The high yeild

Pharmacology lecture 2

This lecture provides a comprehensive overview of the drug development and evaluation
process, which is a complex, time-consuming, and expensive endeavor. Here's a detailed summary:

Method of drug discovery
A. Foraward Pharmacology approach. Drug then disease
B. Reverse pharmacology approach. Disease then drug

Drug Discovery and Preclinical Research
- The process begins with drug discovery, where researchers identify target molecules and screen thousands of compounds to find potential drug candidates [1] [2].
Hits: hundreds — sometimes thousands — of chemical or biological compounds to evaluate their effects on the disease.

Leads: chemical or biological compounds with increased activity at a chosen target (potency) and reduced activity against unrelated targets (specificity)

- Lead optimization is performed to identify the most promising drug candidates, often using high-throughput screening techniques [3].
- Preclinical research follows, involving in vitro and in vivo testing to ensure safety before human trials [4].

The most important aspect of preclinical research is the safety tests.

This is done either through an Investigational New Drug (IND) application in the US or a Clinical Trial Application (CTA) in the EU.
isease then drug

The high yeild

Pharmacology lecture 2

Drug

The clinical development phase is divided into three main stages:

1. **Phase I - Safety
   - Conducted on 20-80 healthy volunteers
   - Focuses on drug safety, dosage, absorption, and duration of activity
   - Typically takes up to one year

2. Phase II - Proof-of-Concept [7]
   - Involves 100-300 patients with the target disease
   - Evaluates efficacy and safety, determining optimal dosage
   - Usually lasts up to two years

3. **Phase III - Regulatory Evidence
   - Enrolls at least 1000 patients
   - Aims to gather comprehensive data on safety and efficacy
   - Documents side effects for inclusion in the product leaflet
   - Takes an average of 1-4 years

Market Approval and Launch

- After successful clinical trials, developers submit a market approval application (NDA/BLA in the US, MAA in the EU) [10].
- The application process can take 6-10 months for authorities to review.
- If approved, the drug moves to market launch, involving price negotiations with potential buyers .

Post-Marketing Surveillance (Phase IV)

- Phase IV studies monitor the drug's safety and efficacy after market approval.
-The aim is to increase pharmacovigilance.
- These studies are particularly important for drugs treating complex conditions or rare diseases [15].