

Testing the HEU-EFS Methodology and the opportunity for innovators: launch of pilots

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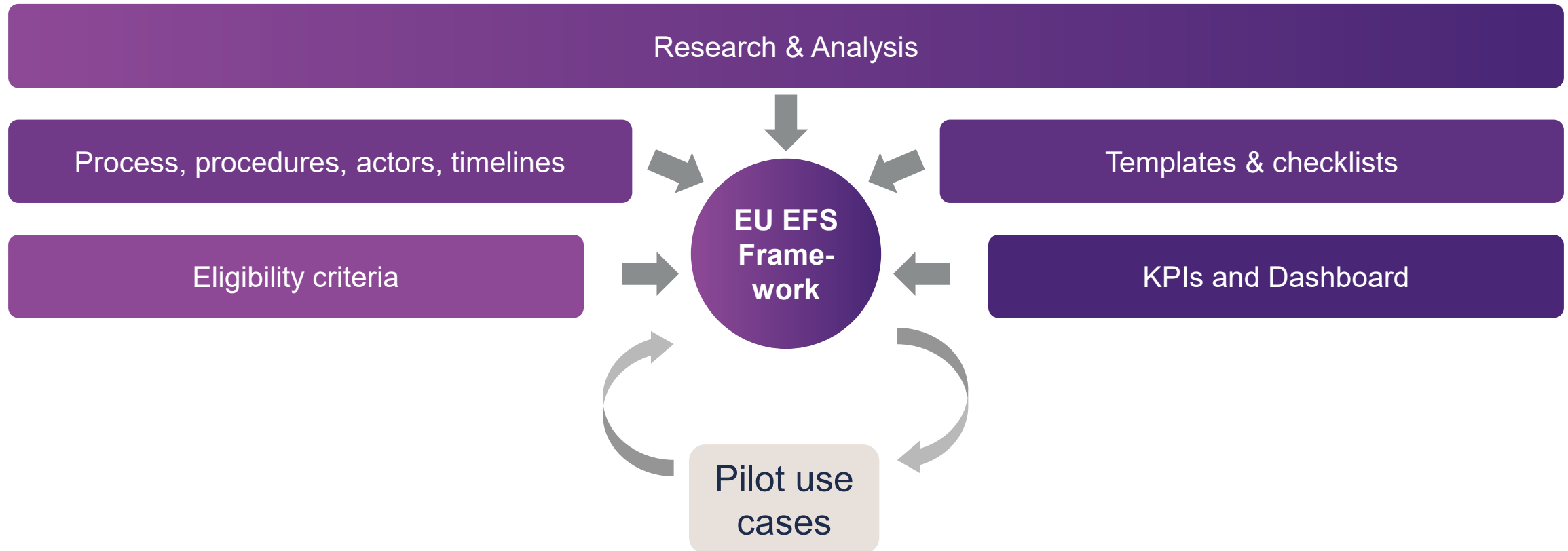
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Pilot Use-Cases: A Critical Pillar of the HEU-EFS project

A key step to gain real-life experience of a new EU EFS methodological framework to help inform, refine and validate the framework.



HEU-EFS is launching public pilots!



Main 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.



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.

Submission process

Key process steps



About Pilot Application and Implementation

- HEU-EFS Point of Contact manages sponsor interaction & execution of pilots
- Training on HEU-EFS process and documentation will be provided after Submission of Application form to HEU-EFS Point of Contact

About the Point of Contact and Screening

- Bocconi University (point of contact) and HEU-EFS Screening Committee responsible for review of pilot application, answer questions and training
- Contact point: pilot@heuefs.eu
- Information: www.heuefs.eu

Key Timelines and Information



Timelines

- Submission of Expression of Interest open from today **until 31st March 2026**.
- Further to pilot selection, sponsors are expected to submit their application to NCAs **no later than November 2026**.



Feedback mechanism

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



Pilots

- A maximum of **10 public pilots** may be selected.
- Application and review process will be handled on a **first-come-first-serve basis**.
- **Note:** proposers should finance their own studies. No public funding will be available from IHI or from HEU-EFS consortium.

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

Interested in finding out more?



Dedicated Webinar on Pilots on
5 December 2025, 15.00 – 16.00 CET

All information on pilots and expression of interest
on www.heuefs.eu

All questions on pilots: pilots@heuefs.eu



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Thank you!

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