

Drug development, Screening and Nomenclature

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Introduction

- How long do you think it takes for a new drug to get approved in the US? About 12-15 years, that's roughly 1/3rd duration of the entire professional career for any of us. Next, how much investment do you think is required to bring a new drug to market? ~\$1 Billion, that's equivalent to employing 665+ employees at the annual salary of \$100k for 15 years.
- Simply put, approval of a new drug is a massive undertaking and selecting the right partners, who prioritize in sync with you and focus on high quality and fast turnaround, goes a long way in avoiding missteps and moving your drug program closer to success.
- Below, NorthEast BioLab attempts to put together a quick, easy-to-follow version of the FDA and U.S. government's step-by-step process for new drug approval.

Phases & Stages

- Step 1: Discovery & Development
- Step 2: Preclinical Research
- Step 3: Clinical Development
- Step 4: FDA Review
- Step 5: Post-market Monitoring
- Other Relevant Drug Development Concepts

- The complexity in drug development has increased manifolds over the past 40 years, requiring preclinical testing, investigational new drug (IND) applications, and completed clinical testing before marketing approval from the FDA.
- Generally, new drug applications (NDAs) or biologics license applications (BLA) are reviewed comprehensively before approval, and then drug performance is resubmitted to regulatory agencies for post-marketing studies. The overarching goal is to bring more efficient and safer treatments to the patients as quickly as possible after a thorough medical evaluation.

- Drug discovery is how new medications are discovered. Historically, drugs were mostly found by identifying active ingredients from traditional medicines or purely by chance. Afterward, classical pharmacology was used to investigate chemical libraries including small molecules, natural products, or plant extracts, and find those with therapeutic effects. Since human DNA was sequenced, reverse pharmacology has found remedies to existing diseases through testing.
- Disease processes, molecular compound tests, existing treatments with unanticipated effects, and new technologies spur drug discovery through the cycle below.
- Today drug discovery involves screening hits, medicinal chemistry, and optimization of hits to reduce potential drug side effects (increasing affinity and selectivity). Efficacy or potency, metabolic stability (half-life), and oral bioavailability are also improved in this step of the drug development process.