

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

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

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**

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

1



Expression of Interest

2



Information Call

3



Online Form

4



Prioritisation

5



Training on HEU-EFS

6



Application to NCA

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 EoI.
- Screening Committee evaluates whether the pilot meets the eligibility criteria and provides feedback, providing dates for Information Call.

WHEN

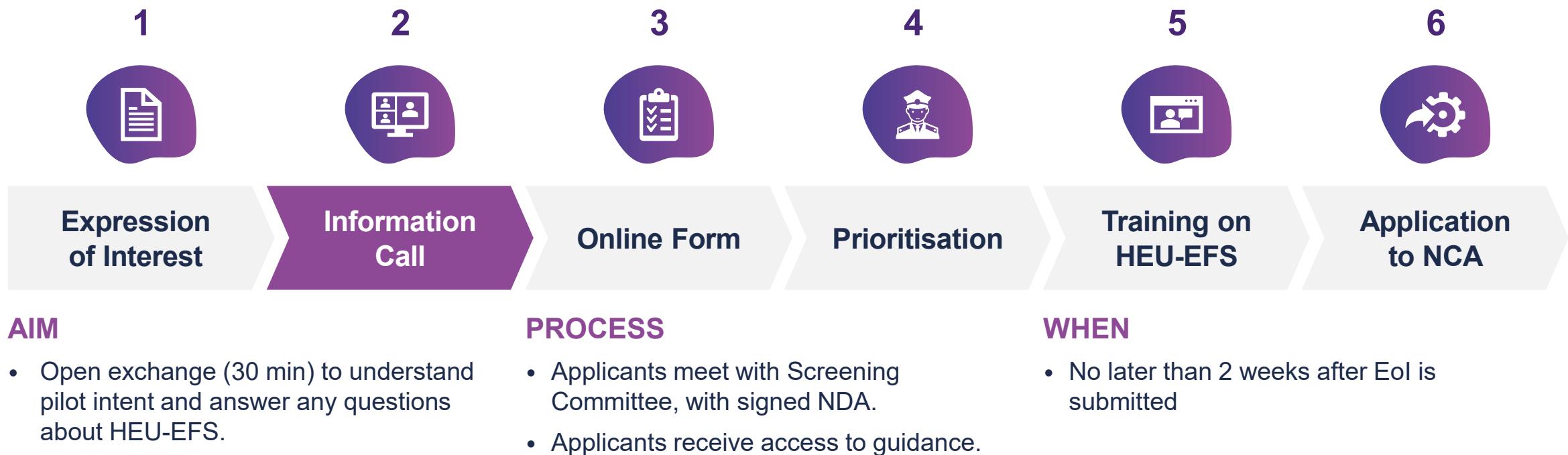
- Applicants are encouraged to submit their EoI at the earliest opportunity.
- Evaluated based on first comes first served basis.

TARGET SUBMISSION DEADLINE

- 31 March 2026.

Submission Process

Step 2: Information Call



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.

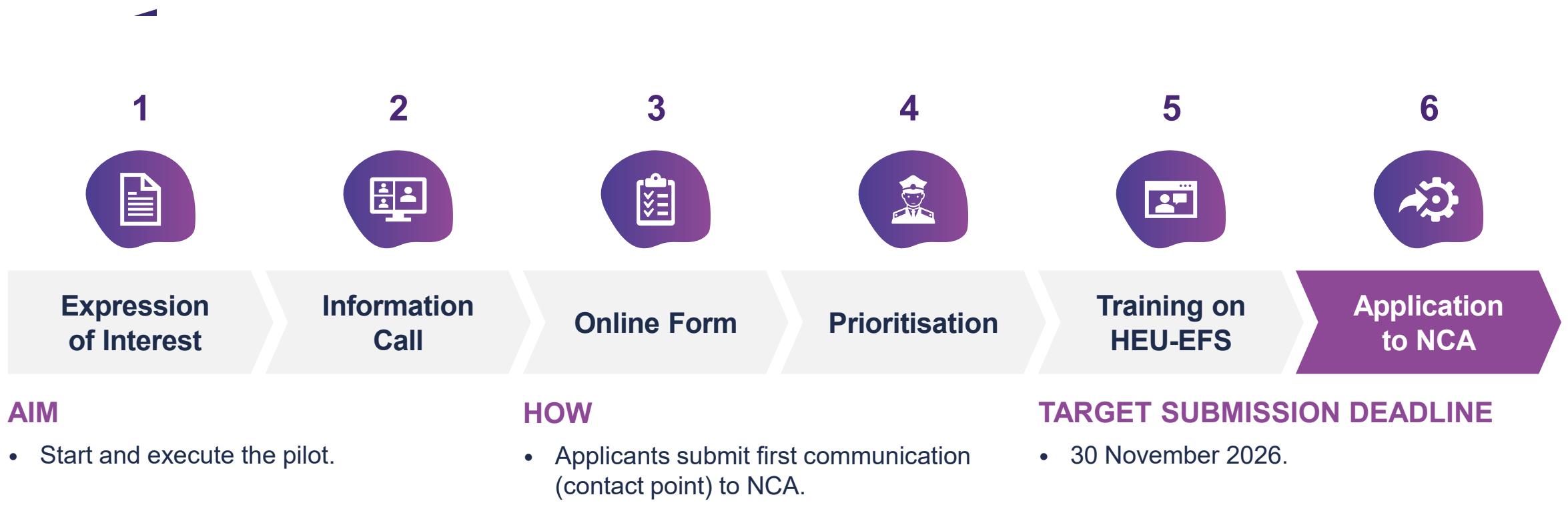
Submission Process

Step 5: Training



Submission Process

Key Process Steps



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](http://www.heuefs.eu)