MedTech Europe
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Industry needs to ensure an efficient implementation and use of the EUDAMED Clinical Investigation and Performance Studies module

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This document gives an industry perspective on the needs which Sponsors have, in order to ensure an efficient implementation and use of the Clinical Investigation and Performance Studies (CIPS) module. This position paper is connected to the broader EUDAMED position paper released in December 2024: Smooth transition to the mandatory use of EUDAMED - Perspectives from manufacturers.

Background:

Compliance activities for the EUDAMED CIPS module are foreseen to be resource-intensive for Sponsors. The 'minimum viable product' (MVP)[1] offers solely manual filling of all CIPS forms for Sponsors, including the Serious Adverse Event reporting form. Also, the CIPS coordinated assessment procedure by Competent Authorities[2] will not be mandatory until 2033, necessitating CIPS application and notification forms to be submitted separately for each country where the same investigation or study is being run, even once the CIPS module becomes mandatory to use as part of the central European database (currently planned for 2027-28).

CIPS functionalities needed for Sponsors to use the system efficiently

MedTech Europe wishes to put forward the following requests regarding essential CIPS module functionalities needed by Sponsors. These requests are based on our findings during the EUDAMED CIPS playground testing. **We ask the European Commission to carefully consider all our requests and communicate their decisions for each so that Sponsors can plan accordingly, in implementing the required software functionality as well as updating their Quality Management Systems.**

Request 1: The Sponsor should not be required to submit applications for registering 'ongoing studies' in EUDAMED once the CIPS module is mandatory to use.

An 'ongoing investigation/study' here is meant as a clinical investigation, performance study or PMCF/PMPF[3] study already authorised to start, or which was started under the MDR/IVDR outside EUDAMED and for which the last patient's last visit/testing was not yet completed at the time when the use of the CIPS module became mandatory.

Only new studies to be authorised or notified after the CIPS module becomes mandatory should be requested to be submitted through the central database. For ongoing studies, only substantial amendments initiated after CIPS mandatory use should be registered in EUDAMED using only the CIV-ID number and not any other study information already submitted at national level.

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[1] See: EUDAMED Functional specifications 7.2

[2] See: Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

[3] Post market clinical follow-up and post market performance follow-up (PMCF/PMPF) studies covered by MDR Art 74(1)/ IVDR Art 70(1)

Rationale:

Sponsors will already have fulfilled their legal obligation to report required information for initiating a study at national level. Therefore, it should not be required for them to retroactively submit their ongoing studies in the CIPS module once it becomes mandatory. Repeating this submission again in the CIPS module would create duplicative work in the reporting requirements which should be avoided.

During EUDAMED playground testing, Sponsors noted that the level of information and documentation required for the registration of ongoing studies would be the same as required for new investigation/study applications or PMCF/PMPF notifications, whereas all this information has already been provided and reviewed via the respective national procedures applicable before the mandatory use of EUDAMED. These aspects would bring a major administrative burden to Sponsors.

Request 2: MedTech Europe requests that the European Commission prioritise and implement Machine to Machine (M2M) and XML functionalities for upload and download of the Serious Adverse Events (SAE) form before the notice confirming the functionality of the CIPS module is published in the Official Journal of the EU.

Rationale:

All activities for Sponsors in the MVP version of CIPS are currently being developed as entirely manual processes. Machine to Machine (M2M) and XML upload and download of Serious Adverse Event (SAE) reports will be prioritised only after the MVP version is implemented, as outlined in the EUDAMED Functional specifications v7.2 (see high priorities No. 3 and 9). The ability to upload and download SAE reports via automated data exchange is critical for the Sponsor to efficiently transact in the system. It also is needed to allow the Sponsor to retain a copy of the submitted information for their own records which is critical to ensure compliance with document and data control requirements of the IVDR and MDR.

The 19-page draft SAE form (not yet in the playground) requires extensive information similar to the Manufacturer Incident Report form which exists in the Vigilance module, and for which the M2M and XML upload is already confirmed in MVP[4]. Sponsors anticipate that it will not be feasible to process all the data for each SAE report without an automated M2M and XML upload and download capability. It is important that the European Commission deliver the capability for the CIPS module to enable Machine to Machine and XML upload and download of SAE reports before the CIPS module is declared functional. This will allow the Sponsor to efficiently and compliantly report SAEs via EUDAMED once the CIPS module becomes mandatory to use[5].

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[4] See: EUDAMED Functional specifications 7.2

[5] According to MDR Article 123.3d and IVDR 113.3f, the CIPS module is mandatory to use 6 months after it is declared functional in a notice published in the OJEU.

Transition to the mandatory use of the CIPS module

The industry needs both guidance and a sufficient transition period to effectively comply with the CIPS module. MedTech Europe therefore makes the following requests to enable a smooth transition to mandatory use of the CIPS module.

According to MDR Article 123.3d and IVDR 113.3f, the CIPS module is mandatory to use 6 months after the notice confirming the module's functionality has been published in the Official Journal of the EU. As per the Medical Device Coordination Group (MDCG) EUDAMED WG decision, the CIPS module is not foreseen to be released in production when it will legally be confirmed functional, only 6 months after: when it will be mandatory to use.

The immediate use of the CIPS module on a mandatory basis as soon as it is released entails multiple risks especially for Sponsors, so MedTech Europe requests to change this approach:

Request 3: MedTech Europe asks the European Commission and the Member States to provide a transition period for the mandatory use of the CIPS module.

The CIPS module should be launched in production and be made accessible for users as soon as the notice confirming the functionality of the CIPS module will be published in the OJEU, and not 6 months later when its use is mandatory.

Guidance on the transition is needed for Sponsors to start the mandatory use of the CIPS module, and to update their Quality Management System in advance, and train their personnel. The CIPS transition guidance should explain, in particular, the regulatory requirements for the different scenarios in EUDAMED to ensure a smooth transition from national to central EUDAMED processes – see Annex I for more detail on the different scenarios.

In that respect, MedTech Europe requests that the European Commission:

- Require serious adverse event (SAE) reporting in EUDAMED solely for newly initiated studies and only once M2M and XML upload and download capabilities are available and implemented for Sponsors. Until then, Sponsors should be able to continue safety reporting via MDCG 2020-10/2 Rev. 1 and MDCG 2024-4 Excel report either outside of EUDAMED or via upload in EUDAMED.
- Allow Sponsors to continue submitting the MDCG 2020-10/2 Rev. 1 and MDCG 2024-4 Excel reports outside of EUDAMED for all ongoing studies (even for those with substantial amendments), including new and ongoing events, for all countries and even after the M2M and XML upload and download capabilities are available.

Rationale:

The Sponsor or their legal representative will first need to obtain access to the EUDAMED CIPS module via the Actor module. Therefore, MedTech Europe requests a transition period for mandatory use of CIPS by allowing access for Sponsors to the central system as soon as the notice confirming the functionality of the CIPS module is published in the OJEU.

The issuance of a CIPS transitional guideline is equally important to ensure smooth transition from national to central submission via the CIPS module once it is launched.

Allowing Sponsors to continue to submit the MDCG 2020-10/2 Rev. 1 and MDCG 2024-4 Excel reports for ongoing studies for all applicable countries, including new and ongoing events, even after M2M and XML upload and download capabilities are available, will enable uniform reporting methods within one investigation/study across participating countries, and will subsequently support consistent data analysis for the entire investigation/study.

MedTech Europe asks the European Commission to consider these requests as they analyse and restart the development of the CIPS module. The industry stands ready to support this important work towards our shared goal of ensuring an efficient implementation and use of the CIPS module.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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Annex I - Study upload scenarios in EUDAMED Clinical Investigation and Performance Study (CIPS) module

This annex maps out the various scenarios for submitting investigation/study applications, Post market clinical follow-up and post market performance follow-up (PMCF/PMPF) notifications[6] and Serious Adverse Events (SAEs) in the EUDAMED CIPS module. Please confirm the below interpretation of the legal requirements and the scenarios in a transitional guidance document to ensure a smooth transition for the CIPS module mandatory use. Thank you!

	Clinical Investigation and Performance Study application and PMCF/PMPF notification once EUDAMED CIPS module becomes mandatory	**SAE reporting once EUDAMED CIPS module becomes mandatory**
Study started under MDD/AIMDD/IVDD and is ongoing when EUDAMED CIPS module becomes mandatory for use		
MDD/ AIMDD/ IVDD	Not Applicable There is no MDR/IVDR requirement to register studies in EUDAMED which started before the Date of Application of MDR/IVDR	No. Continue SAE reporting outside of EUDAMED per MDCG 2020-10/1 Rev. 1, using MDCG 2020-10/2 for studies started before the Date of Application of IVDR/MDR (incl. ongoing and new events) **See Request 3**
Study started before the Date of Application of MDR/ IVDR (under MDD/AIMDD/IVDD) and additional countries were added after the Date of Application of MDR/IVDR. Study is ongoing when EUDAMED CIPS module becomes mandatory for use		
MDR Art 62/ IVDR Art 58	No. Note: ONLY countries initiated after CIPS module becomes mandatory to be submitted as substantial amendment **See Request 1**	No. Instead of Chapter 4.1.1 of MDCG 2020-10-1 Rev. 1, continue SAE reporting outside of EUDAMED per MDCG 2020-10/1 Rev. 1, using MDCG 2020-10/2 for ALL ongoing events and new events reported after CIPS module is mandatory for use **See Request 3**
MDR Art 74(1)/ IVDR Art 70(1)	No. Note: ONLY countries initiated after CIPS module becomes mandatory to be submitted as substantial amendment **See Request 1**	Instead of Chapter 4.1.1 of MDCG 2020-10-1 Rev. 1, continue SAE reporting outside of EUDAMED per MDCG 2020-10/1 Rev. 1, using MDCG 2020-10/2 for ALL ongoing events and new events reported after CIPS module is mandatory for use **See Request 3**
MDR Art 82(1) no IVDR equivalent	Not Applicable. There is no MDR requirement to register MDR Article 82 studies in EUDAMED	Not Applicable. Continue SAE reporting per applicable national requirement, outside EUDAMED

[6] Post market clinical follow-up and post market performance follow-up (PMCF/PMPF) studies covered by MDR Art 74(1)/ IVDR Art 70(1)

Study started after the Date of Application of MDR/ IVDR and before the mandatory use of the CIPS module and is still ongoing when the module becomes mandatory for use		
MDR Art 62/ IVDR Art 57	No. Note: ONLY substantial amendment initiated after CIPS module becomes mandatory to be notified **See Request 1**	Instead of Chapter 4.1.1 of MDCG 2020-10-1 Rev. 1, continue SAE reporting outside of EUDAMED per MDCG 2020-10/1 Rev. 1, using MDCG 2020-10/2 for ALL ongoing events and new events reported after CIPS module is EUDAMED CIPS module mandatory for use **See Request 3**
MDR Art 74(1)/ IVDR Art 70(1)	No. Note: ONLY substantial amendment initiated after CIPS module becomes mandatory to be notified **See Request 1**	Instead of Chapter 4.1.1 of MDCG 2020-10-1 Rev. 1, continue SAE reporting outside of EUDAMED per MDCG 2020-10/1 Rev. 1, using MDCG 2020-10/2 for ALL ongoing events and new events reported after CIPS module is mandatory for use **See Request 3**
MDR Art 82(1) (no IVDR equivalent)	Not Applicable. There is no MDR requirement to register MDR Article 82 studies in EUDAMED	Not Applicable. Continue SAE reporting per applicable national requirement, outside EUDAMED.
Study started after the Date of Application of MDR/ IVDR and after the mandatory use of the CIPS module		
MDR Art 62/ IVDR Art 57	Yes. Initial submission in EUDAMED for all participating EU countries	SAE reporting for ALL events in EUDAMED using M2M and XML upload
MDR Art 74(1)/ IVDR Art 70(1)	Yes. Initial submission in EUDAMED for all participating EU countries	SAE reporting for ALL events in EUDAMED using M2M and XML upload
MDR Art 82(1) no IVDR equivalent	Not Applicable No MDR requirement to register MDR Article 82 studies in EUDAMED	Not Applicable SAE reporting per applicable national requirement, outside EUDAMED