GUIDANCE:
REGISTRATION OF CLINICAL TRIALS

Purpose:
To provide information on why clinical trials are required to be registered in a publicly accessible and recognized database along with the details of where, when and how to register.

What is a Clinical Trial?
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy (ICH, 2016).

Why Register Your Clinical Trial?
Several key international and national level documents outline the requirement and the benefits to registering a clinical trial in a publicly accessible database.

The World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants (October 2024), which was originally adopted in 1964 in response to the conduct of unethical research during World War II, states: *Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant*.

Benefits of Clinical Trial Registration
- Allows awareness of studies avoiding unnecessary duplication
- Increases transparency and accountability
- Prevents publication bias
- Overcoming selective reporting
- Shares knowledge
- Aids in identification of gaps in research
- Timely communication of trial results
- Improves collaboration among Researchers

Where, When and How to Register Your Clinical Trial

For more information on where, when and how to register your clinical trial, please visit Health Canada's Draft Guidance on the Registration of Clinical Trials and Public Disclosure of Results: Registration.

After Registration

It is the Sponsor/Sponsor-Investigator's responsibility to maintain and update the record, in a timely manner, with:

- new information that may affect the willingness of participation;
- safety or efficacy reports or;
- study results.

References:

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