THERAPEUTIC DEVELOPMENT

Target validation.
Potential targets identified in discovery research are confirmed to play a causative role in a given disease.

Target to hit.
Large numbers of chemical or biological agents are screened to identify and robustly validate molecules that "hit" the target.

Hit to lead.
Agents that hit the target are further tested to determine which bind the target with the most specificity and have promising medicinal properties.

Lead optimization.
The properties of lead compounds are reiteratively optimized to enhance potency and drug-like properties, and to reduce side effects by enhancing specificity.

Preclinical testing.
Cellular and animal models are used to test for effectiveness of the optimized lead, identify potential toxicity issues, and determine an optimal starting dose and dosing schedule for clinical or "first-in-human" testing. The final compound is called the clinical candidate.

IND

Investigational new drug (IND).
Prior to clinical testing, one or more clinical candidates are assessed in rigorous good laboratory practice (GLP) studies with the drug product generated through good manufacturing practices (GMP) and then submitted to the FDA for approval for use in clinical trials.

Adapted from (1)

American Association for Cancer Research (AACR) Cancer Progress Report 2019