# The role of patients in the early feasibility studies of medical devices, PEDs and PROs

**Engaging patients in the development of an Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (GA 101112185 — HEU-EFS)**

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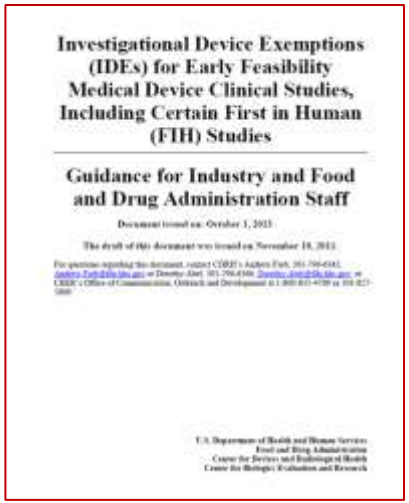
ESC European Society of Cardiology

# Context: Early Feasibility Studies (EFS)





**Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies**

**Guidance for Industry and Food and Drug Administration Staff**

Introducing new category of clinical investigations, part of regulatory pre-market approval pathway for high-risk MD

## WHAT?

A limited clinical investigation of a device early in development.

## WHEN?

Typically, before the device design has been finalized, for a specific indication (e.g. innovative device for a new or established intended use, marketed device for a novel clinical application).

## WHY?

It can be used to evaluate the device design concept with respect to initial clinical safety and device clinical performance or effectiveness (if appropriate) as per intended use in a small number of subjects when this information cannot practically be provided through additional preclinical assessments or appropriate preclinical tests are unavailable.

# Context: the HEU – EFS Project



**EFS in the EU:**

- EFS are provided for in the MDR 2017/745.
- ISO 14155:2020 “Clinical investigation of medical devices for human subjects” introduced a taxonomy for different clinical investigation types.
- However there is no standardised procedural framework, guidelines or common reference standards to conduct EFS in the EU.

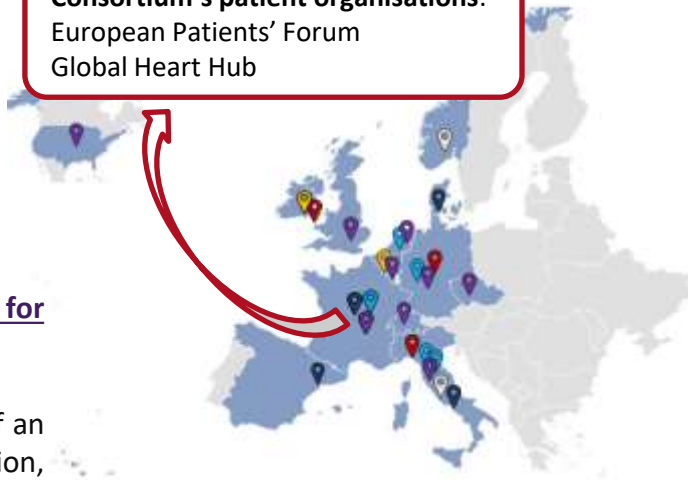

**Awarded to**

**Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (GA 101112185)**

Timeline: 2023 - 2027

Aim: Formulate recommendations for the establishment of an Early Feasibility Studies Program within the European Union, with a focus on ensuring patient safety.

**Consortium’s patient organisations**:
European Patients’ Forum
Global Heart Hub



# HEU EFS: the Patient Engagement Plan

ESC Cardiovascular Round Table

**1st Pillar**

Patient organisations (EPF, GHH) as partners of the HEU-EFS Consortium

**2nd Pillar**

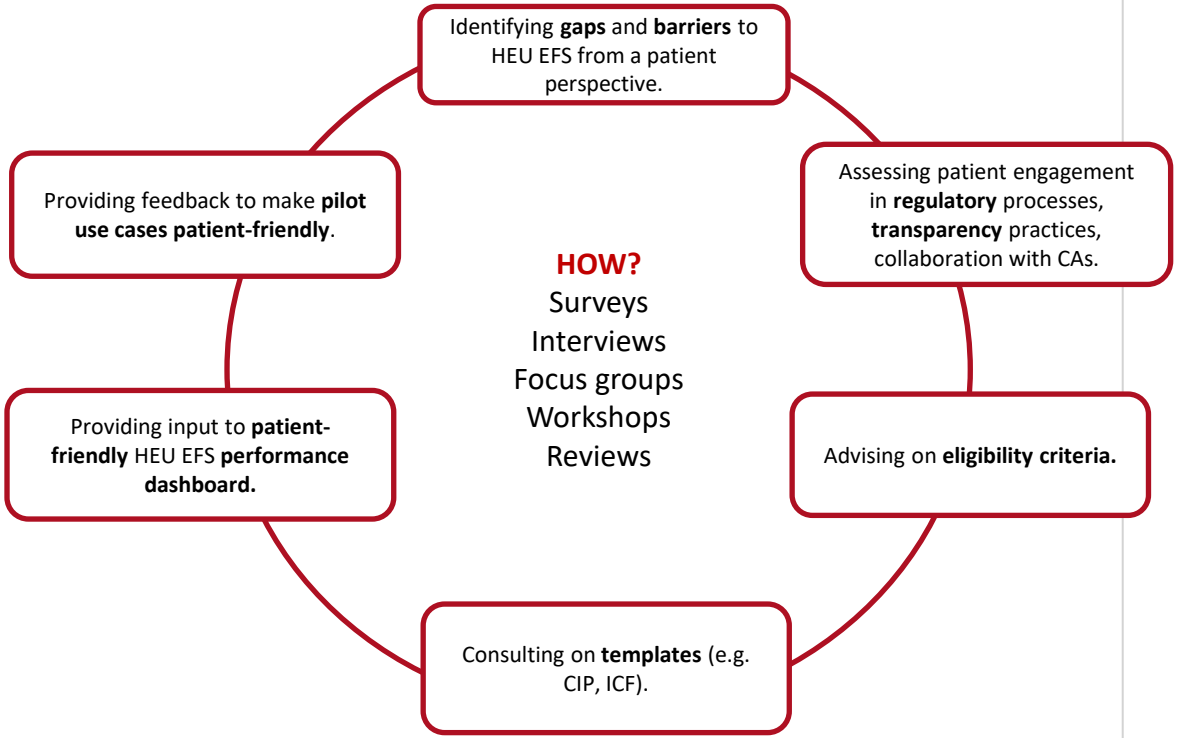
**Patient Advisory Group (PAG)**

11 patients providing first-hand experience and perspectives (disease areas: cardiovascular, orthopedic, diabetes, neurological).

**3rd Pillar**

**Patient Engagement Ambassadors (PEAs)**

1 Ambassador per WP, involved in Patient Engagement Plans

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# Barriers faced by patients in clinical investigations

ESC Cardiovascular Round Table

**Aim:** identify key gaps and challenges currently faced by patients participating in clinical investigations by collecting patient experience data.

**Results:**

- Fragmented and limited information on the study available.
- Lack of clarity in the information provided.
- Practical challenges, e.g. travel and mobility issues, travel costs, cross border access.
- Lack of post-trial communication.

**Recommendations:**

- Use of clear language and visual aids for greater comprehensiveness for timely communication.
- Develop support systems for patients e.g. including compensation policies, logistical supports.
- Ensure appropriate patient follow-up.
- Create space for co-creation of clinical trials design and implementation.

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# Identifying criteria for patient eligibility in EFS

ESC Cardiovascular Round Table

**Aim:** identifying criteria to determine eligible patients, while ensuring their safety, benefits and alignment with clinical goals.

**1° step:**
Factors to consider when assessing eligibility of patients for EFS, based on literature review.

**2° step:**
Consultation workshop with PAG to assess set of criteria.

**3° step:**
Refine list of criteria, based on feedback received and patient experiences

**Results:**

**Criteria that sponsors may consider for identifying eligibility of participants**

- Alignment of indication. and study participants.
- Risk benefit analysis.
- Disease severity.
- Unmet medical needs.

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- Patient preferences.
- Diversity and inclusion.
- Transparency and patient feedback.

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# Conclusions



**The HEU EFS Project as an example of conducting research WITH patients during design, development, and delivery of recommendations for an EU EFS program.**

**More efficient lifecycle planning:** collecting patient data early on to inform the business case, increasing the chances of developing innovative, cost-effective, and safe MDs.

**Minimalise-stage failures:** reducing late-stage pipeline failures and market access failures, saving resources by aligning technology with patients' needs.

**Align with healthcare transformation:** supporting active role of patients, co-creating solutions, enhancing dialogue.

# Thank you for your attention!

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