Stage	Description	Key Activities	Duration	Outcome
Drug Discovery	Early research to identify potential drug candidates.	- Identify disease targets - Screen compounds (in silico testing). - Perform High-Throughput Screening (HTS) - Lead optimization to ensure specificity and potency.	4-7 years	- Discover lead candidates. - Identify 1-2 optimized drug candidates ready for preclinical testing.
Preclinical Research	Testing lead compounds in vitro, in vivo to assess the safety and toxicty	- In vitro testing (cell cultures). - In vivo testing (animal studies). - Safety tests to check for toxicity. - Application for (IND) in the US or (CTA) in the EU.	4-7 years	- Most promising candidates (lead compounds) move to clinical trials. - Regulatory approval to start human testing.
Phase I -SAFETY	First trials in humans to evaluate safety, dosage, and pharmacokinetics (how the body absorbs and processes the drug).	- Test on 20-80 healthy volunteers. - Focus on safety, tolerability, and determining a safe dosage. -determining pharmacodynamics and pharmacokinetics	1 year	- Safety profile in humans. - Optimal dosage range for further trials. Note :- women of childbearing age are excluded from trials
Phase II –PROOF OF CONCEPT	Trials to evaluate efficacy and further assess safety in patients with the target disease.	- Test on 100-300 patients who have the target disease. - Assess efficacy and safety. - Determine minimum effective dose and maximum tolerated dose. - Narrow down effective treatment regimens.	2 years	- Evidence of the drug's efficacy in treating the disease. - Refined dosage and safety data.

Phase III – REGULATORY EVIDENCE	Large-scale trials to confirm efficacy and safety on a broader population, gathering data for regulatory approval.	- Test on 1,000+ patients. - Monitor long-term side effects, drug interactions, and overall safety. - Data used for regulatory approval (NDA or MAA).	1-4 years	- Comprehensive data on drug's safety and efficacy. - Documentation for market approval submission (NDA in US, MAA in EU).
Market Approval	Submission of all trial data to regulatory bodies for review and potential approval.	- Prepare documentation for New Drug Application (NDA) or Marketing Authorization Application (MAA). - Includes data from discovery to Phase III trials. - Review by regulatory agencies (FDA, EMA) may take 6-10 months.	6-10 months	- If approved, the drug can be marketed. - Price negotiation with healthcare providers or insurers may vary by country.
Phase IV MONITORING,MARKETING AND SAFETY	Post-market surveillance to monitor long-term safety and efficacy once the drug is on the market.	- Ongoing monitoring of safety in real-world clinical practice. - Detects rare or long-term side effects not identified in earlier phases. - Assess interactions with other drugs. - Required for some drugs treating rare diseases.	Ongoing (post-launch)	- Continual safety evaluation in a broader, real-world setting. - Pharmacovigilance: reporting additional safety or efficacy concerns.