Harmonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion **(HEU-EFS)**

EU project on Early Feasibility Studies for Medical Devices

CALL FOR INTEREST:

JOIN OUR PATIENT ADVISORY GROUP

European Patients' Forum, Global Heart Hub

February 2024

Co-funded by the European Union

Disclaimer:

The Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project is funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the parties can be held responsible for them.

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ABOUT THE PROJECT

The European Patients Forum (EPF) and Global Heart Hub (GHH) are pleased to announce a call for representatives for a Patient Advisory Group (PAG) for the project 'Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS)'. By increasing innovation in Europe, an overarching goal is for patients in Europe to have access to new, more innovative, safe, and effective medical devices.

You can **find out more about the project** at the bottom of this document; you can also learn more on our newly launched project website here as well as on EPF's project page here and GHH's project page here.

ABOUT THE PATIENT ADVISORY GROUP (PAG)

The PAG represents the hub for patient centricity and patient engagement across the project implementation. It aims to discuss and provide recommendations for structured patient contribution to Early Feasibility Studies, in short EFS, (e.g. time and type of involvement) to make more patient-centred medical devices. The PAG will operate in connection with all relevant working groups. EPF and GHH will support the work of the PAG.

We are searching for a group of maximum **10 individuals** to ensure representation of profiles from different geographies, disease areas, genders, age ranges and levels of health literacy. We are looking for **patients, family members/carers of patients, or employees/volunteers of a patient organisation** in any of these disease areas: **cardiovascular, neurological, orthopaedic, diabetes.**

WHO ARE WE LOOKING FOR?

General (for all applicants):

- Must be 18 years of age or older
- Must be from one of the following countries: EU countries[1], Iceland, Liechtenstein, Norway
- Representatives don't need to be proficient in the topic but need to indicate a strong interest in medical devices, early feasibility studies and digital health
- Availability to travel to the project's general assembly meetings once a year (within Europe)

Please find more details below about the experience, skills and attributes required.

[1] Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

Experience (advantageous)

- Previous experience of being involved in multi-stakeholder projects is advantageous
- Previous experience of participating in events, workshops, studies (e.g. surveys, focus groups, interviews), or similar about innovation and development of medical devices is advantageous

Skills

- Able to communicate clearly and always in a respectful and inclusive manner
- Able to work comfortably in an online environment
- Maintaining confidentiality when required
- Able to interpret large blocks of information and contribute to discussions

Attributes

- Be willing and confident to participate in meetings and group conversations, sharing views and making arguments
- Be collaborative and constructive but prepared to provide and receive challenging input

Foreseen activities

The members of the group will attend several meetings:

- The PAG's regular online meetings
- The project's Annual General meetings (4-year project): once a year face-to-face where about 3 members from the PAG will be able to attend; a virtual mid-term session per year (first one is 10 April 2024)
- Other meetings with project consortium partners as needed
- The induction meeting (online) at the end of March (to be confirmed)
- eLearning activities (online) foreseen in spring 2024

IS THERE A COMPENSATION FOR THE WORK OF THE PATIENT ADVISORY GROUP?

Each participant will receive compensation during the time of commitment. Travel and accommodation for in-person meetings will also be covered.

APPLICATION FORM AND DOCUMENTS

Please complete the application form online here. The application form consists of questions about your personal details (name, country of residence, experience), short questions about your motivation for applying, a declaration of interest, and information on how EPF will process your personal information.

Please do not forget to attach your CV to the application form. Please submit your application form online with attached supporting documents **by Tuesday, 20 February 2024 (COB, CET).**

TIMELINE AND SELECTION PROCESS

- 1 February – launch of the call
- 20 February – close of the call
- 28/29 February 2024 – short calls with shortlisted applications

WHAT HAPPENS ONCE WE HAVE RECEIVED YOUR APPLICATION?

1. The information will be evaluated by both EPF and GHH staff working on the project;
2. After the evaluation of applications, shortlisted candidates will be invited to an informal conversation as part of the selection process (max 20 minutes). This is not an interview, and you are not expected to prepare for it;
3. If you are selected, the next steps will be confirmed in future communications;
4. Everyone who applies will be notified about the outcome.

The informal conversations as per point 3 above will take place on **February 28 (all day) and February 29 in the morning. More information and the possibility to select a slot on one of those days will be provided to those shortlisted.**

If you have further questions, you are very welcome to contact us: Yasemin Zeisl at EPF (yasemin.zeisl@eu-patient.eu) and Silvia Scalabrini at GHH (silvia@globalhearthub.org)

Thank you very much for your continuous support in our activities. We really look forward to working together on this worthwhile and ambitious project.

Best wishes, EPF & GHH

PROJECT INFORMATION

Full title: Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS)

Duration: 48 months (1 October 2023 – 30 September 2027)

Status: Ongoing

Funding programme: Horizon Europe under Innovative Health Initiative Joint Undertaking (IHI JU), Grant agreement no. 101112185

What will the project do?

The ambition of the HEU-EFS project is to create a harmonised framework for conducting Early Feasibility Studies (EFS) in the EU. EFS are small-scale research studies or tests done in the very early stages of developing a medical device or treatment to see if it is practical, safe, and worth pursuing further. EFS help assess whether an idea or concept has potential before investing more time and resources into full-scale development and testing. Currently, there are no standardised procedural rules or guidance frameworks for carrying out EFS in the EU – a gap that the HEU-EFS project aims to fill. This also supports efforts by EU regulators to promote a stricter process for the generation of clinical evidence before medical devices can enter the market and be used by patients.

What are the expected outcomes?

- **Adoption of the HEU-EFS methodological framework** across EU member states, creating a harmonised approach to conducting EFS in the EU;
- **Increased number of EFS** carried out in the EU due to harmonised rules and procedures;
- **Recording and monitoring of EFS** in the EU through an ad hoc database;
- **Improved quality of clinical evidence** produced, including patient contributions in medical device developments, and **increased efficiency** in producing evidence;
- **Attracting more clinical research/trials and R&D investments** in the EU due to harmonised and stimulating innovation environment;
- **Building a network and fostering collaboration** among relevant stakeholders.

What role do the European Patients' Forum (EPF) and Global Heart Hub (GHH) play in the project?

- EPF is teaming up with GHH to make EFS for medical devices more patient-centred by ensuring that patients are actively and meaningfully involved in the process. To do this, EPF and GHH will set up and engage a Patient Advisory Group of individuals with different profiles who will make contributions to, and give advice on, various workstreams across the project.

Why does this matter for patients?

Adequately including patient perspectives in Early Feasibility Studies:

- ensures that newly developed medical devices are better tailored to patients' needs.
- helps to understand the dimensions and impact of a disease on the lives of both patients and caregivers (e.g. quality of life, treatment preferences, burden of disease's evaluation, etc.).
- supports patients' active role in managing their own health, co-creating healthcare solutions.

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