FAQ pilot coordinated assessment for sponsors

1. **Can I submit multiple expressions of interest for different studies?**
   Yes, multiple applications for different studies can be submitted within the limit of available Member States after each submission. Member States available.

2. **Can I submit an application that includes a Member State not participating in the pilot coordinated assessment?**
   In principle, yes; however, the pilot coordinated assessment will only cover the participating Member States and you will need to contact the Member State(s) not participating separately and be prepared to submit a national level application.

3. **Is there a minimum number of Member States for the pilot coordinated assessment to take place?**
   At least two Member States need to participate in a pilot coordinated assessment.

4. **If I participate in the pilot coordinated assessment, do I still need to apply at national level?**
   As per Article 78(14) MDR, as modified by Article 1(3) of Regulation (EU) 2024/1860 , the conclusion of the assessment, as communicated through the final assessment report, will not be legally binding during the pilot. Therefore, once the conclusion has been transmitted, individual applications will have to be submitted to the relevant competent authorities, which will issue individual national decisions. However, it is foreseen that the national decisions will be both expedited and harmonised, thus reducing overall the effort and time for approval (see consolidated version of the MDR).

5. **Are there any fees involved in the pilot coordinated assessment?**
   The pilot coordinated assessment doesn't involve any costs. However, each Member State sets its fees on the currently necessary national decisions.

6. **What is the deadline for applying to be part of the pilot coordinated assessment?**
   The deadline for this year's first round of calls is 30th of June 2025.

7. **Am I expected to submit the application soon after sending the expression of interest?**
   No, the actual date of the application will be determined by discussions with the Member States and the secretariat, based on the sponsor's foreseen timelines. Flexibility may be given to accommodate possible changes in the sponsor's timelines upon agreement with the Member States.

8. **How long after expressing interest will the pilot coordinated assessment start?**
   The sponsors are expected to indicate in their expression of interest the desired starting month (and week, if known) for the pilot coordinated assessment. However, a staggered approach might be implemented depending on the volume of the applications received. Please see the "Who can apply and eligibility conditions" and priority criteria on the call's webpage. In all cases, the secretariat will contact the sponsors to further discuss the process in detail.

9. **How long will the pilot coordinated assessment take? Will taking part in the pilot coordinated assessment ensure faster approval at national level?**
   The pilot coordinated assessment will follow the timelines detailed in Article 78 MDR and Article 74 IVDR.
   Taking part in the pilot coordinated assessment is foreseen to lead to an expedited and harmonised subsequent decision at the level of Member States involved in the process. For more details, please see the "List of national requirements" and "Documents for national submission" tables.

10. **How will the application file be submitted?**
    The application file will be submitted by using secure CIRCA-BC. The secretariat will provide a comprehensive package, including tutorials, to each applying sponsor.

11. **Is there any support available for the interested sponsors?**
    Yes, the Commission established a dedicated secretariat to assist the sponsors during the process. The secretariat can be contacted at SANTE-CA-CIPS@ec.europa.eu.

12. **How will the results of the pilot coordinated assessment be used? Who will have access to these results?**
    The results of the pilot coordinated assessment will only be shared with the participating Member States, who will have access to the detailed outcomes. However, Member States not participating in the pilot coordinated assessment may

have the opportunity to follow the steps of the procedure for learning purposes, should the sponsor accept this.

13. **Is there a requirement to obtain the ethics approval before submitting the technical file for the pilot coordinated assessment?**
    No, obtaining the ethics approval before starting the pilot coordinated assessment is not required. However, some Member States require the ethics approval before the submission at national level, see question number 4. In addition, it is best for the ethics approval to be available as soon as possible to enable the expedited assessment at the time of national submission.

14. **What language(s) will be required for the documents?**
    The pilot coordinated assessment will take place in English. However, the Member States may request the documentation or parts of it in the national language for subsequent national submissions.

15. **Will sponsors need to anticipate the implementation of specific IT tools before participating in the pilot?**
    No specific IT tools need to be integrated into the sponsor's internal IT systems before participating in the pilot. For the application, the sponsor will use CIRCA-BC, (browser-based). General communication will take place by email.
    Moreover, before the launch of the pilot, the sponsors will receive a comprehensive package on the usage of IT tools during the process. Additionally, a bilateral exchange will happen between the sponsor and the secretariat to ensure the good functionality of the existing IT tools used by the secretariat.

16. **Is it foreseen that substantial modifications of the clinical investigation in the scope of the pilot will also be treated in a coordinated manner?**
    Yes, the intention is also to run substantial modifications through the coordinated assessment. This facility is expected to be developed in the near future. The same approach for assessing the application will also apply to the substantial modifications.

17. **How will safety information reports of the CI that are part of the pilot coordinated assessment be assessed?**
    From a sponsor's perspective, the reportable events will have to be reported to all participating Member States as per the normal practice.

18. **Once the expression of interest is submitted, what are the next steps for the sponsor?**

    The Member States will review the expression of interest and confirm the selection. Within 3 weeks, the sponsor will be informed if they were accepted or not. Moreover, the secretariat will provide an information package outlining the next steps and organize bilateral exchanges if needed.

19. **Can the sponsors engage in a pre-submission dialogue with the competent authorities who plan to be involved in the coordinated assessment?**

    If selected, pre-submission dialogues with the Member States may be organised.

20. **How is a reporting Member State selected?**

    The sponsor will propose the reporting Member State (i.e. the Member State which will coordinate the assessment) in the application. The Member States will then agree on one Member State as reporting Member State. If they do not agree on a reporting Member State, the reporting Member State suggested by the sponsor will assume that role. See Article 78 of MDR and Article 74 of IVDR.

21. **If one of the Member States I plan to run the clinical investigation in is not participating in the pilot coordinated assessment, may I submit a national application in parallel?**

    Yes, the two processes are independent. There is no need to wait for the result of the pilot coordinated assessment to submit a national application in a Member State not participating in the respective pilot coordinated assessment. However, it is ideal that the two applications are as close as possible in terms of content to ensure harmonization for the respective study.

22. **If my study involves both a device and a medicinal product, can it be considered for the pilot coordinated assessment?**

    This pilot coordinated assessment focuses on standalone MDs for clinical investigations and IVDs for performance studies. For studies involving both a medicinal product and a MD/IVD (combined studies), it is possible to go in parallel through a coordinated assessment under the CTR, and a pilot coordinated assessment under the MDR/IVDR.

    Furthermore, combined device-medicinal product studies are the subject of the COMBINE programme. One of the projects under the COMBINE programme is a pilot of "all-in-one" coordinated assessment of combined studies, which is distinct from the device-specific pilot described in this FAQ.

23. Is the pilot coordinated assessment for CI/PS the same as the COMBINE "all-in-one" coordinated assessment?

No, the pilot coordinated assessment for CI/PS is distinct from the COMBINE pilot. While both projects are running in parallel, they have different scopes and objectives. For studies falling under COMBINE, please refer to the COMBINE programme webpage.

24. Where can I find the documents that are needed for the clinical investigation applications with respect to MDR in the absence of EUDAMED?

The list of documents created to support the clinical investigation applications in the absence of EUDAMED can be found in the annex of the MDCG 2021-08 document.

25. Will I need to submit additional documents at the national level after the pilot coordinated assessment is completed?

The documents needed for the approval of a clinical investigation in the context of the pilot coordinated assessment are the following:

a) In principle, the documents found in the annex of the MDCG 2021-08 document (see question 24), and the documents mentioned in the "List of national requirements" table. This will be done through sCIRCA-BC portal (see question 15).
b) For the confirmatory submission at national level following the pilot coordinated assessment, the documents required are found in the "Documents for national submission" table. Please be aware that due to national administrative requirements, some Member States may require a complete submission comprising points a) and b). This submission may be done through specific national systems.

The details will be discussed with the involved Member States during the pre-submission meeting.

26. If I am an entity located outside the EU, would an EU legal representative need to send the application?

In principle, the submission of an expression of interest may be filled in either by the entity outside the EU or by its EU legal representative. However, please be aware that According to Article 62(2) MDR a legal representative in the EU is needed to apply to the pilot coordinated assessment and, subsequently, for the national confirmation.