Clinical Trials Quebec™

The Oversight Process for the Development of a Health Innovation

This infographic presents the steps of the development of a new drug, from laboratory design to use by the public.

Health Canada is the federal agency that regulates and supervises clinical research

Health Canada has an active role in:

- **protecting** the rights and safety of the public
- **assessing** data validity and integrity
- **ensuring** compliance with the *Food and Drugs Act* and the *Food and Drug Regulations*, including good clinical practices

Health institutions and **ethics boards**, in collaboration with Health Canada, evaluate the research project to validate its compliance.

Researchers study a number of **molecules** that can possibly become **promising drugs**.

Researchers test the efficacy and safety of a potential drug based on the results of basic research, by conducting preclinical trials on animal or human cells (in vitro), or on laboratory animals (in vivo). This step is essential before tests can be conducted on humans (clinical research).

Phase I

Used to assess the **safety** and find the **maximum tolerated dose** of the study drug
(15 to 30 people)

Phase II

Used to test the **efficacy** of the study drug and its **side effects**
(about 100 people)

Phase III

Used to confirm the **efficacy** and **safety** of the study drug by comparing it to a placebo or standard treatment
(100 to several thousand people)

Health Canada reviews the results of clinical trials. If the results are satisfactory, Health Canada issues a **Notice of Compliance** and a Drug Identification Number (DIN) authorizing the prescription of the new drug in Canada.
If the results are not satisfactory, the drug will not be authorized for sale in Canada.

L'Institut national d'excellence en santé et en services sociaux (INESSS) analyzes the overall value of the drug (clinical benefits, economic value, and so on). INESSS then sends its recommendations to the Minister of Health and Social Services (MSSS).

The MSSS evaluates INESSS recommendations and considers the outcome of pan-Canadian negotiations. The MSSS determines the conditions under which the new drug will be available to the public via **Régie de l'assurance maladie du Québec** (RAMQ). If the recommendation is negative, the drug will not be covered by RAMQ.

Phase IV

(optional)

The safety, side effects and efficacy of the drug are **continuously monitored** under the actual conditions of use. The monitoring takes place while the drug is available to the public.

Basic research	Preclinical research	Clinical research	Submission to authorities	Health technology assessment, drug approval and access
2 to 3 years	2 to 3 years	5 to 7 years	6 months to 2 years	6 months to 2 years

In Partnership With Québec

In Collaboration With INESSS LE SAVOIR PREND FORME

For more information, visit clinicaltrialsquebec.com