



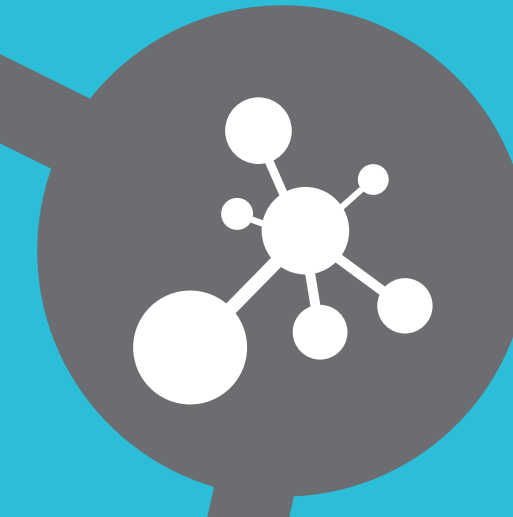
Illness or its symptoms treated in a new way



RESEARCH:
3–5 years



Target identification and validation: Trying to identify a target in the human body – most commonly a protein or gene – with a role in development of illness or causing symptoms.



Drug molecules identification: Selection of suitable drug molecules for further research from up to thousands of potential molecules.



Preclinical research: Confirmation that molecules are sufficiently safe for testing in humans: In vitro in test tubes and cell culture, and in vivo in animal tests.



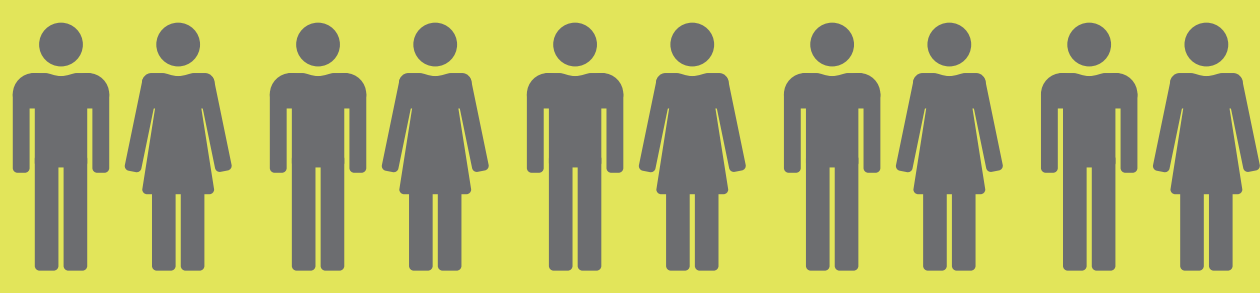
Lead molecules optimisation: Molecules modified and tested. Aim is to identify a few molecules with best possible efficacy and safety as drug candidates.



Clinical trial authorisation application: Clinical trial of a drug requires authorisation from authorities.



Participants in clinical trial:
20–100



PHASE I:

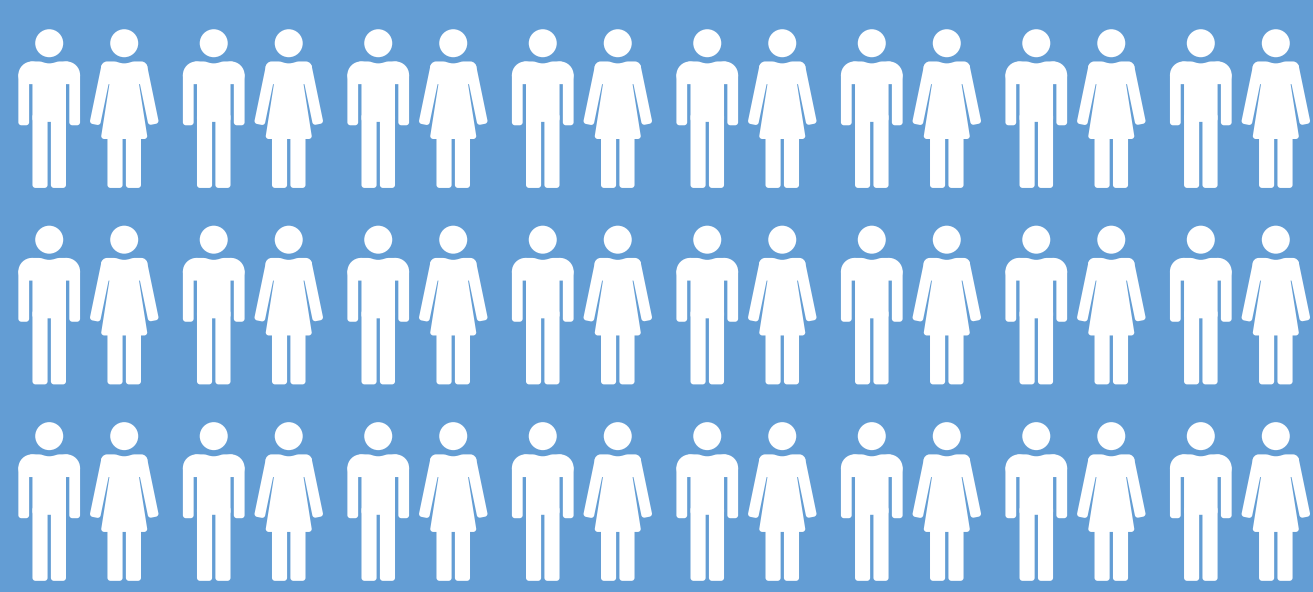
- First tests on humans: healthy volunteers
- Oncology drug clinical trials start directly with patients
- Safety and behaviour of drug in the body tested
- Only about one in ten molecules that enter clinical trials becomes a finished drug



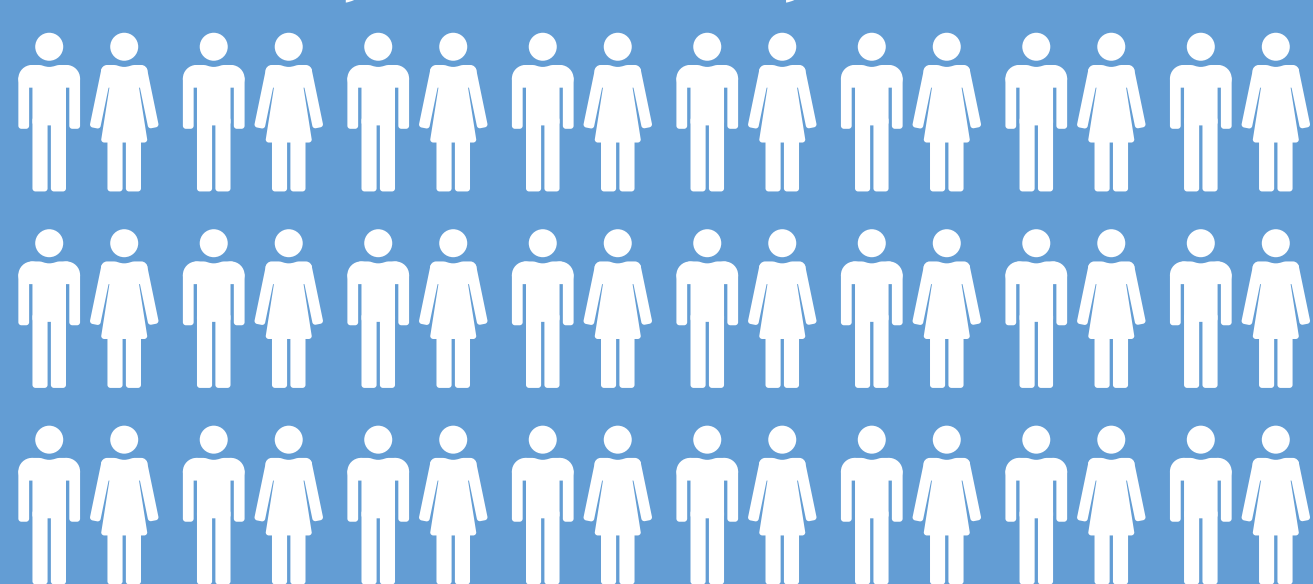
EARLY-PHASE DEVELOPMENT:
about 1 year

PHASE III: 2–4 YEARS

- Aim is to confirm efficacy and safety of drug with statistically significant number of patients
- Hundreds of trial clinics around the world



Patients in clinical trial:
1,000–5,000

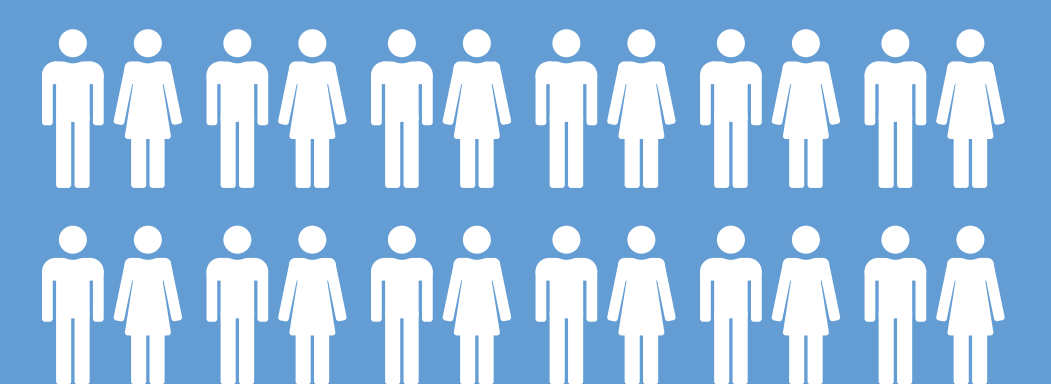



LATE-PHASE DEVELOPMENT:
3–7 years

Marketing authorisation application: about 1 year
Approval of drug by authorities can be sought based on clinical results.

PHASE II: 1–3 YEARS

- Drug tested for first time on actual patients
- Consistency of effects and original idea checked
- Safety and behaviour of drug in the body studied



Patients in clinical trial:
100–500



NEW DRUG AVAILABLE FOR USE IN PATIENTS



Developing an idea into a finished drug takes 10–15 years.

Total costs of developing a new drug up to **EUR 700–800*** million.

*Includes costs of unsuccessful projects.



DRUG SAFETY FOLLOW-UP, PHASE IV:
Data collected on use and possible adverse effects of drug throughout its entire lifespan.