HEU-EFS Open Call For Pilots

FREQUENTLY ASKED QUESTIONS

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Do you envisage EFS to become a prerequisite for the "pivotal" clinical investigation, and what impact could this have on a manufacturer/sponsor resources?

It is not the intent of the program to mandate the conduct of an Early Feasibility Study (EFS) for all technologies. Rather, sponsors/manufacturers should utilize the clinical evidence plan established by the Medical Device Regulation (MDR) to document the appropriate clinical evidence pathway and revise that plan as needed throughout the product development lifecycle. EFS represent a valuable tool at the sponsor's disposal to refine and finalise the device design by assessing the technology in a limited patient population before moving into confirmatory clinical investigations such as pivotal clinical investigations.

Can an EFS reduce the number of patients in a premarket clinical investigation under the MDR even if the device will receive some design changes after the EFS?

No, the evidence gathered from Early Feasibility Studies (EFS) is not sufficient to obtain the CE mark. EFS is to answer very specific clinical questions to finalise the device design/device procedure.

Is it possible to perform Early Feasibility Studies (EFS) on healthy volunteers to evaluate technical performance?

For low-risk devices this is a possibility. However, this falls outside the scope of the HEU-EFS pilots, which focus on Class III high-risk devices addressing unmet medical need, that are breakthrough devices, or intended to improve anatomical understanding- for which an EFS will be conducted. For invasive high-risk devices, the MDR (EU) 2017/745 (Medical Device Regulation) requires that participation in the clinical investigation will produce a direct benefit for the patient; if the patient is healthy, then this may not be approved by the National Competent Authority (NCA) and Ethics Committee, however, this would fall outside the scope of the HEU-EFS pilots.

Are different requirements for the different classes of medical devices possible? The benefit risk ratio is different, e.g., for a compression bandage vs a stent.

Yes, the Medical Device Regulation (MDR) uses a risk-based approach to medical device safety. Article 70 of the MDR describes that there are different processes for clinical investigations for non-invasive class IIa and class IIb devices and invasive IIa, IIb and class III devices. Risk classification is determined according to Annex VIII of the MDR. The ISO standard for Risk Management of Medical Device ISO 14971 lays out the framework for establishing a risk management system. Based on the determined benefit–risk ratio for a device the MDR Article 2(24), Article 61, and Annex I (Chapter I) describes further details. Different device classes are inherently associated with varying levels of risk; however, each device requires individual benefit -risk analysis. For initiating an Early Feasibility Study (EFS), it is essential that the individual device overall benefit–risk ratio is favourable, irrespective of the device risk class.

Do we know why some countries in Europe such as France, Germany, Belgium have higher number of Early Feasibility Studies (EFS) compared to others?

We are currently exploring these details through ongoing individual consultations with the National Competent Authorities (NCA). For further details on the analysis of the EFS included in the EFS-Database, see Deliverable D1.3 Characteristics and state of play of EFS.

Early feasibility studies aren't only conducted in one or two countries? Is it easy for a startup to contact the NCA in their country?

Based on the Medical Device Regulation (MDR), the EU National Competent Authorities (NCA) provide information on their website on how they can be contacted, and the MDR details of the approval process, the required documentation, applicable timelines. Fees fall within the national remit and are therefore described by each NCA: see Contact Point of National Authorities.

Do some countries provide consolidated EC/NCA submission and approvals for EFS?

The ethical approval of clinical investigation applications falls within the national remit of each EU/EEA Member State. Consequently, the approval by the respective National Competent Authority (NCA) of a clinical investigation, including an (Early Feasibility Study) EFS, may occur after, or in parallel with the Ethics Committee (EC) review. In some countries, a consolidated or joint process is in place, one example of this would be Belgium or the Netherlands. However, as mentioned potential sponsors then need to check the NCAs website for details.

Could you please provide examples of what you call „harmonized standards"? What does „harmonized" refer to? Investigator Brochure content? Ethical criteria? Safety surveillance?…

In the HEU-EFS project we are aiming to harmonise the process for conducting Early Feasibility Studies (EFS) within the European Union (EU), so when we refer to harmonisation, we mean finding alignment between national Member State processes, procedures and practices. To promote harmonisation, we have also developed a dedicated process, and prepared several templates and checklists (i.e., clinical investigation plan, informed consent form, master clinical trial agreement, insurance agreement) to ensure that the preparation of the clinical investigation application is harmonised as well. These will be made available to applicants participating in the pilot phase.

Acceleration and efficiency processes seem like an important way forward. Can this be done within the MDR framework or would that require amendment?

By providing opportunities for early dialogue before the application, and informational and training materials to prepare the application, the sponsor should be better able to determine what is needed for the Clinical Investigation (CI) application. This allows the sponsors to tailor application materials to better inform National Competent Authorities (NCAs), who will already be familiar with the sponsor and the device from the initial Contact Point. The

envisaged reduction of timelines for validation and review by the National Competent Authorities will be strongly encouraged yet applied on a voluntary basis in the pilot projects.

Why are you confident that the review timelines for EFS can be shortened when NCAs often exceed timelines for clinical investigations?

The Early Feasibility Study (EFS) process proposed by the HEU-EFS project envisages the introduction of a contact point, to introduce the EFS to the relevant National Competent Authorities (NCAs) followed by early dialogue between sponsors and NCA(s), where issues or questions that might normally cause delays can be addressed before the application process. These early exchanges may help to reduce inefficiencies at a later stage. Moreover, the eligibility criteria (see D3.1 Eligibility criteria for EFS) have been thoughtfully defined to ensure the EFS studies remain very focused in scope. In addition, the standardized templates and checklists (e.g., clinical investigation plan, informed consent form, master clinical trial agreement, insurance agreement) and the informational and training materials developed by the project are expected to enhance the overall quality of applications. This, in turn, will further contribute to improving the efficiency of review processes and shortening timelines. Within the process there is a high expectation that the sponsor should respond quickly to any requests for further information that may come from the NCA during the validation and/or review process. It is also important that the sponsor involve stakeholders such as relevant Principal investigator of clinical site and the clinical site personnel where appropriate.

Are the checklists and templates going to come on top of what National Competent Authorities (NCAs) already request?

Checklists are provided as guidance for sponsors, who may also use their internal templates. While our aim is to design a harmonised framework with harmonised templates, we provide checklists for sponsors to verify whether documents are aligned with the Consortium templates. The checklist identifies the minimum requirements, the minimum set of information, that must be included in the documents. The documents (and any other templates and checklists from the HEU-EFS program) are intended as aids but are not mandatory. All are meant to improve the quality and completeness of sponsor applications to improve efficiency during the process, thus providing opportunities to potentially accelerate the process.

Are the checklists and templates also applicable for low risks devices?

Checklists and templates can be adapted and used for devices of all risk classes. However, as the HEU-EFS pilots are for high-risk medical devices (i.e., Class III and Class IIb), and the templates and checklists are tailored towards this.

Are all National Competent Authorities (NCAs) informed of the work and pilots?

All NCAs that are members of the Medical Device Coordination Group (MDCG) Subgroup for Clinical Investigation and Evaluation and Performance Studies and Evaluation (CIEPSE) have been informed of the ongoing work of the HEU-EFS project through communications, surveys, interviews, workshops, and public events. The members of the subgroup have been contacted to verify the information collected as part of the mapping of

processes and documents required for approval of pre-market clinical investigations (HEU-EFS Pre-Market Approval Pathways Database, to be shortly released on the project website). A subset of EU National Competent Authorities have participated in surveys, focus groups, and 90-minute one-to-one interviews to discuss their experiences with Early Feasibility Studies (EFS). In addition, several National Competent Authorities are part of the HEU-EFS Advisory Board.

Are pilots expected to come just from sponsors? Will healthcare providers/health systems be able propose a pilot?

Yes, if a healthcare provider or health system develops a medical device, it may act as a sponsor of a clinical study and therefore can propose a pilot in line with eligibility criteria specified in Deliverable 3.1 Eligibility criteria for EFS. The requirements for the sponsors are identified in the Medical Device Regulation (MDR).

Could you please share the Early Feasibility Studies (EFS) templates and guidelines (if available) for the sponsor to reference while waiting for your work to be completed?

All public deliverables, publications and training materials will be uploaded to the project website (https://heuefs.eu/deliverables/) once approved by the Innovative Health Initiative (IHI). Sponsors participating in the pilot after successful submission of the application to the Screening Committee will be provided guidance.

Will the pilot case proposal application from a Company need to list the medical device as well clinical sites?

Initial information collected from the Expression of Interest for the pilots is general only (e.g., therapeutic area, estimated risk class). Information on the open call for pilots, along with general eligibility criteria, can be found on the HEU-EFS website (https://heuefs.eu/open-call-for-pilots/), along with the initial Expression of Interest online form.

Will you provide recommended clinical sites if a sponsor participates in the pilot?

The consortium will not provide a list of recommended clinical sites. Sponsors can gain insight on clinical sites with Early Feasibility Studies (EFS) experience from the HEU-EFS database, part of HEU-EFS Deliverable D1.3 Characteristics and state of play of EFS covering the analysis of EFS studies carried out so far around the world.

How can you apply for a pilot? Is there a deadline?

Information on the open call for pilots can be found on the HEU-EFS website (https://heuefs.eu/open-call-for-pilots/), along with the initial Expression of Interest online form. The open call is already active, and the deadline for applying is March 31, 2026. Applicants should aim to submit the application of the Early Feasibility Study (EFS) to the National Competent Authority (NCA) no later than November 30, 2026.

What date/timeline are the final proposal/recommendations due to be submitted?

The final recommendations of the HEU-EFS project will take into account the learnings from the pilot cases, and will be finalised before the project end (September 2027). Preliminary recommendations have already been completed and were outlined in the November 4, 2025, public webinar, which is available on the website (https://heuefs.eu/heu-efs-public-forum-on-early-feasibility-studies/). The "Resources" section of the website (https://heuefs.eu/deliverables/) also includes publications and deliverables, many with recommendations incorporated into the documents.

Any geographical limitation for submitting interest for pilots?

Sponsors may be from anywhere, but the pilots must be carried out in at least one jurisdiction within the EU Medical Device Regulation (MDR), i.e. EU Member States and European Economic Area). In case the sponsor is located outside the EU/EEA, a legal representative of the sponsor in the region is required.

How many pilots do you expect?

The Screening Committee will identify up to 10 pilots. The application process to HEU-EFS Screening Committee is aimed to be completed by March 31, 2026, and the Sponsor's application for the Early Feasibility Study (EFS) clinical investigation should be targeted to be submitted to the chosen National Competent Authority (NCA) by November 30, 2026.

As an SME we would be concerned about sharing our product details with the consortium- how will this be handled?

There will be no product details requested to be provided as a part of the HEU-EFS pilots application process. Sponsors will only provide such data that allow confirmation of alignment with the HEU-EFS eligibility criteria (Deliverable 3.1 Eligibility criteria for EFS) and timelines. Any data provided as part of the pilot screening process will be handled as strictly confidential, under a signed Non-Disclosure Agreement (NDA). It will be stored by Bocconi University (Project Coordinator) and accessible only to members of the Screening Committee. Confidential data will not be shared with other public or private project partners. Further information on the open call for pilots can be found on the HEU-EFS website (https://heuefs.eu/open-call-for-pilots/).

When will the project end? When will you launch the pilots?

The pilot project phase has been launched on November 4, 2025. Expressions of Interest can already be submitted through the online form on the website (https://heuefs.eu/open-call-for-pilots/). The pilot application process to the HEU-EFS Screening Committee is aimed to be completed by March 31, 2026, and the application for the EFS clinical investigation should be targeted to be submitted to the chosen National Competent Authority (NCA) by November 30, 2026. The HEU-EFS project will run through September 2027. A dedicated webinar for the pilots was organized on December 5, 2025 (https://heuefs.eu/webinar-on-heu-efs-pilot-programme/). Presentations and recording from the webinar are available on the webinar page. Sponsors are also invited to contact pilot@heuefs.eu for any questions.

Will the consortium help with the submission to the National Competent Authority (NCA)?

The HEU-EFS project is designed to help prepare sponsors, National Competent Authorities, Ethics Committees, clinical sites and patients for participation in Early Feasibility Studies (EFS). All project materials (both completed and preliminary) will be provided to sponsors to aid in the application and pilot process. However, the sponsor is responsible for completing and submitting the formal application to the National Competent Authority for approval of the clinical investigation – targeted to be submitted by November 30, 2026. The HEU-EFS Consortium will not support in preparation of documentation for application.

References:

- Open Call for Pilots: https://heuefs.eu/open-call-for-pilots/
- HEU-EFS Deliverables: https://heuefs.eu/deliverables/

For any questions, please reach out to pilot@heuefs.eu.