

HEU-EFS Pilots

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HEU-EFS has Launched Public Pilots!



Overall Objectives of Pilots

1

To test the HEU-EFS project methodological framework with selected pilot use-cases.

2

To recommend adjustments needed to improve the methodology.

Public Pilots Launched



**Increase the
Number of Pilots**



**Expand the
Patient Conditions**



**Obtain Valuable Feedback
from entities not involved
in HEU-EFS Preparation**



**Increase
Awareness**

What is in for Pilot Proposers?

Proposers have a distinctive chance to evaluate the methodological framework of the upcoming EU EFS Programme by advancing their innovation through a pilot regulatory process.

Specifically, Participants Will:



Get the opportunity to test streamlined process and templates for EFS submissions.



Benefit from a unique learning opportunity and engage with our consortium experts.



Contribute feedback that will shape the development of the future EU EFS programme.

Pilot Eligibility Criteria



General Criteria (Deliverable 3.1)



Pilot Criteria

High-risk devices (Class III and Class IIb), where a clinical investigation will be required as part of the conformity assessment.

- **Breakthrough Device / Unmet Patients Needs**
- **Anatomical Understanding**
- **New / Expanded Intended Uses or Indications for Use for Patients**

- Submitting in EU or EEA Country
- EFS planned submission to NCAs by **November 2026**

As presented in [previous presentation](#).

More information on www.heu-efs.eu.

Key Process Steps of the Pilots



Your Key Contacts

HEU-EFS Point of Contact

Dedicated email
pilot@heuefs.eu
accessed by
Bocconi
University.

HEU-EFS Screening Committee



Giuditta Callea

Bocconi University – Principal Investigator, Leader WP1



Alexandra Poulsson

Norwegian Institute of Public Health – Leader WP3



Tom Melvin

University of Galway – Leader WP2

Terms of reference here: <https://heuefs.eu/wp-content/uploads/2025/11/Terms-of-Reference-Steering-Committee-1.pdf>

Submission Process

Step 1: Expression of Interest



AIM

- Give high-level information on sponsor and application (timing, target NCA, therapeutic area, risk class, eligibility criterion, expected no. of patients to enroll).

HOW

- Applicants fill in <https://heuefs.eu/open-call-for-pilots/>
- Point of Contact confirms receipt of Eol.
- Screening Committee evaluates whether the pilot meets the eligibility criteria and provides feedback, providing dates for Information Call.

WHEN

- Applicants are encouraged to submit their Eol at the earliest opportunity.
- Evaluated based on first comes first served basis.

TARGET SUBMISSION DEADLINE

- 31 March 2026.

Submission Process

Step 2: Information Call



AIM

- Open exchange (30 min) to understand pilot intent and answer any questions about HEU-EFS.

PROCESS

- Applicants meet with Screening Committee, with signed NDA.
- Applicants receive access to guidance.

WHEN

- No later than 2 weeks after EoI is submitted

Submission Process

Step 3: Online Form



AIM

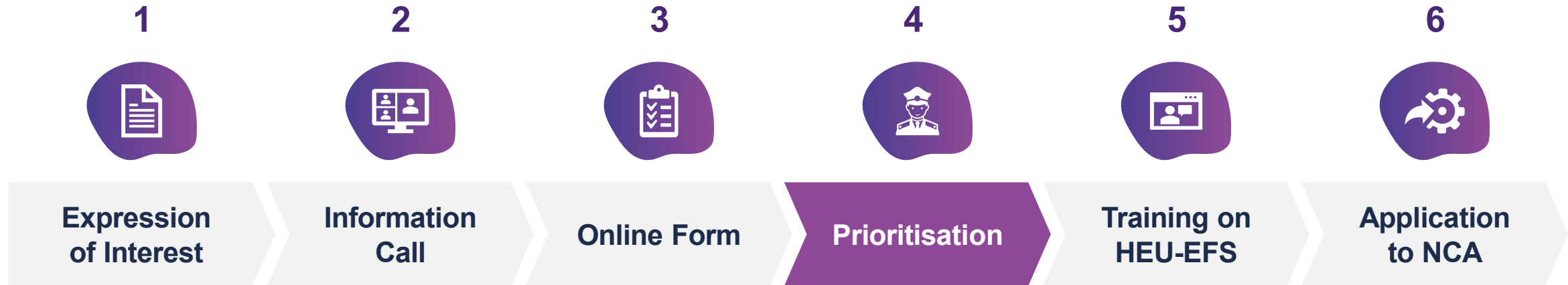
- Give relevant information on parts of the framework to test, pilot, country, technology, timing of submission, clinical site and ethics committee identified or not, to ensure eligibility with the program.
- No technical documentation (e.g., CIP, IB, ICF) to be submitted.

HOW

- Applicants fill in an online form that will be made available after confirmation received further to EoI.

Submission Process

Step 4: Prioritization



AIM

- Verifying:
 - Parts of the framework to test.
 - Compliance with HEU-EFS eligibility requirements and timelines.
 - Readiness (clinical site and ethics committee are known).
- No advice will be provided on technical aspects of the EFS content.

WHO

- HEU-EFS Screening Committee.

WHEN

- Minimum 2 review cycles per month.
- More frequent meetings will be scheduled if necessary.

Submission Process

Step 5: Training



AIM

- Get detailed online training on HEU-EFS guidance.

WHO

- HEU-EFS website (open access format).

WHEN

- After Screening Committee positive feedback.
- Recommended before preparation of application to NCA.

Submission Process

Key Process Steps



AIM

- Start and execute the pilot.

HOW

- Applicants submit first communication (contact point) to NCA.

TARGET SUBMISSION DEADLINE

- 30 November 2026.

NOTE

Applicants should finance their own studies: no public funding will be available from IHI or from the HEU-EFS consortium.

Key Information



Feedback Mechanism

- **Feedback Mechanism** on experiences with pilot implementation to be provided throughout the pilot execution.



Pilots

- A maximum of **10 public pilots** may be selected.
- Application and review process will be handled on a **first-come-first-serve basis**.
- **No Funding is available** for the study roll-out from HEU-EFS or IHI



Contact and Info

- All information here: <https://heuefs.eu/open-call-for-pilots/>.
- Expression of Interest [here](#).
- Key contact: pilot@heuefs.eu

Thank you !

www.heuefs-eu