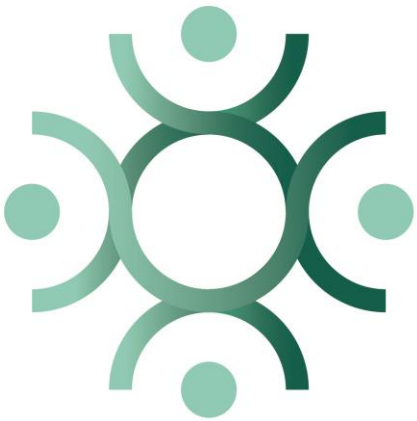

MALTA
MEDICINES AUTHORITY

Guidance for Application for Pre-submission Meeting Request for Clinical Investigations/Performance Studies

Ref No: GL-MDF17/02
August 2024
Medical Devices & Pharmaceutical Collaboration Directorate

1. Introduction

Sponsors or legal representatives who wish to conduct a clinical investigation or a performance study in Malta, must apply for an authorisation from the Malta Medicines Authority and from the relevant Ethics Committee/s in Malta before commencement.

Before the submission of an application or notification for a clinical investigation or a performance study, the Malta Medicines Authority strongly recommends that the applicant arranges a pre-submission meeting with the Authority, to discuss the clinical investigation and obtain further information from the Medical Devices review team on the requirements for authorisation.

Any further clarification on this guidance document may be obtained from the Malta Medicines Authority, by sending an email to *mdforms.medicinesauthority@gov.mt*.

2. Scope

The purpose of this guidance document is to outline the requirements when applying for Pre-submission meeting requests with the Malta Medicines Authority.

3. Terms, definitions & abbreviations

Clinical Investigation
A clinical investigation is defined as any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device. [Regulation (EU) 2017/745 Article 2(45)]
Clinical investigation is referred to as investigation in this document.

Ethics Committee
Ethics committee means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of the Medical Devices Regulation, taking into account the views of laypersons, in particular patients or patients' organisations. [Regulation (EU) 2017/745 Article 2(56) and Regulation (EU) 2017/746 Article 2(59)]

Ethics Committee/s in Malta
Health Ethics Committee; Research Ethics Committee.

Intended purpose
Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. [Regulation (EU) 2017/745 Article 2(12) and Regulation (EU) 2017/746 Article 2(12)]

In-vitro diagnostic medical device

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

[Regulation (EU) 2017/746 Article 2(2)]

Legal Representative

Where the sponsor of a clinical investigation is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to the regulations and shall be the addressee for all communications with the sponsor provided for these regulations. Any communication with that legal representative shall be deemed to be a communication with the sponsor. [Regulation (EU) 2017/745 Article 62(2) and Regulation (EU) 2017/746 Article 58(4)]

Medical Device

A medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception,
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) of the Medical Device Regulation (medical devices, accessories for medical devices, and products listed in Annex XVI) and of those referred to in the first paragraph of this point. [Regulation (EU) 2017/745 Article 2(1)]

Performance Study

A performance study is defined by the In Vitro Diagnostics Regulation (IVDR) as a study undertaken to establish or confirm the analytical or clinical performance of a device. [Regulation (EU) 2017/746 Article 2(42)]

Performance study is referred to as study in this document.

Sponsor
Sponsor means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation or the performance study. (Regulation (EU) 2017/745 Article 2(49) and Regulation (EU) 2017/746 Article 2(57)

Abbreviations

IVDR Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU

MDR Medical Device Regulation referring to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC.

4. Documentation required

In order to apply for a pre-submission meeting, the applicant must fill in the relevant local form.

4.1 General Details related to Applying

4.1.1 Application Form Title

The application form related to this guidance document is *MT-MDF14 Application for Pre-Submission Meeting Request for Clinical Investigations / Performance Studies* which may be accessed from the Malta Medicines Authority website https://medicinesauthority.gov.mt, under the section for medical devices.

4.1.2 Application Format

MT-MDF15 Application Form is in a fillable pdf format. Form should be filled in electronically using the shaded areas. Handwritten forms may not be accepted if writing is considered illegible.
Forms should be signed and submitted as a scanned copy or as a signed pdf file.

4.1.3 Official Languages

The official languages in Malta are Maltese and English. All application forms and supporting documentation must be completed in either Maltese or English.

4.2 Filling in the Application Form

All sections must be completed. The application form is divided as follows:

- Section A - Application Introduction & Applicant Details
- Section B – Manufacturer Contact details
- Section C – Authorised Representative Contact Details
- Section D – Product Information
- Section E – Additional Information Required
- Section F – Details of payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.2.1 Section A: Application Introduction

Section A is divided into two sections:

Section A.1: Date of application and applicant contact details
The individual completing the application shall provide the following information: Date of the application, applicant's name, surname, email address and contact number.

Section A.2: Applicant
Applicant refers to the sponsor or the legal representative of the clinical investigation.
The organisation type making the request, whether the manufacturer or the authorised representative, must be selected. If the organisation is a manufacturer, Section B must be filled in. If the organisation is an Authorised Representative both Sections B and C must be filled in.
It is the responsibility of the applicant to update the Authority of any changes in the details of the application.

4.2.2 Section B: Manufacturer Contact Details

The details of the manufacturer should be included in this section. Local organisations should be registered with the Authority and the reference number must be quoted in this section.

4.2.3 Section C: Authorised Representative Contact Details

An Authorised Representative is required when the manufacturer is located outside the Union. The details of the Authorised Representative should be included in this section. Local organisations should be registered with the Authority and the reference number must be quoted in this section.

4.2.4 Section D Product information

Section D is divided into the following sections:

D.1 Name of product

D.2 Generic name of product

D.3 Catalogue number (where applicable)

D.4 Product intended purpose

D.5 Regulation applied:
In this section, it must be stated whether the product is a medical device falling under the MDR or an in-vitro diagnostic medical device falling under the IVDR
D.6 Class of proposed medical device:
Reference should be made to MDR Annex VIII and IVDR Annex VIII for classification rules.

D.7 Regulatory status of the proposed medical device.
It must be specified whether the device is:

- Non-CE-marked Medical Device,
- CE marked Medical Device to be used within its intended purpose,
- CE marked Medical Device to be used outside the scope of its intended purpose,
- Any other regulatory status, if applicable.

4.2.5 Section E Additional Information Required

Section E is divided into the following sections:

E.1 The applicant must state whether the investigation / study will be conducted in another country.

E.2 The planned timelines for this investigation / study are to be specified.

E.3 Any questions related to this investigation / study are to be listed in this section.

E.4 Any available documentation related to the investigation / study must be submitted with the application.

4.2.6 Section F: Details of Payment

Reference should be made to the *GL-MDF07 Guidance on fees in relation to Medical Devices* available on the Malta Medicines Authority website https://medicinesauthority.gov.mt, under the section for medical devices.

Where applicable, the applicant is requested to attach **Proof of Payment.** This document will be verified by the Finance & Corporate Services Unit at the Malta Medicines Authority, confirming receipt of funds.

4.2.7 Data Protection Consent Statement

Applicant shall confirm consent, by ticking the box in this section, to the processing of personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

4.2.8 Malta Medicines Authority Declaration for Form Submission

Applicant shall sign the Malta Medicines Authority declaration that all the information submitted within this application form is correct and complete.

4.3 Documents Required

- Acknowledged application request submitted to the Ethics Committee/s in Malta if available
- Any available documentation related to the investigation / study
- Proof of payment

5. References

The Malta Medicines Authority - Medical Devices section
https://medicinesauthority.gov.mt/medicaldevices?l=1

GL-MDF07 Guidance on fees in relation to Medical Devices

GL-MDF13 Guidance for Application / Notification for Clinical Investigations under Regulation (EU) 2017/745 on Medical Devices

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act
https://legislation.mt/eli/act/2020/7/eng

S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations https://legislation.mt/eli/sl/458.59/eng

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Signature on File

List of Appendices

N/A