

Harmonised approach to **Early Feasibility Studies** for Medical Devices in the **European Union (HEU-EFS)**

HEU-EFS Screening Committee Terms of Reference



Disclaimer:

The Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project is funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the parties can be held

Introduction

The Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project aims to develop a harmonised framework for early feasibility studies (EFS) in the EU. As part of the project, several pilot EFS will test and validate the methodology, providing recommendations for adjustments. A public call was launched to identify potential pilots. A Screening Committee was appointed to screen and identify pilot use-cases for running EFS studies in accordance with project goals, eligibility criteria and governance. There is no fee for applicants to the pilot.

Purpose

The Screening Committee's purpose is to:

- Review submitted pilot proposals for EFS under the HEU-EFS project against predefined eligibility criteria. Pilots refer to candidate medical-device / health-technology proposals submitted for evaluation for EFS within the HEU-EFS project.
- Identify the elements of the HEU-EFS methodology that will be tested through the pilots.
- Provide feedback to pilot proposers regarding the suitability for inclusion within the HEU-EFS pilots.
- Identify EFS compliant with eligibility criteria.
- Inform the National Competent Authorities (NCAs) about future submissions of pilots EFS under the HEU-EFS project.
- Ensure the screening process is transparent, consistent, fair, and free from undue influence.
- Uphold confidentiality, integrity and proper governance of all documentation, deliberations and decisions.

Composition

The Screening Committee shall consist of at least 3 members selected by the HEU-EFS Project Coordinator from among relevant stakeholders in the consortium.

In addition to the HEU-EFS Project Coordinator, membership should represent a mix of:

- Academic expertise in the field of medical devices and EFS,
- Regulatory and HTA expertise,
- Clinical and technical expertise in medical devices and EFS,
- Patient/health-care provider or user-representative(s).

A Chairperson shall be appointed by the Project Coordinator. A Secretariat (provided by the HEU-EFS project) will support logistics, documentation, and minute-taking.

Members will sign a Non-Disclosure Agreement (NDA) and Conflict of Interest (Col) statement for each pilot proposal.

Roles & Responsibilities

The Committee is tasked with:

- Reviewing the Expression of Interest (Eol) submitted by pilot project candidates to ensure they meet eligibility and timing requirements as outlined in the call for expression and in the self-evaluation checklist.
- Attending a dedicated, confidential, 30-minutes online meeting with submitters of Eol compliant with eligibility and timing requirements to discuss in detail the proposed pilot and identify the elements of the proposed methodology (i.e., early dialogue, accelerated pathway, template or checklist of Clinical Investigation Plan, Informed Consent Form, Master Clinical Trial Agreement, Insurance Agreement, provision of information to allow the calculation of Key Performance Measures, provision of feedback regarding the pilot) to be tested through the pilot.
- Receiving pilot use-case proposals submitted via a self-assessment application form, ethically approved by Bocconi University Ethics Review Committee and reviewing them on a first come first served basis against agreed criteria to assess the suitability of the proposed pilot to test the HEU-EFS framework.
- Holding meetings (in-person or virtual) to discuss and deliberate on shortlisted proposals, if there is a greater number than we believe can be accommodated.
- Identifying up to 10 pilot EFS use cases compliant with eligibility and timing criteria.
- Maintaining relations with the NCAs with respect to future submissions of pilots EFS under the HEU-EFS project.
- Ensuring documentation of decisions (submitted use-cases, minutes, deliberations, declarations of interest) is maintained and stored securely.
- Advising the consortium on improvements to the screening process, criteria refinement, lessons learnt.

Screening Criteria

Proposals will be reviewed using criteria such as (but not limited to):

- Relevance to the HEU-EFS mission (harmonised EFS, medical-device context in EU).
- Compliance with HEU-EFS pilot eligibility and timing criteria as set in the call for expressions maintained up-to-date on HEU-EFS website.
- Readiness to submit EFS to National Competent Authority by November 2026.
- Feasibility of the use-case: resource availability, timeline, team, clinical/technical readiness.

The Secretariat will provide a screening template and instructions for evaluators.

Meetings & Decision-Making

The Committee will review submissions on an ongoing basis, shall meet on an as needed basis during the screening cycle (e.g., when proposals are submitted) with additional *ad-hoc* meetings if required. A quorum shall be constituted by at least two-thirds of the appointed members. Decisions/recommendations shall be reached by consensus. Minutes of all meetings shall be prepared by the Secretariat, circulated to Committee members for approval, and archived securely. The Committee may invite external experts or observers (non-voting) for specific proposals, provided confidentiality obligations are adhered to.

Conflict of Interest

Each Committee member must complete and submit a Declaration of Interest at the time of appointment. Changes in interests are required to be reported without delay.

A conflict of interest arises when a member has any actual, potential, or perceived interest (financial, professional, personal) that might influence—or be perceived to influence—their impartiality in reviewing a use case.

If a member identifies a conflict for a specific use-case (e.g., they are affiliated with the proposing organisation, have financial interests, or are closely collaborating with proponents), the following shall apply:

- The members must recuse themselves from the evaluation, discussion and decision-making for that use-case.
- The recusal shall be recorded in the minutes (including nature of conflict, proposal impacted, decision to recuse).

- The Committee shall maintain transparency by documenting all declared conflicts and recusals, and ensure that the review process remains fair and unbiased.

Confidentiality & Non-Disclosure

All members of the Committee undertake to maintain the confidentiality of all proposal submissions, deliberations, screening, and decisions. Prior to accessing any submission materials or Committee documentation, all members must sign a Non-Disclosure Agreement (NDA) specific to the HEU-EFS project, covering:

- Non-disclosure of any proprietary, commercial, or sensitive data included in proposals or presented during deliberations.
- Restriction on using such information for personal or organisational advantage.
- Obligation to return or securely destroy all confidential materials at the end of their term or screening cycle.

Breach of confidentiality by any member may lead to removal from the Committee, and notification to the Project Steering Committee for further action in line with governance and legal obligations.

The Secretariat shall maintain a register of signed NDAs and ensure secure IT systems and document storage (access limited to authorised personnel).

Tenure

The Committee is established for the duration of the use case selection period of the HEU-EFS project unless otherwise reconstituted by the Project Coordinator. A member may resign or be removed (for cause or conflict issues) by the Project Coordinator or Steering Committee. In the event the Screening Committee cannot function (e.g., insufficient quorum, resignations), the Project Coordinator may appoint replacement members or form an *ad-hoc* sub-committee.



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