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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HEU EFS

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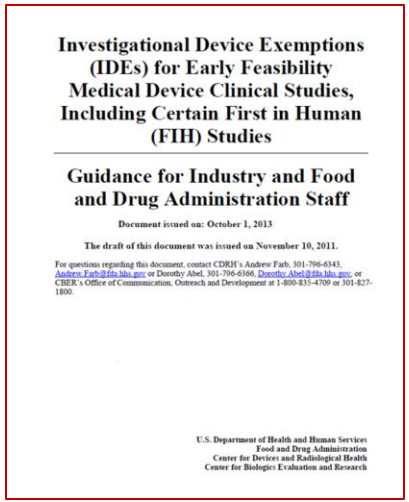
ESC European Society of Cardiology

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

Document issued on: October 1, 2013

The draft of this document was issued on November 10, 2011.

For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6566, Dorothy.Abel@fda.hhs.gov; or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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

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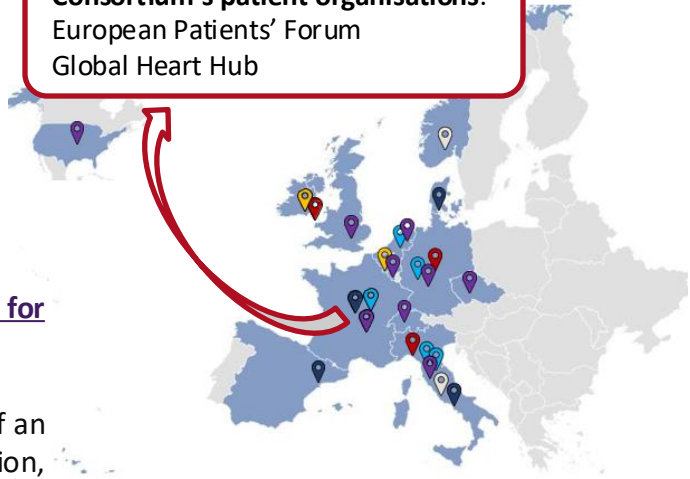
[Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union](#)**(GA 101112185)**

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

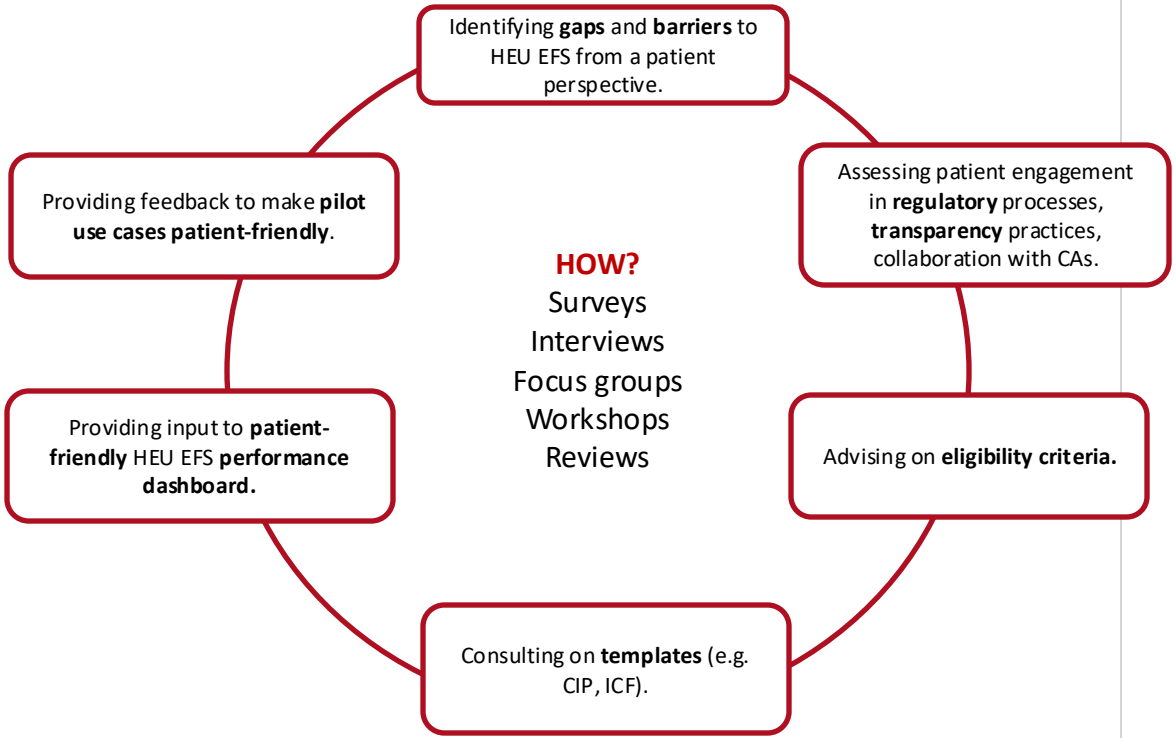
Patient Advisory Group (PAG)

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.

+

- 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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