**PRECLINICAL RESEARCH**

Studies on cells and tissue

**PHASE I**

Healthy people and/or people affected by the disease

**PHASE II**

People affected by the disease

Larger group (up to 500)

**PHASE III**

People affected by the disease

Larger group (thousands)

**LICENSING**

Treatment is approved by regulatory agency (e.g. Health Canada, FDA)

**PHASE IV**

Tests over longer period of time

In different groups of people

And/or in combination with other treatments

Most promising compounds from cellular tests are tried on animals to see if a treatment is likely to be useful.

- **Tests**
  - Possible harm
  - Side effects
  - Dosage
  - Compared to placebo (sham treatment)
  - Compared to other treatments or, if unavailable, to placebo

**Efficacy**

- Compared to placebo
- Compared to other treatments

- Adverse reactions

70% move to next phase

Several months

33% move to next phase

Months - 2 years

25 - 30% move to next phase

1 - 4 years

10 to 15 years later

*Statistics based on general data for clinical trials in all disease areas.*

Source: www.fda.gov/patients/drug-development-process/step-3-clinical-research