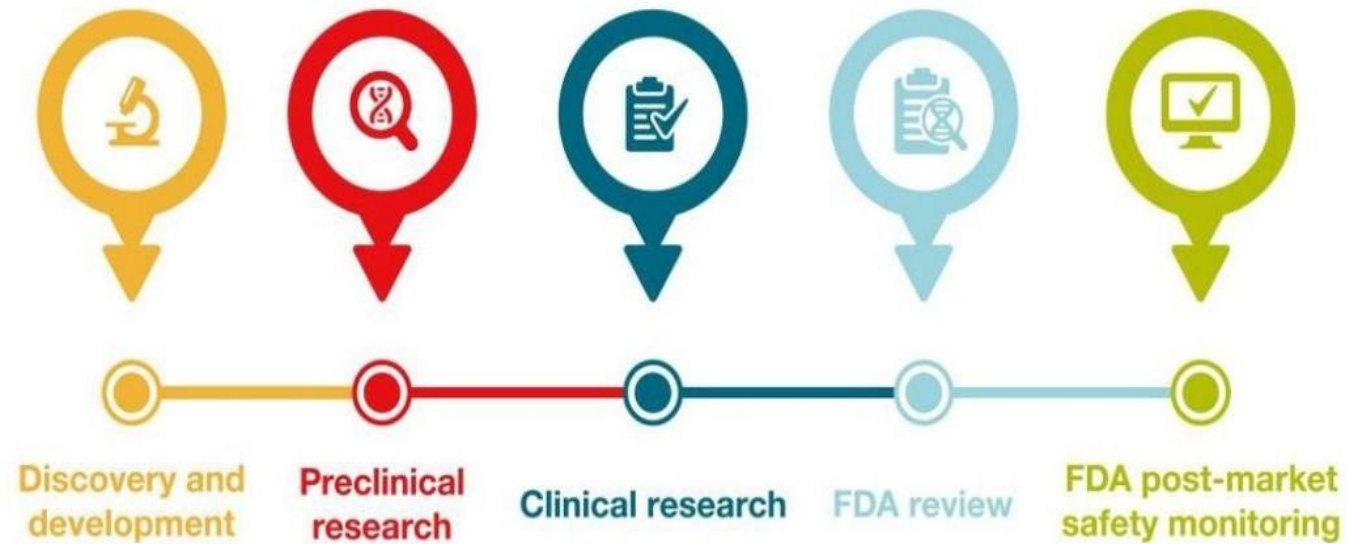
COURSE NAME : COMPUTER AIDED DRUG DESIGN(BP 807 ET)

VIII SEM / IV YEAR

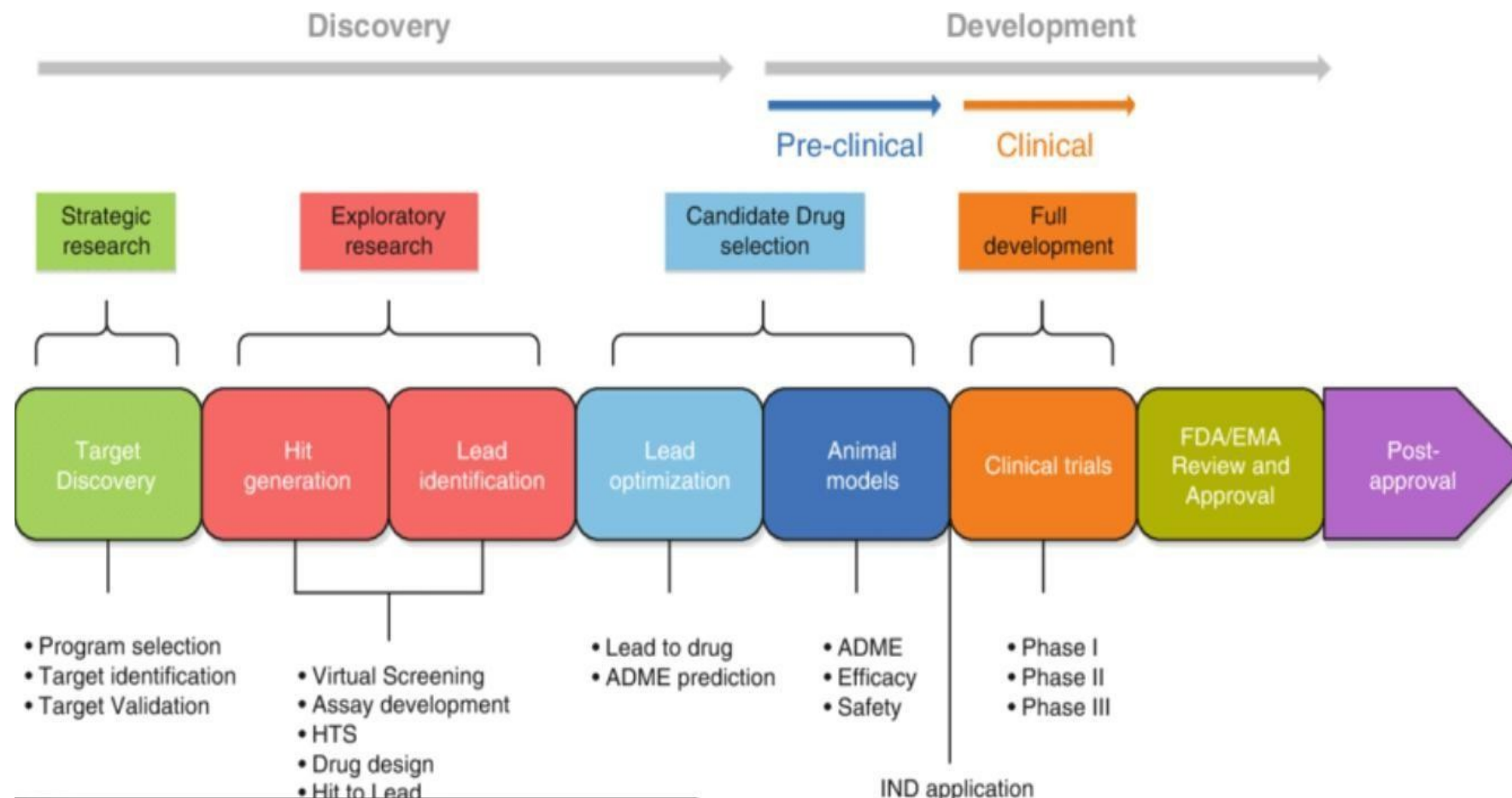
TOPIC 4: LEAD DISCOVERY BASED ON CLINICAL OBSERVATION

DIFFERENT PHASES ARE INVOLVED IN DRUG DISCOVERY

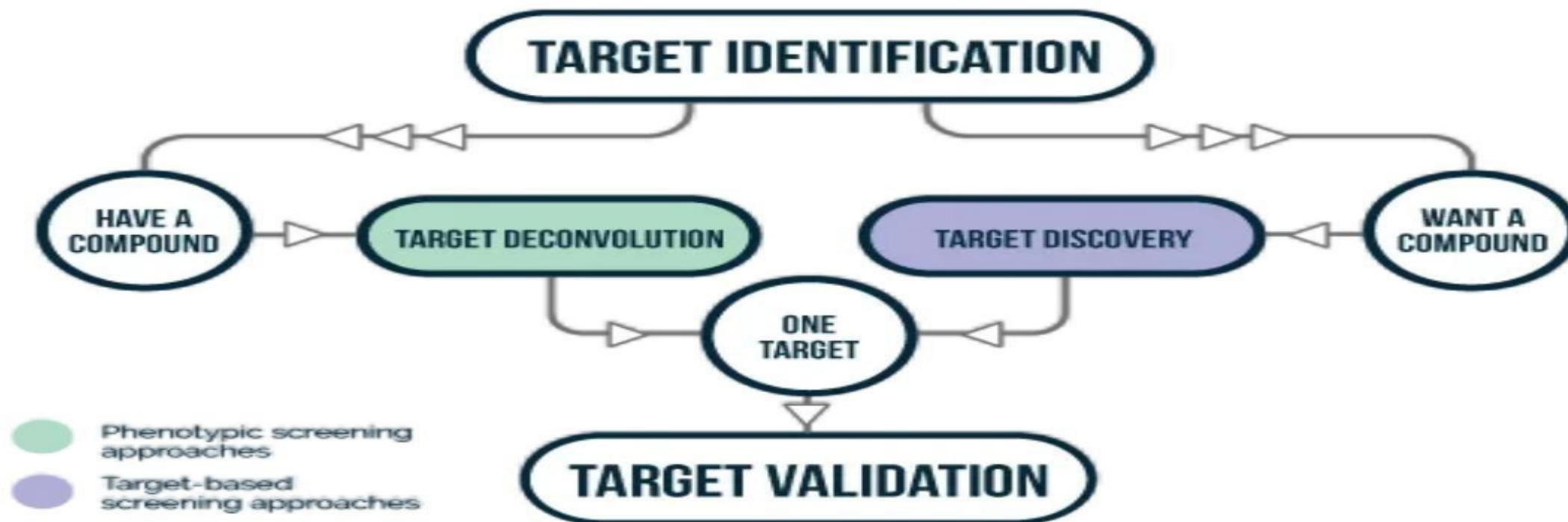
The five drug development phases



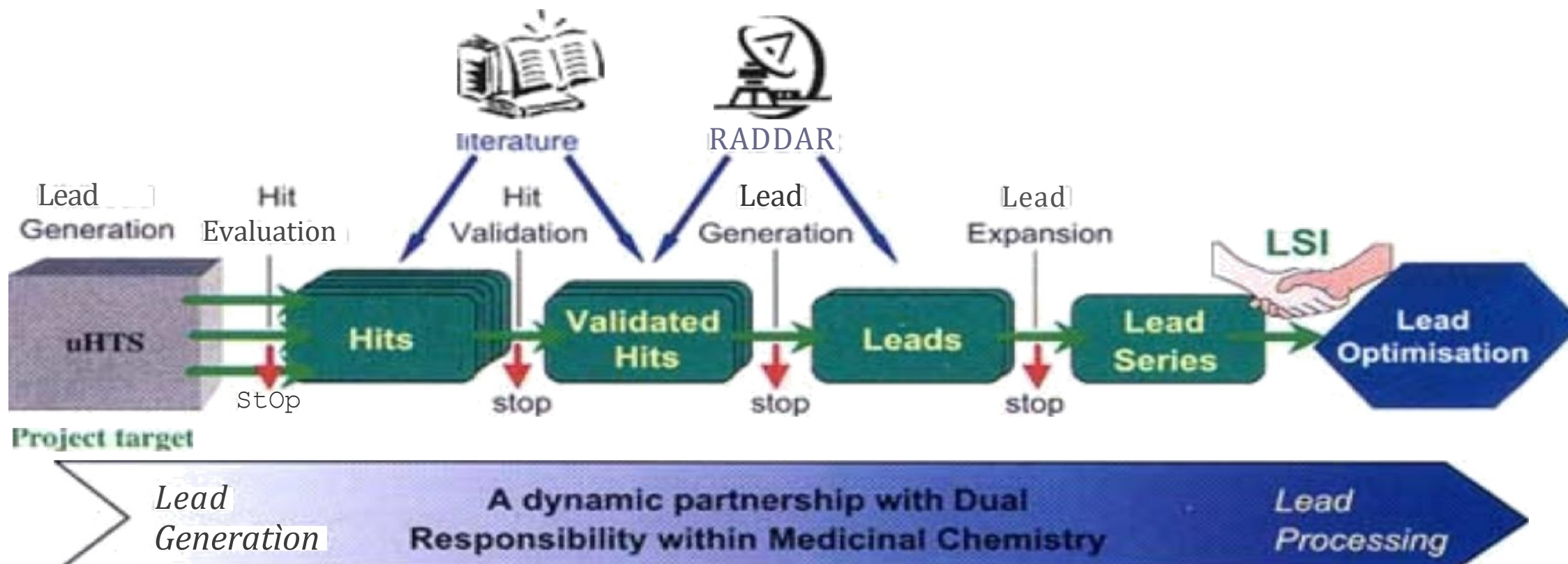
LEAD DISCOVERY BASED ON CLINICAL OBSERVATION (CLINICAL & PRECLINICAL) STUDIES



TARGET IDENTIFICATION & TARGET VALIDATION IN LEAD DISCOVERY PROCESS



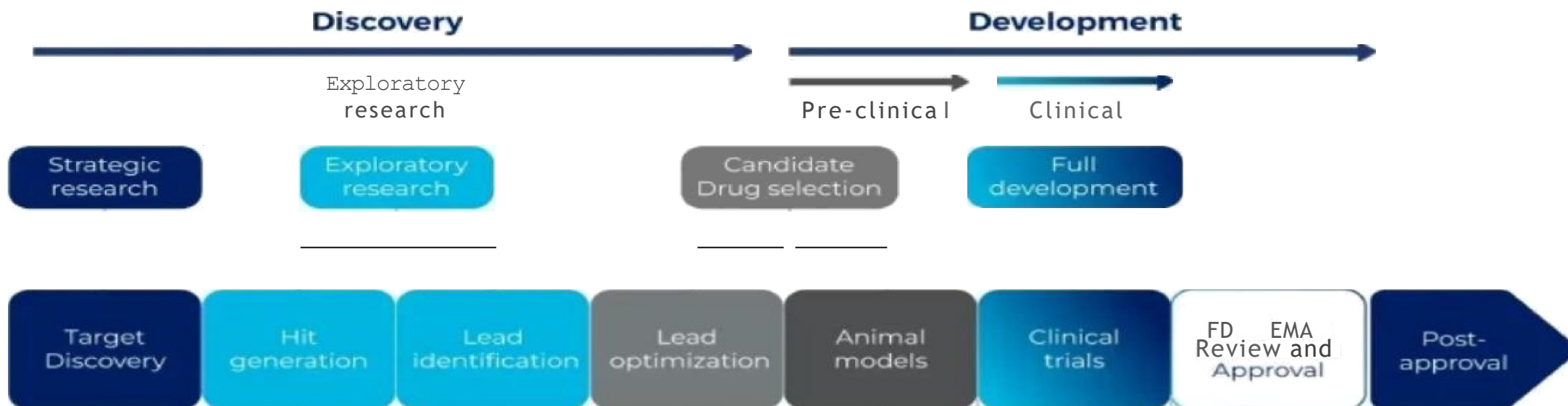
STUDY OF LEAD GENERATION & LEAD PROCESSING ON CLINICAL OBSERVATION



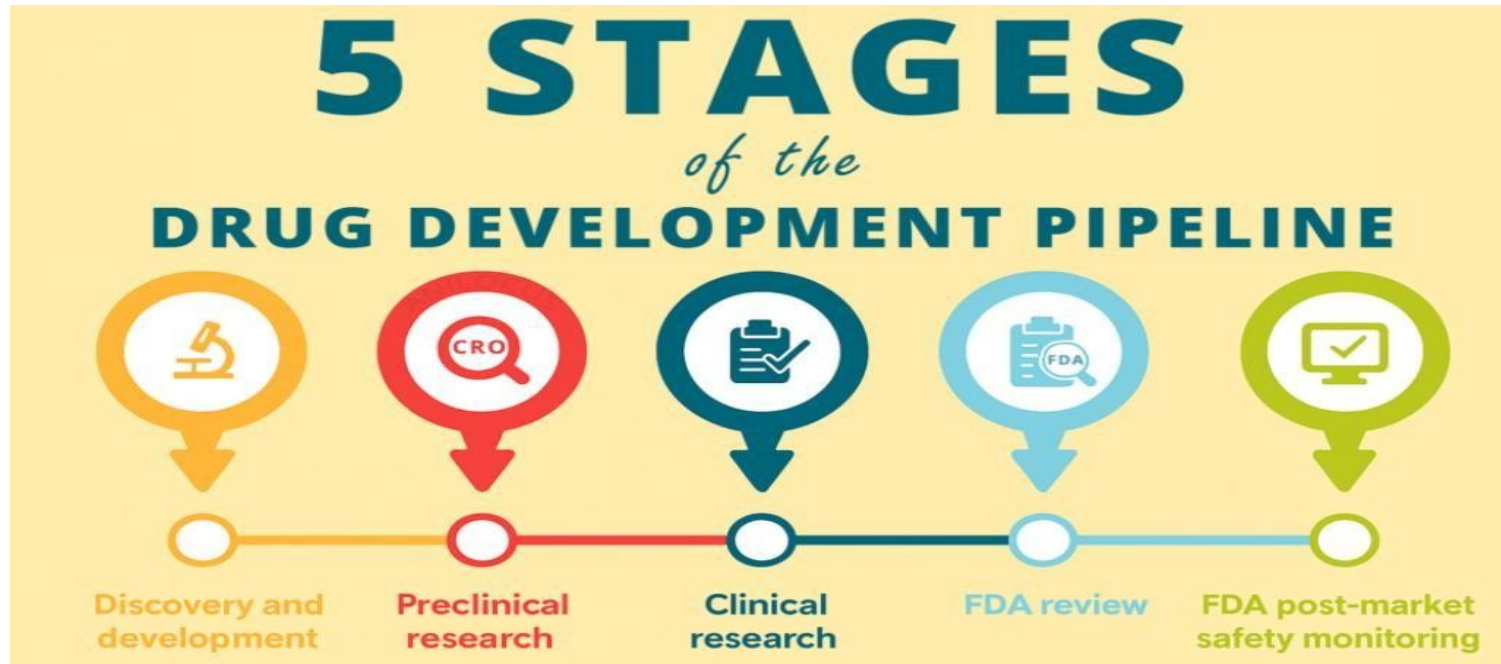
DEVELOPMENT OF LEAD DISCOVERY INTO PRECLINICAL REGULATORY PROCESS



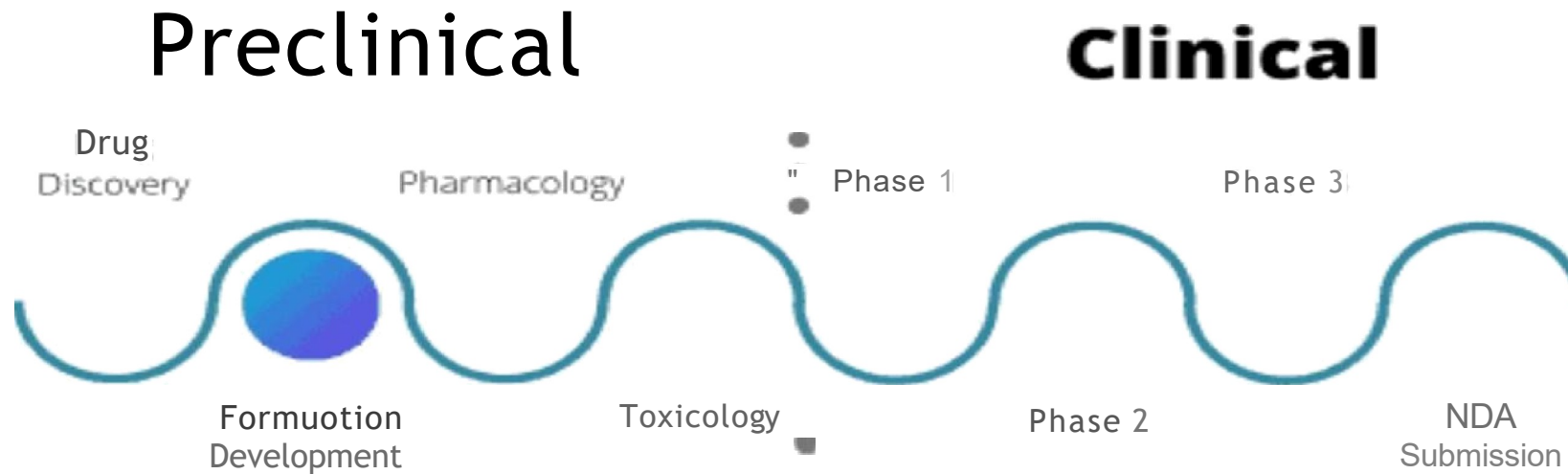
LEAD DISCOVERY BASED ON CLINICAL OBSERVATION



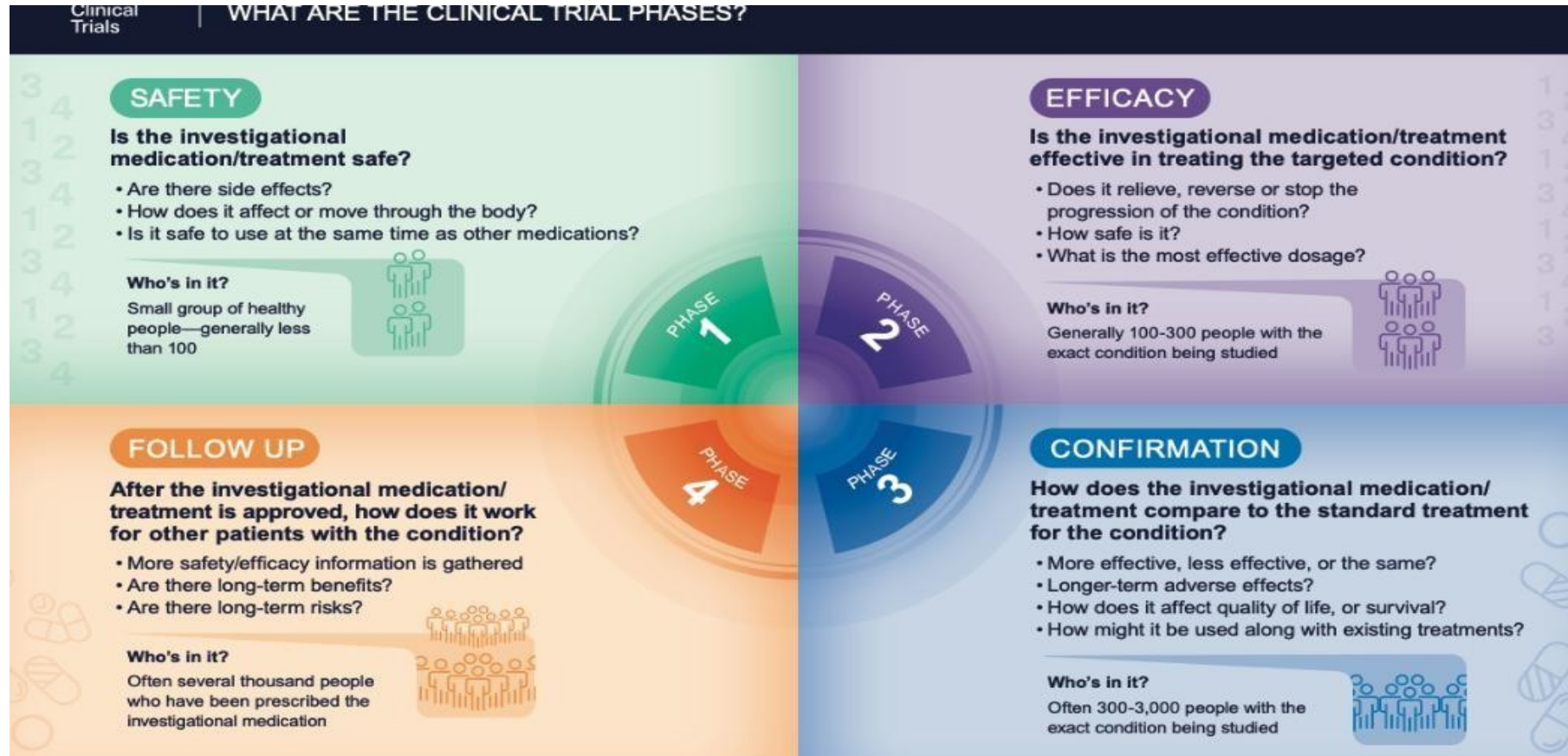
STAGES OF DRUG DEVELOPMENT PIPELINE



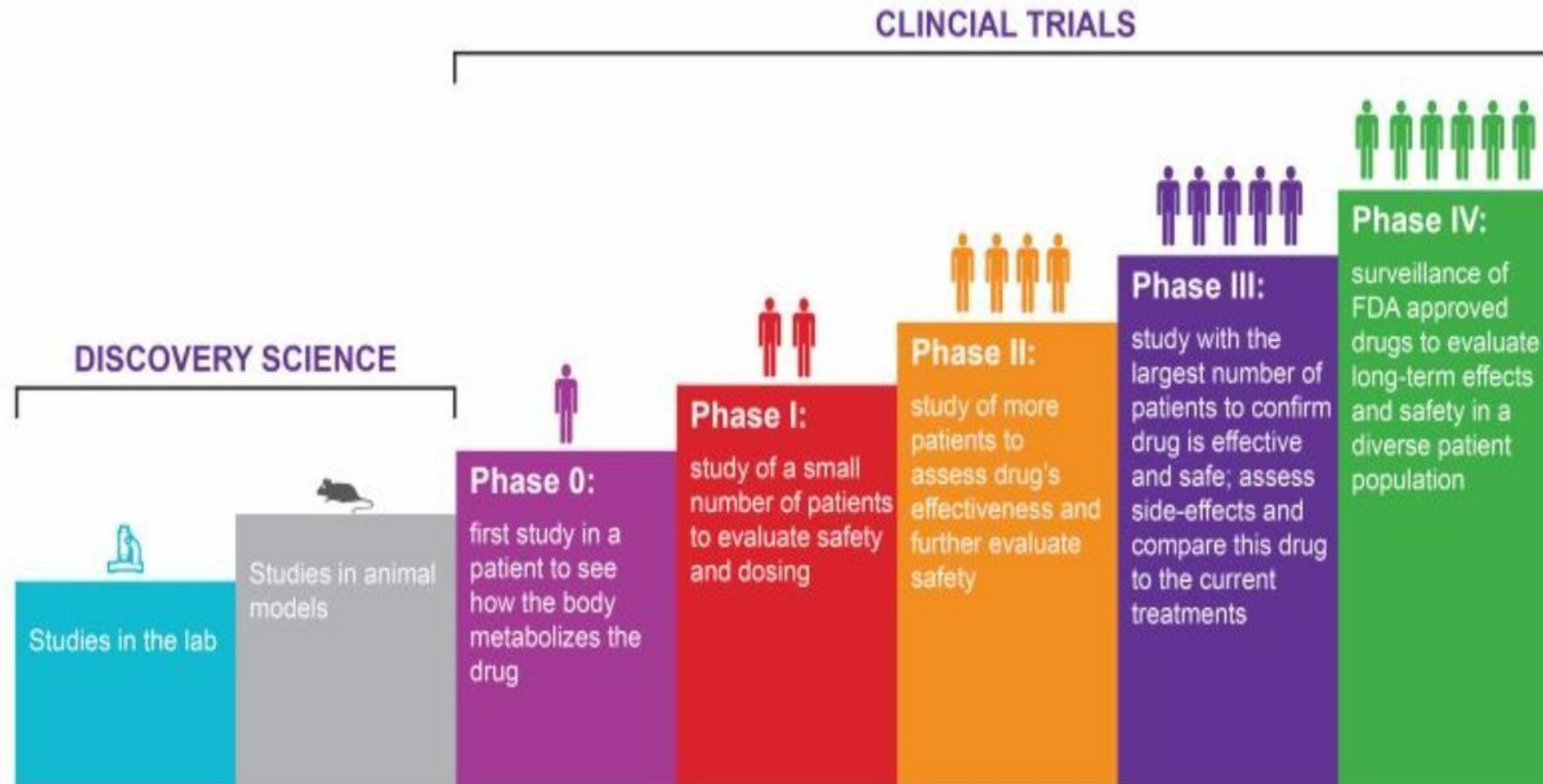
DEVELOPMENT STAGES OF PRECLINICAL AND CLINICAL SEGMENT



CLINICAL TRIAL PHASES

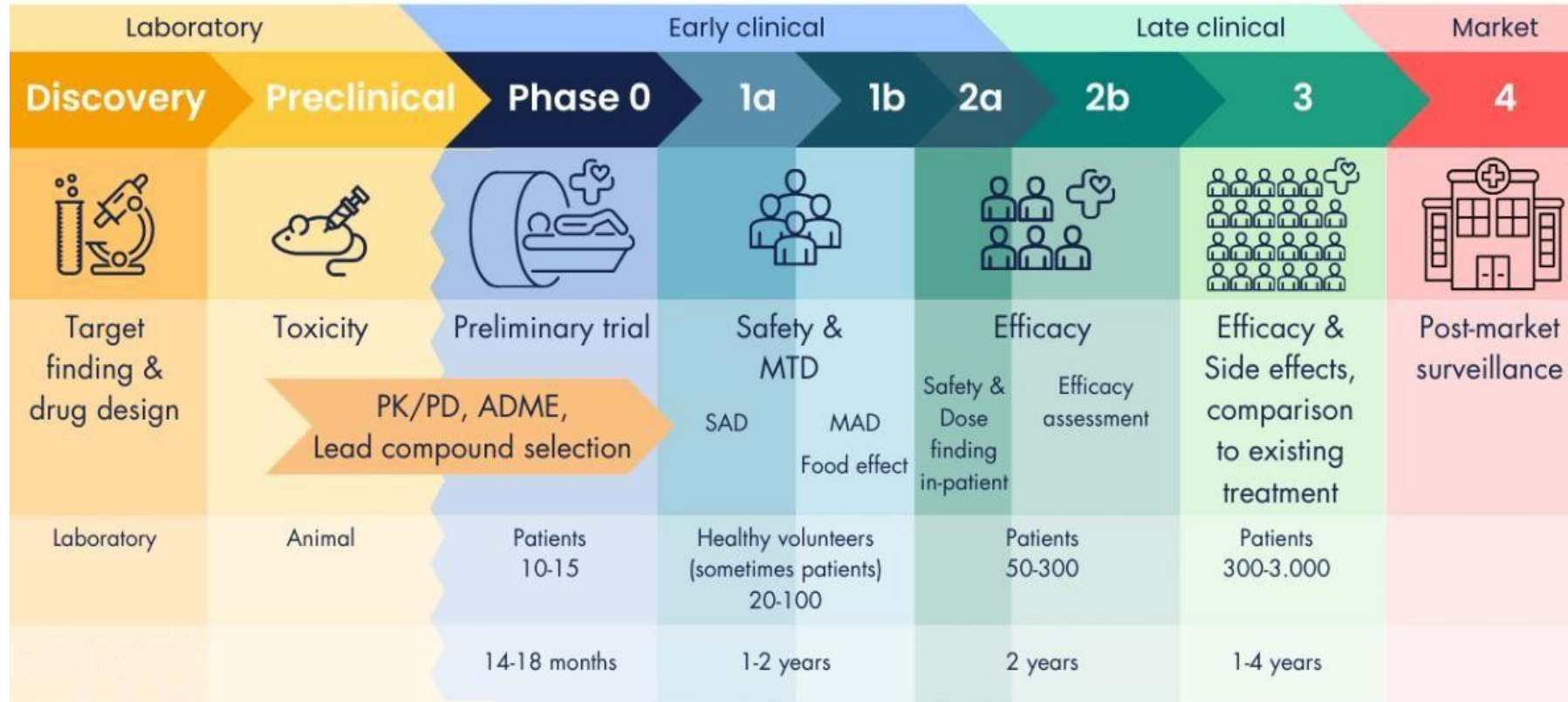


STUDY OF DISCOVERY SCIENCE AND CLINICAL TRIALS



DRUG DEVELOPMENT ON UNDER CLINICAL OBSERVATION

Phases of drug development



PK Pharmacokinetics
PD Pharmacodynamics

ADME Absorption, Distribution, Metabolism and Excretion
MTD Maximum Tolerated Dose

TRACER

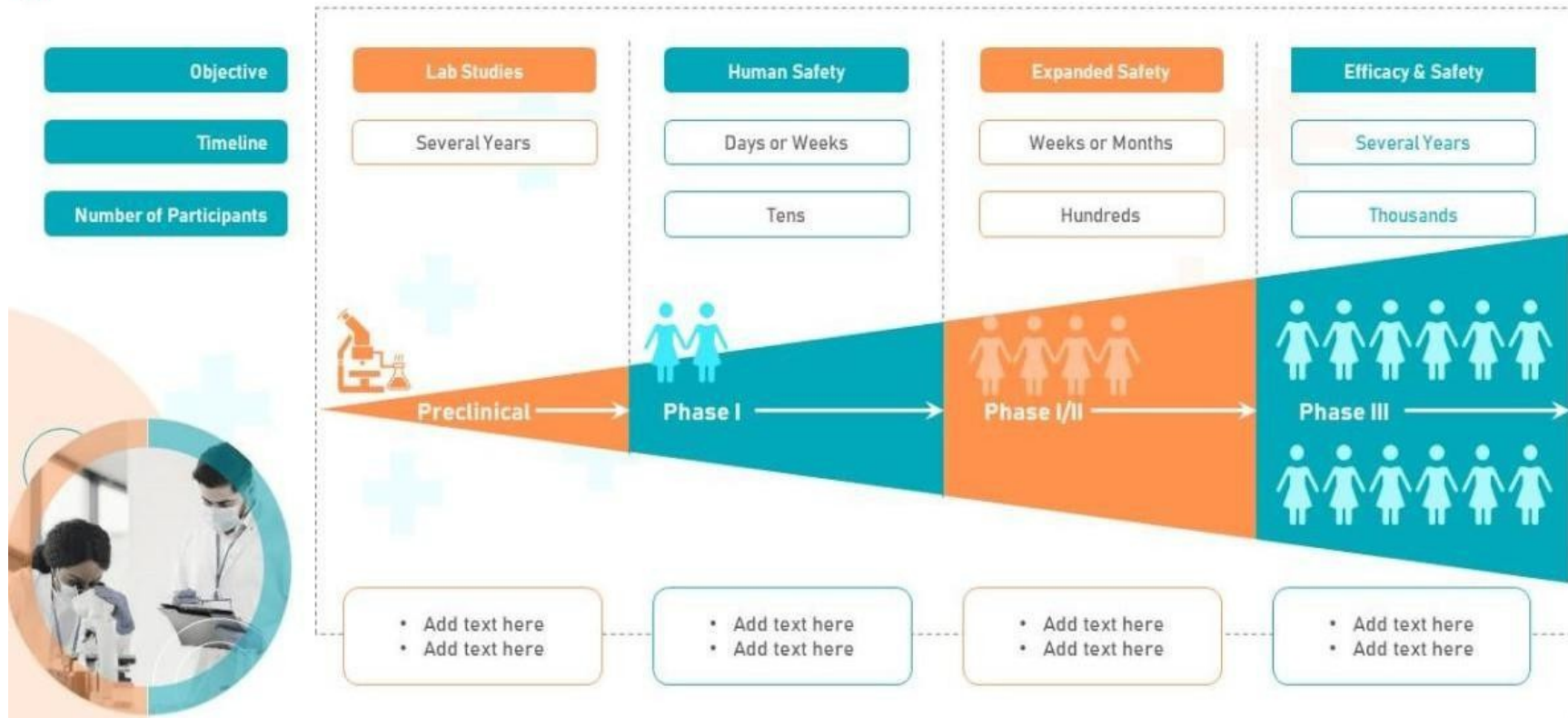
Simplified representation of phases in drug development. Study content and dates and numbers given may vary between studies. No rights can be derived from this figure.

OBJECTIVES & TIMELINES OF CLINICAL TRIAL PHASES

OBSERVATION

Clinical trial phases with objective and timeline

This slide highlights the process flow of clinical study for the new drug investigation. It also provides information regarding fundamental aim, time period, and the number of volunteers for each phase.



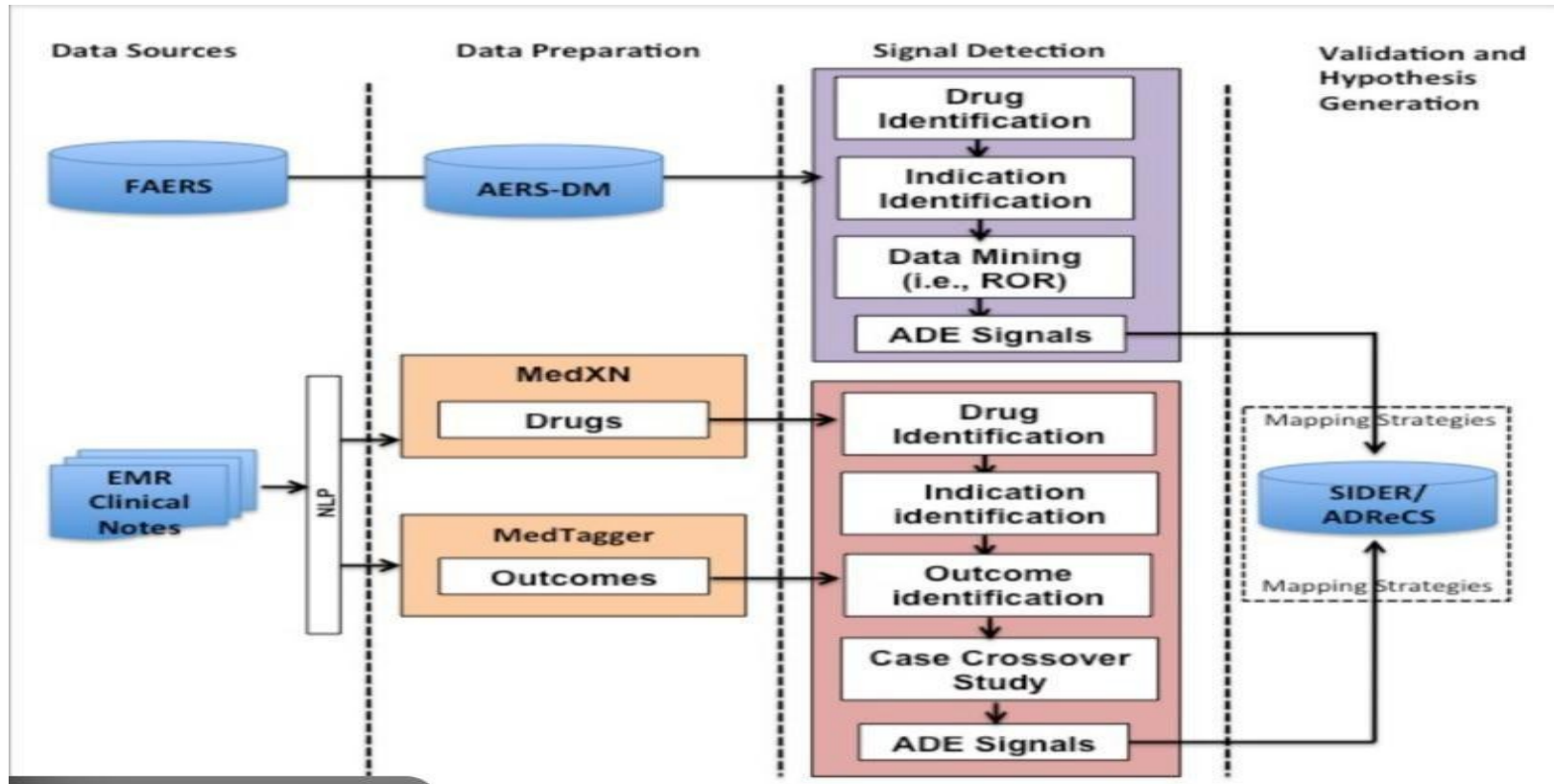
FDA DRUG APPROVAL PROCESS

FDA DRUG APPROVAL PROCESS

Overview of the FDA Drug Approval Process



COLLECTIONS OF DATA AND CLINICAL STUDY OBSERVATION



DRUG DISCOVERY DEVELOPMENT PROCESS

Drug Discovery and Development Process Step 5 – Post-Market Drug Safety Monitoring (1/2)

This slide provides information about the fifth step in the drug discovery and development process i.e. Post-Market Monitoring. Post-market Monitoring includes various elements such as supplemental applications, manufacturer inspections, drug advertising, generic drugs, active surveillance etc.



ASSESSMENTS

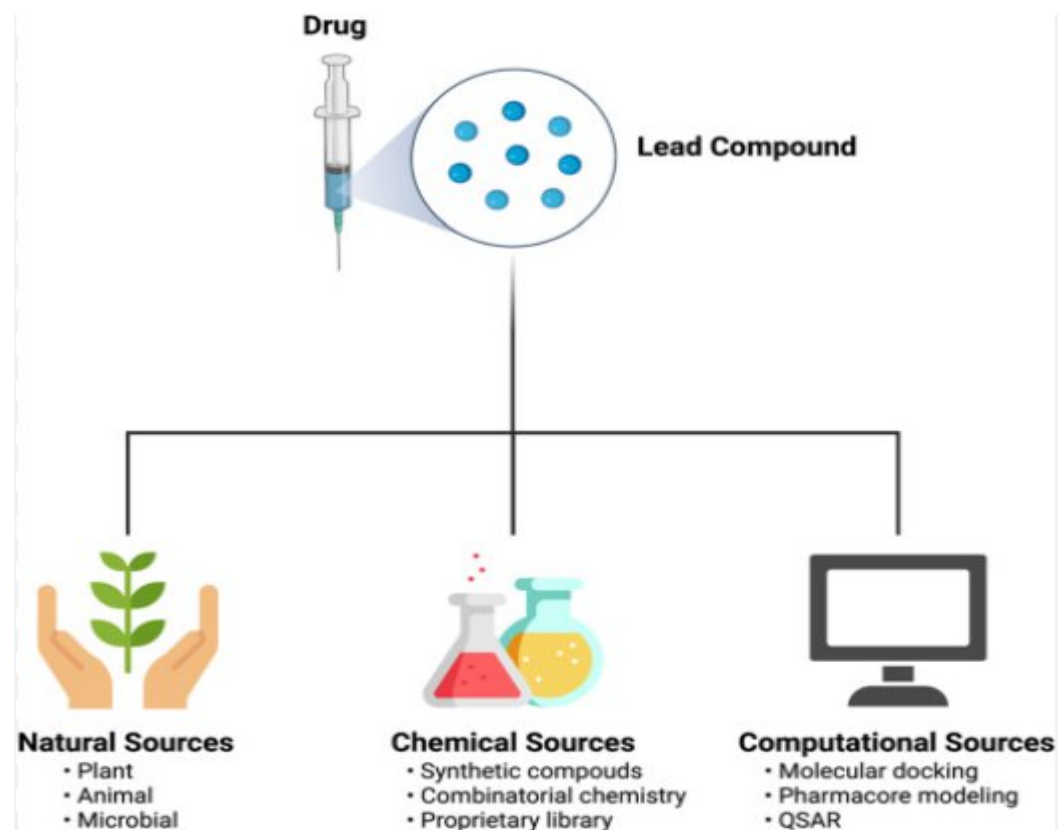
Question 1 : Considering cost, time and failure rate in drug development, argue for or against prioritising clinical-observation leads in early-stage research over conventional screening methods.



Question 2: Discuss the potential role of real-world evidence and large-scale clinical databases in enhancing clinical-observation-based lead discovery. What are the strengths and pitfalls of this approach?



SUMMARY



REFERENCES

- Michne, W. F. (2010). Lead Discovery: The Process. In Z. Rankovic & R. Morphy (Eds.), Lead Generation Approaches in Drug Discovery (Chapter 1, pp. 1-17). John Wiley & Sons.
- Moffat, J. G., et al. (2013). “Neoclassic drug discovery: the case for lead generation using phenotypic and functional approaches.” Journal of Biomolecular Screening, 18(10), 1090-1094. doi:10.1177/1087057113498282.
- Ma, S., Hou, J., Liu, S., Zhu, F., Wei, P., & Chen, N. (2023). “Lead Drug Discover Strategies from Natural Medicines Based on Network Pharmacology.” Medical Research Archives, 11(2). doi:10.18103/mra.v11i2.3559

