BOARD OF INVESTMENT

Clinical Research in Mauritius

This document provides an informative summary of the procedure to apply for a clinical research protocol in Mauritius.

Contents

INTRODUCTION

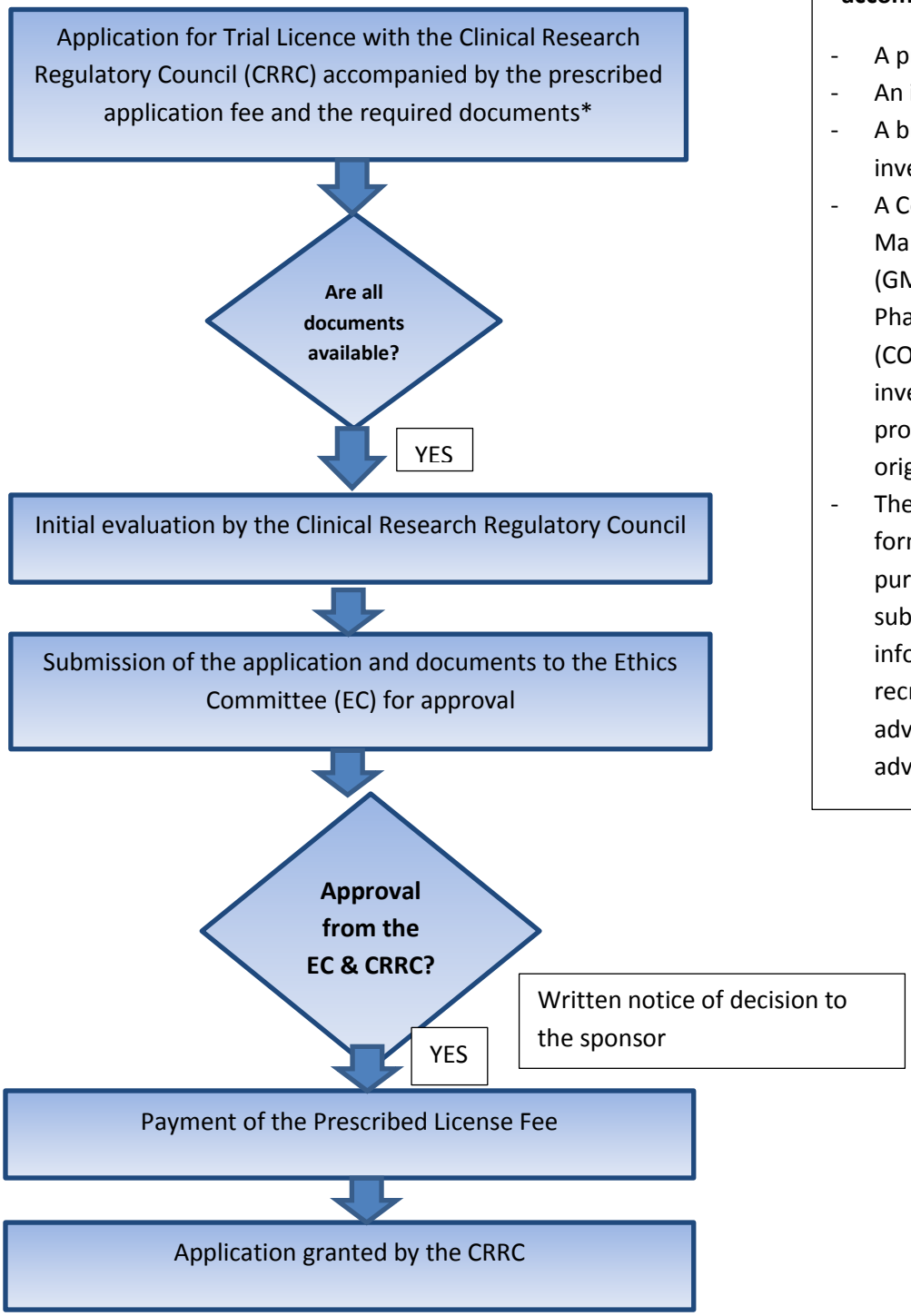
The Government of Mauritius has introduced the Clinical Trials Act with the aim to provide the legal framework to conduct clinical trials.

With the Clinical Trials Act adoption by the National Assembly on the 19 April 2011, Mauritius has seen a major development in its life sciences and research sector. The Act provides the legal framework for the conduct of clinical trials for the purpose of discovering or verifying the effects of investigational medicinal products. Clinical research conducted in Mauritius can provide solutions to a broad range of genetic, infectious and lifestyle diseases like diabetes, cardiovascular diseases, cancer, hypertension amongst others prevailing in Mauritius and countries of the region.

The Clinical Trials Act provides for the setting up of a:

- Clinical Research Regulatory Council (CRRC) responsible for the regulation and control of trial licenses being issued.
- Ethics Committee (EC) to advise the CRRC regarding welfare, safety, health and protection of human subjects participating in clinical trials.
- Pharmacovigilance Committee (PC) to monitor all clinical trials being performed and ensure Good Clinical Practice (GCP).

I. APPLICATION FOR A TRIAL LICENSE



An Application shall be accompanied by 25 copies of:

- A protocol;
- An investigator's brochure;
- A brief C.V of every investigator;
- A Certificate of Good Manufacturing Practice (GMP) and a Certificate of Pharmaceutical Product (COPP) in relation to every investigational medicinal product from its country of origin; and
- The separate and different forms to be used for the purposes of patient and subject information, informed consent, recruitment of subjects, adverse event reports and adverse reaction reports.

The sponsor shall also provide -

- information as to the quantity of every investigational medicinal product to be used in the clinical trial;
- information relating to the measures to be taken for the health, welfare, safety and protection of subjects;
- information relating to financial aspects of the clinical trial, in particular -

    i sources of funding for the clinical trial and information on the financial or other interests of the sponsor relevant to the clinical trial;

    ii the arrangements for the reimbursement of expenses incurred by the subjects;

    iii any provision for compensation in the event of injury or death resulting from the clinical trial, including details of any insurance cover to be contracted for the protection of subjects;

    iv details of any insurance or indemnity to cover the liability of the sponsor and investigator;

    v summary details of any financial arrangements between -

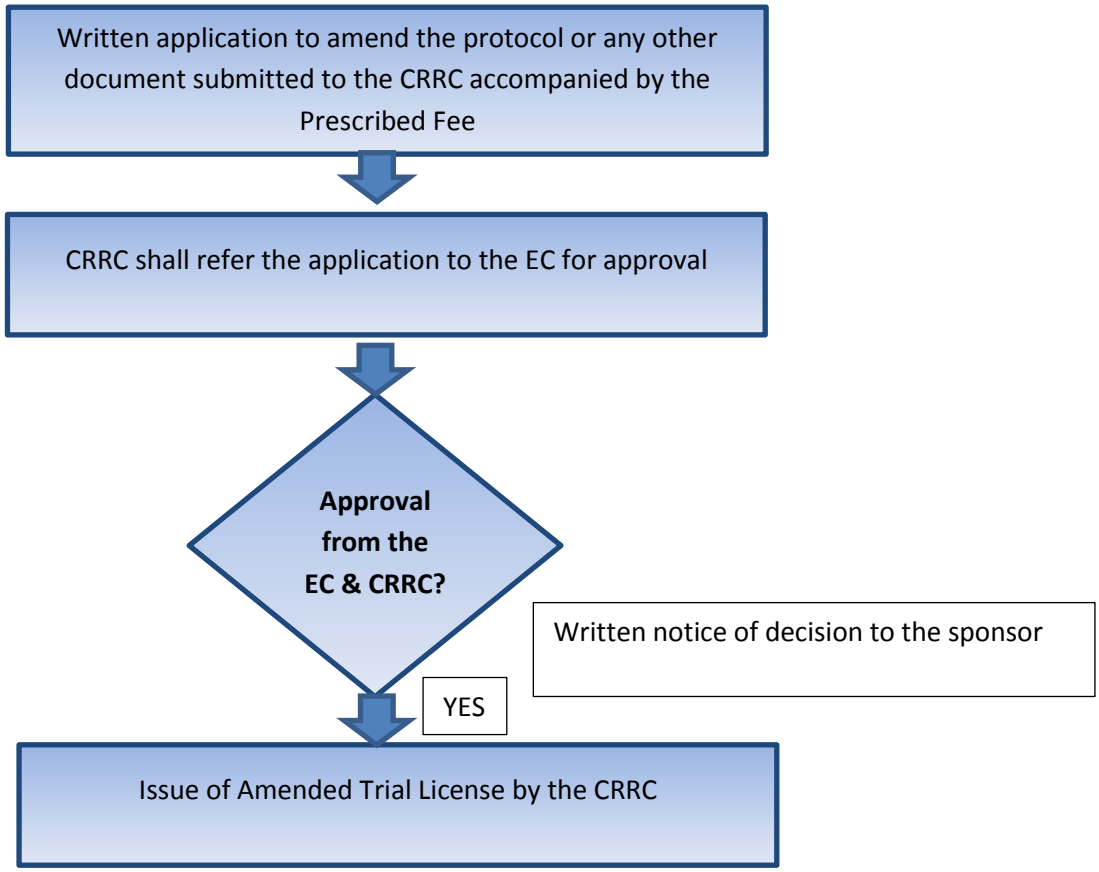
        (A) the sponsor and the investigator; and

        (B) the sponsor and the owner or occupier of the site;

- information relating to the anticipated benefits and risks of the clinical trial;
- information relating to the location, structure and amenities of any site where the clinical trial is to be conducted; and
- such other information as the Council may require.

<u>If all the relevant documents are provided, a trial licence is deliverable within 60 days.</u>

II. AMENDMENT OF A TRIAL LICENSE



III. GOOD CLINICAL PRACTICE

- Clinical trials shall be conducted in accordance with the conditions and principles of good clinical practice.
- The rights, safety and well-being of a subject shall prevail over the interests of science and society.
- Every sponsor shall ensure that any person involved in conducting a clinical trial is qualified by education, training and experience to perform his tasks.
- Every sponsor and investigator shall comply with guidelines prepared or approved by the Council.

The Clinical Research Regulatory Council and Ethics Committee are strictly following the ICH European Guidelines to permit the conduct of Clinical Research in Mauritius:

- **ICH E6:** ***Good Clinical Practice: Consolidated guideline***

- **ICH Harmonised Tripartite Guideline E8: General Considerations for Clinical Trials**

  This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

- **ICH Harmonised Tripartite Guideline E10: Choice of Control Group and related issues in Clinical Trials**

IV. TRIAL MASTER FILE & ARCHIVING

Every sponsor shall keep a trial master file for a clinical trial in respect of which he holds a trial licence.

A sponsor shall make the trial master file readily available at all reasonable times for inspection by the Council or any person appointed by the sponsor to audit the arrangements for the clinical trial.

The trial master file shall at all times comprise documents which –

- enable both the conduct of the clinical trial and the quality of the data produced to be evaluated;

- show whether the clinical trial has been conducted in compliance with –

  (i) this Act and regulations made under it; and

  (ii) the guidelines referred to in section 4(f); and

- contain information specific to each phase of the clinical trial.

A sponsor shall keep, for not less than 15 years after the completion of a clinical trial, the trial master file which shall be –

- readily available at all reasonable times to the Council; and

- complete and legible.

V. PROGRESS & COMPLETION OF CLINICAL TRIAL REPORTS

Every sponsor shall furnish to the Council a written report on the progress of a clinical trial, containing such particulars as the Council deems necessary, not later than 6 months after –

- the date on which the trial licence is issued;

- the end of every subsequent period of 6 months; and

- the completion of the clinical trial.

VI. COMPLETION & DISCONTINUANCE OF CLINICAL TRIAL

A sponsor shall, not later than 90 days after a clinical trial is completed, notify the Council of the completion.

Where a clinical trial is discontinued, its sponsor shall forthwith notify the Council in writing of the discontinuance and the reasons therefor.

VII. FEES

Fees	(Rs)
Application fee	10,000
Fee payable for the issue of an amended trial license	20,000
License fee	
Clinical trial (Phase I) license fee	100,000
Clinical trial (Phase II with a known product) License fee	150,000
Clinical trial (Phase II with an unknown product) License fee	200,000
Clinical trial (Phase III with a known product) License fee	150,000
Clinical trial (Phase III with an unknown product) License fee	200,000
Clinical trial (Phase IV) license fee	20,000
Annual service fee	20,000

VIII. CHAIRPERSONS OF THE REGULATORY BODIES

Clinical Research Regulatory Council	***Dr S.K. Surrun,* Consultant, City Clinic**
Ethics Committee	**Judge Satyabhoosun Domah**, Judge, Supreme Court
Pharmacovigilance Committee	**Dr Jayanandra Dusowoth**, Senior Specialist, SSRN Hospital

All applications for Clinical Research must be addressed to:

The Secretary – Mr Reesaul
Clinical Research Regulatory Council
Atchia Building
Suffren Street
Port Louis

IX. CONTACT

Foreign Contract Research Organisations (CROs) willing to setup in Mauritius, are invited to contact the **Board of Investment (BOI).**
The BOI, the national investment promotion and facilitation agency of the Government of Mauritius, provides the following services free of charge:

- Counseling on investment opportunities in Mauritius
- Providing tailor made information for the setting up of a business in Mauritius
- Organisation of meetings and site visits
- Assistance in identification of joint venture partners
- Assistance with site locations
- Assistance for occupation permits, licenses and clearances.

Mr. Nitin Pandea
Director
Tel: +230 203 3807
Email: health@investmauritius.com