UNDERSTANDING THE DRUG DISCOVERY PROCESS

The process of discovering, testing, and eventually gaining approval for selling a drug is a long and arduous one. Here, we look at the different stages involved, and the approximate length of time that each stage takes, to eventually arrive at an approved drug that can be given to patients.

1. RESEARCH & DEVELOPMENT
   - 3–6 YEARS
   - Drug development begins long before clinical testing. It starts with the identification of a target for a drug to act on, then the identification of compounds that could potentially hit that target.

2. TARGET IDENTIFICATION
   - WHAT WILL THE DRUG AFFECT?
   - Understandings of the causes of diseases or conditions can help researchers know what processes or pathways drugs to treat the condition need to be able to target.

3. COMPOUND SCREENING
   - UP TO 10,000 COMPOUNDS
   - Compounds are screened in laboratory tests for their ability to affect the identified target. They are also screened to check they don’t interfere with other related targets.

4. LEAD IDENTIFICATION
   - WHICH COMPOUNDS TO TEST?
   - Though screening is unlikely to uncover a perfect drug candidate, promising compounds can be identified. The structures of these molecules can be modified to try and improve their activity.

5. IN VITRO STUDIES
   - LATIN FOR ‘IN GLASS’
   - Laboratory experiments on cells or molecules outside of their usual biological surroundings. This gives some idea of efficacy against the identified target. Toxicity can also be assessed.

6. IN VIVO STUDIES
   - LATIN FOR ‘IN THE LIVING’
   - Drugs that look promising in in vitro testing will progress to testing in animals. These include tests on toxicity, efficacy, and how quickly the drugs are absorbed and subsequently eliminated.

7. PHASE 1 TRIALS
   - USUALLY 20–80 PEOPLE
   - The primary goal of phase 1 trials is to determine the drug’s side effects. Additionally, how quickly the drug is metabolised and excreted from the body can be determined during these trials.

8. PHASE 2 TRIALS
   - USUALLY 100–300 PEOPLE
   - Phase 2 trials help to determine how effective the drug is in patients who have the condition it is trying to treat. Controlled trials compare the effects of the drug to that of a placebo.

9. PHASE 3 TRIALS
   - USUALLY 1,000–3,000 PEOPLE
   - Gauges efficacy, dosage, and safety in a larger population. Also compares efficacy to existing treatments, as well as interactions with other drugs and effects of different dosages.

10. REVIEW & APPROVAL
    - 1–2 YEARS
    - If a drug is deemed effective in clinical trials, it is submitted to regulating bodies to be approved. It’s estimated that only around 1 in 5000 drug candidates makes it all the way to approval.

11. EVALUATION
    - EVIDENCE FROM TRIALS
    - The regulating body reviews the evidence provided by the pharmaceutical company for the drug’s efficacy and safety. Drugs offering important advances are given priority.

12. APPROVAL & MANUFACTURE
    - ~75% SUBMISSIONS APPROVED
    - If the benefits of taking the drug are deemed to outweigh its risks, it is approved. The cost of developing a drug that gains marketing approval is estimated to be $2,558 million.

13. POST-RELEASE MONITORING
    - INDEFINITE DURATION
    - After a drug is approved and available for use by patients, it is still monitored for any side effects in the general population that may not have occurred in the drug’s clinical trials.