MDCG 2022-20

Substantial modification of performance study under Regulation (EU) 2017/746

December 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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1 Acronyms

EUDAMED European database on medical devices

GSPR General safety and performance requirements

NCA National competent authority

PMPF Post-market perfomance follow-up

REC Research ethics committee

2 Introduction

The sponsor of a performance study is required to submit an application/notification[1] to the Member State(s) in which a performance study is to be conducted, accompanied by the documentation referred to in Chapter I of Annex XIV of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR). The application/notification must be submitted by means of the electronic system referred to in Article 69 of the IVDR.

Additionally, the sponsor of a performance study is required to notify[2] the Member State(s) in which a performance study is being or is to be conducted if it intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the performance study by means of the same electronic system.

In the absence of the European database on medical devices (EUDAMED), a series of performance study application/notification documents have been created to support performance study procedures with respect to the IVDR – see **MDCG 2022-19**.

To add to these documents, a template for 'Substantial modification of performance study under Regulation (EU) 2017/746' is also provided.

Insofar as possible, the modification of the performance study form includes the same data fields as the EUDAMED system in development.

Use of templates

This document is intended to be facilitative and its use by the competent authorities and sponsors is encouraged, however it is important to check with the individual Member State in which the performance study is planned to be conducted for any specific

[1] Performance study application (IVDR Art. 66(1)), PMPF study notification (IVDR Art. 70(1)).
[2] Article 71 IVDR

national requirements. It is foreseen that this template will be withdrawn once the EUDAMED module for performance studies is fully functional.

3 Annex – Templates

Title	Document
Substantial modification of performance study under Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices	 Application form PS Substantial modificati