IMPORTS, EXPORTS, MANUFACTURES OR PLACE IN THE MARKET MEDICAL DEVICE FOR THE PURPOSE OF CLINICAL RESEARCH

-CLINICAL RESEARCH USE-

Introduction

Clinical research plays a vital role in advancing healthcare and improving patient outcomes by systematically investigating the safety and effectiveness of various medical interventions. It involves conducting studies in human subjects to evaluate the efficacy of medications, medical devices, diagnostic products, treatment regimens, and medical procedures in an appropriate clinical environment. Through rigorous scientific investigation, clinical research generates essential evidence that informs healthcare practices and policies, improves patient outcomes, and facilitates the development of new therapies and interventions. The results of clinical research studies are critical in determining the safety and efficacy of medical interventions and are used to guide medical decision-making, ensuring that patients receive the best possible care.

The Medical Device Authority (MDA) of Malaysia recognizes the crucial role of clinical research in advancing healthcare and improving patient outcomes. In support of this, the Medical Device (Exemption) Order which was revised and gazetted on February 2024, providing an exemption from registration under Section 5 Act 737 for medical devices used in clinical research. The exemption allows researchers to use these devices without going through the registration process, provided that they meet certain criteria and are being used in an appropriate clinical environment. This exemption helps to support research efforts in Malaysia and allows researchers to use the most appropriate medical devices to conduct their studies.

Scope and Application

This guidance document specifically outlines the eligibility criteria for exemption, the notification procedures, as well as the obligations of applicants or sponsors on the notification of exemption for all classes of unregistered medical devices intended for Clinical Research Use (CRU), which is not intended to investigate the device itself but to facilitate research that would not be feasible without it.

This notification must be obtained prior to conducting clinical studies involving medical devices, and serve to facilitate the process of importing or placing medical devices in the research site.

Terms and definitions

For the purpose of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

Clinical research

means any systematic investigation or study that determines the safety and effectiveness of medications, devices, diagnostic products, medical procedures and treatment regimens intended in or on one or more human subjects, in an adequate human clinical environment;

[SOURCE: Medical Device Exemption Order 2024]

Export

Means to bring or cause to be brought out of Malaysia.

Import

means to bring or cause to be brought a medical device manufactured in another country or jurisdiction, into Malaysia by land, sea or air

Medical Device

a) Any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

iii. investigation, replacement or modification, or support of the anatomy or of a physiological process;

iv. support or sustaining life

v. disinfection of medical device; or

vi. providing information for medical or diagnostic purpose by means of in-vitro examination of specimens derived from the human body which does not achive its primary intended action in or on the human bosy by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

b) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, publis health or public risk, declare to be a medical device by order published in the Gazette.

Eligibility for notification of exemption

Clinical Research Use (CRU) allows for the use of unregistered medical devices in the context of another health research in Malaysia. CRU is not intended for investigating the device itself, but rather to facilitate research that is not feasible without the use of such a device.

The MDA has categorized Clinical Research Use (CRU) into three categories of usage as shown in **Table 1**.

No.	Type of CRU studies	Description
1.	**companion diagnostic test**	A companion diagnostic test is a type of medical test that is used to identify patients who are likely to benefit from a particular therapy or treatment. This type of test is usually developed in conjunction with a specific drug or therapy.
2.	**Screening diagnostic test**	A screening diagnostic test is a type of medical test that is used to identify the presence or absence of a particular disease or condition in individuals who are asymptomatic, or do not yet show any signs or symptoms of the condition. It is typically used in health surveys or population screening programs, where large numbers of people are tested to determine the prevalence of a particular disease or condition in a given population.
3.	**Clinical trial of a medical technique**	A clinical trial of a medical technique is a type of clinical research that evaluates the safety and effectiveness of a new surgical or medical technique or procedure. The goal of these trials is to determine whether the new technique is better than existing techniques or whether it offers additional benefits in terms of improved outcomes, reduced recovery time, or fewer complications. The results of the trial can then be used to inform clinical practice and improve patient outcomes.

Table 1

Process for using Unregistered Medical Devices for Clinical Research Use (CRU)– An Overview

A visual representation of the process for using a medical device for clinical research or research supportive use is illustrated in the diagram 1 as follows:

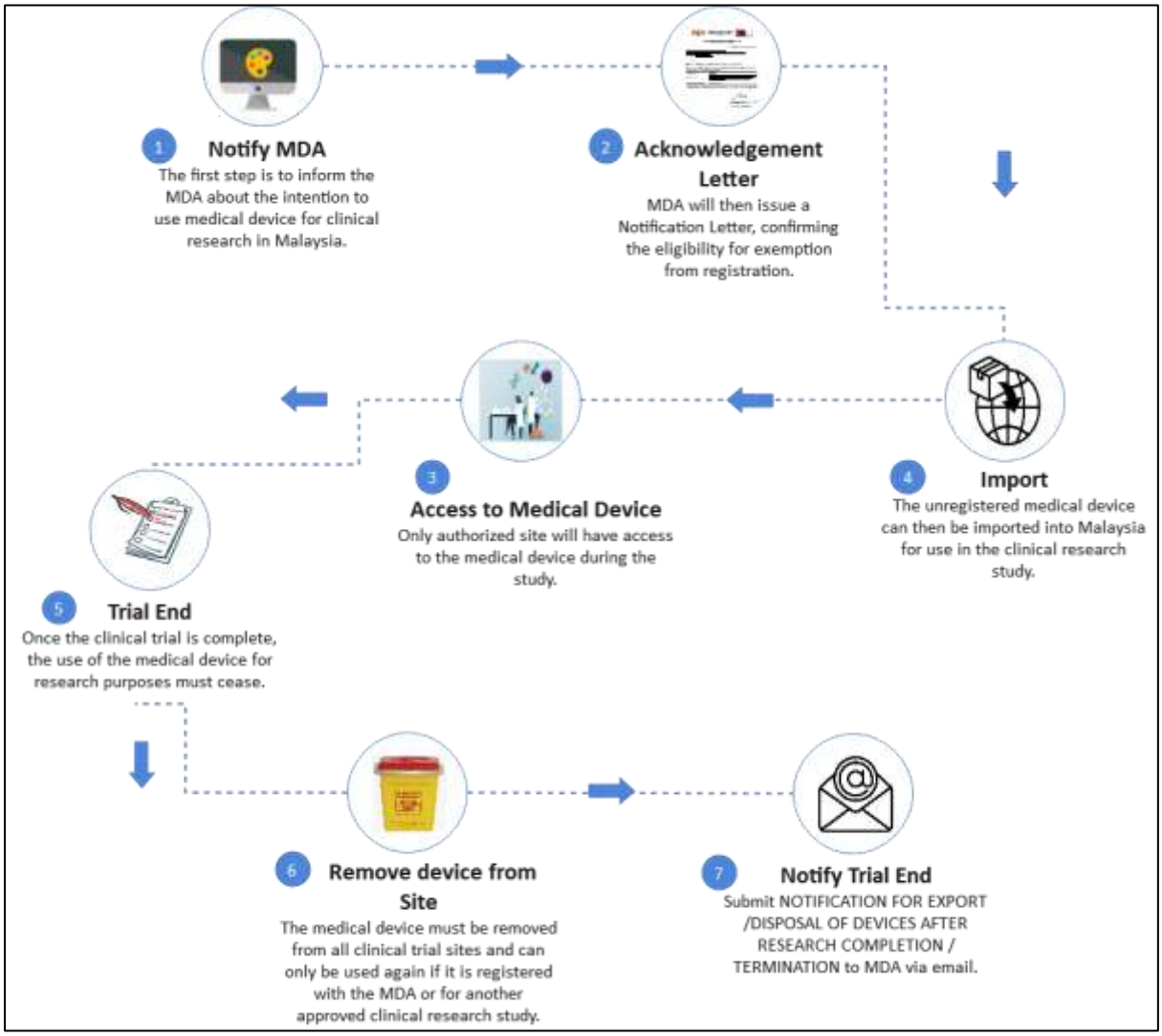

Diagram 1

Notification Process

An applicant who wishes to import and/or supply of a medical device for the purpose of Clinical Research Use shall notify the Authority by following the steps as summarized in Annex A.

Notes:

1. The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not under the purview of the Authority.

2. The applicants who require confirmation if their product is a medical device may refer to guidance document MDA/GD/0006 Definition of Medical Device or submit the 'Product Classification application form' to classification@mda.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website https://portal.mda.gov.my/industry/product-classification.html.

Submission of notification

1) Notification shall be submitted to the Authority at least 14 working days prior to importation or supplying the medical device;

2) The notification process involves completing an online application through the MeDC@St online system and submitting supporting documents.

3) For start, the applicant must create a MeDC@St account (refer to Annex B for details).

4) The details on how to complete the notification are explained in Annex C.

5) If the applicant wishes to make changes or add medical devices or trial sites, a subsequent notification may be submitted following the instructions outlined in Annex D.

Post handling of medical devices after Clinical Research Completion / Termination

After the clinical research has ended, the applicant shall:

1) ensure that these medical devices are properly disposed of or exported out of Malaysia.

2) Submit form 'Notification for Export /Disposal of Devices After Research Completion /Termination - Clinical Research Use' as in Annex E via email.

Administrative charge and Reviewing Process

1) Each new and subsequent notification shall be subject to an administrative charge of RM 300 and RM110 respectively.

2) If, after consideration of all the information provided, the Authority considers that the information provided is incomplete, the Authority may request the missing/incomplete information from the applicant. Any additional information, particulars or documents required by the Authority shall be provided by the applicant within 7 working days from the date of request by the Authority.

3) Failure to meet any of the criteria and/or to reply within the specified timeframe may result in rejection of the notification. The fee for the notification is non-refundable. However it would not affect the right of the applicant to make a fresh notification. The Authority has the right to revoke a written Acknowledgement on Notification if in its opinion, there has been a breach or non-compliance with the specified terms and conditions and/or duties and responsibilities of the applicant

Duties and responsibilities of applicant

1. Import or supply medical devices only after obtaining an Exemption Certificate from the Authority.

2. Use the medical device strictly in accordance with the specified purpose outlined in the Notification form submitted to the Authority.

3. Ensure proper labelling of medical devices in adherence to labelling requirements.

4. Guarantee the safety and compliance of medical devices with essential principles governing safety and performance during use.

5. Adhere to any directives issued by the Authority and allow inspections at any time, without prior notice.

6. Store all information pertaining to medical devices on the premises, making it available upon the Authority's request.

7. Note that this approval does not extend to the importation or continuous supply of medical devices; registration is required for requests beyond Clinical Studies' requirements.

8. The Exemption Certificate is not to be utilized for promotional or advertising purposes.

9. This Certificate of Exemption becomes invalid or will be automatically cancelled if:

    i. There are changes to medical device information and intended purpose.

    ii. There is a violation of the stated terms.

    iii. The concerned medical device has been registered by the Manufacturer or an authorized Representative.