GUIDANCE FOR PHARMACIST PRINCIPAL INVESTIGATOR

Background and Purpose

During the public consultation on the Therapeutics Products Port-over to the Health Products Act in 2015, HSA received suggestions to consider allowing registered pharmacists to be principal investigators (PIs) in clinical trials. MOH noted the potential benefit of having registered pharmacists as PIs in appropriate trials in the push for meaningful clinical research and pharmacists can add value to research by leading and carrying out translational and implementation science type research, tailored to the local setting. This could also strengthen the types of research done.

The Health Products (Clinical Trials) Regulations were hence amended on 1 October 2021 to allow registered pharmacists to be PIs of clinical trials.

Scope of guidance

The guidance is intended to apply to clinical research involving locally registered products of lower risk profiles, including regulated clinical trials.

General Requirements for Pharmacist PIs

The following conditions should be satisfied:

(i) the pharmacists are appropriately qualified by education, training and experience;

(ii) the pharmacists have adequate resources; and

(iii) the pharmacists are able to fulfil the responsibilities of the PI[1] under the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations ("the CT Regulations")

Other Considerations:

Scope of clinical trials

The risk profile of clinical trials of therapeutic/medicinal products and risks to research participants may vary, depending on whether the product is locally registered (and if so, whether its use in the clinical trial is a well-established use or a new unapproved use), or locally unregistered (e.g., investigational products comprising new chemical/biological entities).

[1] The legal responsibilities of a PI include trial supervision and study task delegation, medical care of trial subjects, consent-taking, serious adverse event reporting, investigational product management and labelling, and trial record keeping.

Registered pharmacists may be the PIs for lower risk clinical trials involving locally registered products. These may include Health Services Research[2], Pharmacokinetics[3], Pharmacodynamics[4], Pharmacogenomics[5], Therapeutic Drug Monitoring[6] / Drug Optimisation, Diagnostic Tools[7], Non-interventional[8] and Clinical trials[9]. This list is non exhaustive and is meant to serve as a guide. Such studies should meet the minimal risk definition in the HBRA and be conducted in compliance with the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) E6 Guideline for Good Clinical Practice.

Qualifications and Experience of pharmacist PIs

The following requirements ensure that Pharmacy PIs fulfil a minimum standard for research experience or proficiency. Their research setting should have an established ethical and research governance framework in Singapore, which supports the PI and defines proper accountability for the conduct of research studies by the Pharmacy PI.

The pharmacist PI must have a PhD and/or PharmD and/or other appropriate Postgraduate Qualification, hold a primary appointment in a local institution and salaried by the institution, with a demonstrated track record of research for example, as evidenced by the award of nationally competitive funding, substantial publication record or a laboratory or clinical research program that carries out research in Singapore.

Requirement for physician as a Co-investigator

The pharmacist PI should involve physicians, who are locally registered, as their co-investigators for all interventional clinical trials. This will allow the physicians to provide direct medical supervision and monitoring of the trial subjects. This fulfils the regulatory requirement that all medical care given to a trial participant, and all medical decisions relating to the trial made on behalf of the trial participant should be the responsibility of a qualified physician. This includes obtaining medical history, physical exam and reviewing adverse events.

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[2] Health services research is a multidisciplinary scientific field that examines how people get access to health care practitioners and health care services, how much care costs, and what happens to patients as a result of this care

[3] Pharmacokinetics is a branch of pharmacology dedicated to determining the fate of substances administered to a living organism.

[4] Pharmacodynamics is the study of the biochemical and physiologic effects of drugs.

[5] Pharmacogenomics is the study of the role of the genome in drug response and analyses how the genetic makeup of an individual affects his/her response to drugs.

[6] Therapeutic drug monitoring (TDM) is a branch of clinical chemistry and clinical pharmacology that specialises in the measurement of medication concentrations in blood, focusing on drugs with a narrow therapeutic window. The aim is to improve patient care by adjusting the dose of drugs for which an improved outcome has been shown in the general or special populations.

[7] Examples include pharmacogenomics strategy, drugs levels for levels monitoring

[8] Non-Interventional Study or Non-Interventional Trial: a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation.

[9] A clinical trial is an investigation in respect of a therapeutic product, that involves human subjects, and that is intended to –

(a) discover or verify its clinical, pharmacological or pharmacodynamics effects;
(b) identify any adverse effect that may arise from its use;
(c) study its absorption, distribution, metabolism and excretion; or
(d) ascertain its safety or efficacy.

Monitoring and audits

The healthcare institution (who is the trial sponsor of an investigator-initiated trial) should perform routine monitoring and/or audit of pharmacist-initiated clinical trials to ensure the proper conduct of the clinical trial, as part of the legal responsibility of a trial sponsor under the Health Products (Clinical Trials) Regulations. PIs should maintain proper documentation and be prepared to provide the required documentation to show that proper research protocol has been carried out in compliance with applicable regulatory requirements and principles of Good Clinical Practice.

All clinical trials regulated by HSA, including trials where the PI is a pharmacist, may be subject to a Good Clinical Practice (GCP) inspection to assess compliance with protocol and applicable regulations, GCP and SOPs.

Other considerations

In addition to what is stated in the document, for the purpose of being PIs on research grant applications, the pharmacist should also refer to any additional requirements/eligibility conditions that may be imposed by the funding agency.

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