IDEA

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.

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

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.

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

EARLY-PHASE DEVELOPMENT:
about 1 year

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

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

LATE-PHASE DEVELOPMENT:
3–7 years

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

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

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.

ORION
Building well-being