Medical Devices and Patient Involvement in the Cardiovascular Area

EUPATI Webinar – Patient Involvement in Medical Devices

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Global Heart Hub

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Who We Are

Global Heart Hub is the first global non-profit alliance of heart patient organisations, established to provide a voice for those living with or affected by cardiovascular disease

PATIENT COUNCILS:

- Heart Failure
- Heart Valve Disease
- Cardiomyopathy

WORKING GROUPS:

- ASCVD
- Women and Heart Disease
- Hypertension
- Clinical Trials
- Patient Engagement

INDIVIDUAL ADVOCATES

GLOBAL COMMUNITY

131 patient organisations

42 countries

28.7M+ patient organisations community reach

MISSION

- Mission: **create and unite a global cardiovascular patient** community to advocate for the best possible outcomes for people living with heart disease

VISION

- Vision: be the **leading voice for the needs of heart patients globally** ensuring that they are equal stakeholders in cardiovascular healthcare

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What We Do

- Awareness
- Advocacy
- Activation
- Academy

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Patient Engagement in Medical Devices

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Current Status – Limited Active Participation

		
Many designs with no sufficient patient input	Limited outreach to Patient Organisations (POs)	Main interest in patient journey with device
		

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The importance of patients' involvement

- Understanding Patient Needs → Tailored solutions
- Improving Device Usability → User-Centric Design
- Enhancing Safety and Efficacy → Real World Insights
- Building Trust and Transparency → Empowering Patients
- Driving Innovation → Collaborative Development
- Addressing Barriers to Adoption → Identify Challenges Early
- Facilitating Regulatory Approval → Patient Perspective in Clinical Studies

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HEU EFS

HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

HEU-EFS
Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union

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Early Feasibility Studies (EFS)

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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 nonclinical assessments or appropriate nonclinical tests are unavailable. Information obtained from an early feasibility clinical investigation can guide device modifications. An early feasibility clinical investigation does not necessarily involve the first clinical use of a device.

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Early Feasibility Studies (EFS)

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	Early Feasibility	Feasibility	Pivotal
Device Design	Not Yet Final	Near Final	Final
Preclinical data provides all info re. Device design	No	Yes	Yes
Purpose of study	Guide Device Modifications	Preliminary Safety & Efficacy (S&E) to help design Pivotal	Demonstrate S&E
Understanding of device risks	Unknown Risks	Risk Understood	Risks Understood
Number of patients involved in the study	~10	15 – 45	100s, depending on indication, device type, etc.

Source: Meditrial

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Early Feasibility Studies in European Union

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HOW EFS IS REGULATED IN EU? →

EFS in EU is **regulated** by:

- Medical Device Regulation (2017/745),
- International Standardization Organization 14155 (2020),
- Medical Device Coordination Group (2021-6)

BUT ↓

Absence of **standardized procedural framework**, guidelines or common reference for **EFS** in **EU**

The EU is at risk of losing competitiveness and attractiveness for innovation and investments compared to other market.

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The **aim** of **HEU-EFS** Project is to formulate **recommendations** for the establishment of an **Early Feasibility Studies Program** within the **European Union**, with a focus on ensuring **patient safe access to innovative medical device** and **enhancing the EU market competitiveness.**

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The Consortium

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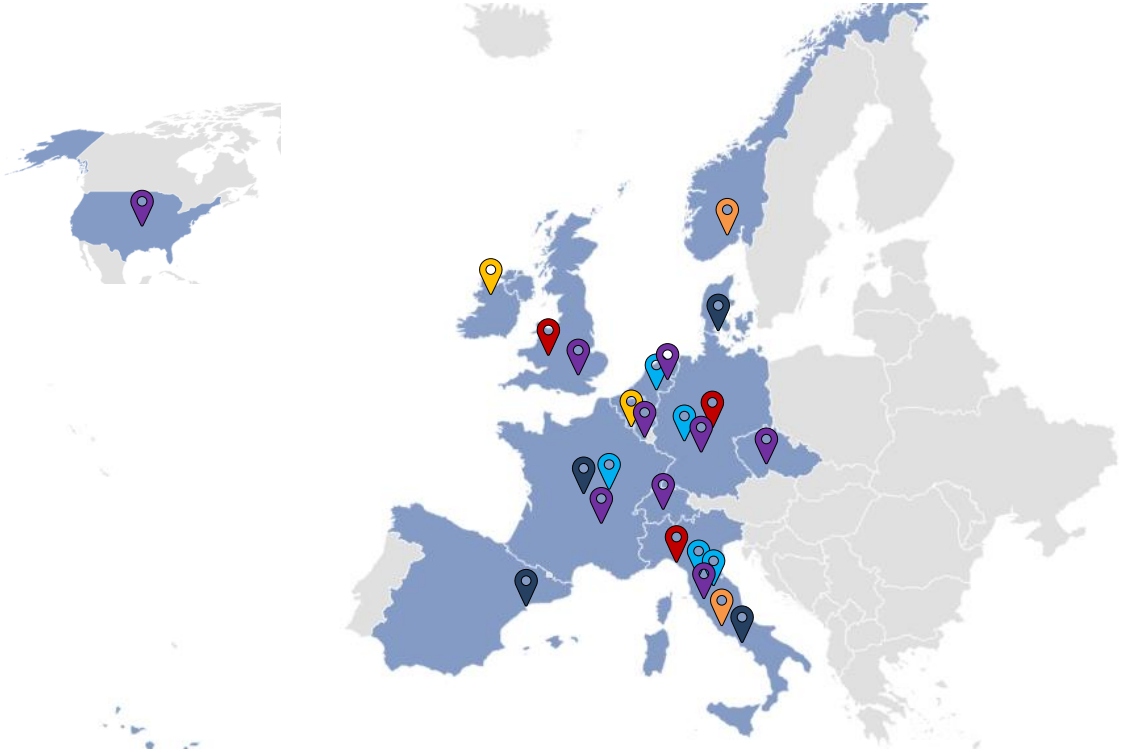

ACADEMIA
- Bocconi University (leader)
- Marburg University
- Trinity College Dublin

HEALTH CARE PROVIDERS
- Assistance Publique Hôpitaux De Paris
- Fondazione Policlinico Universitario Agostino Gemelli IRCCS
- Fundació Clínic per a la Recerca Biomèdica & Hospital Clínic de Barcelona
- Odense Hospital

HTA AGENCIES
- AGENAS, Italy
- NIPH, Norway

PATIENT ORGANISATIONS
- European Patients' Forum
- Global Heart Hub

CRO
- Meditrial

SMEs
- Carmat
- Newronika
- Idris Oncology
- Qurasoft

TECHNOLOGY DEVELOPERS
- Edwards Lifescience (coordinator)
- Abbott
- DePuy Synthes
- Medtronic
- Philips
- WL Gore

innovative health initiative

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Patient Engagement in HEU-EFS

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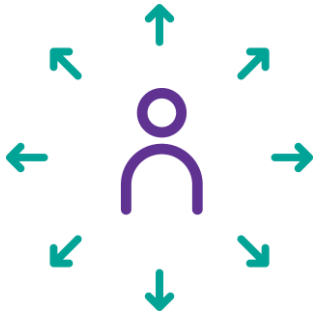
To facilitate **patient engagement** throughout the project we collaborate with two other parties: **P**atient **A**dvisory **G**roup (PAG) and **P**atient **E**ngagement **A**mbassadors (PEA).

Patient Advisor Group

A group of 11 patients with different profiles (i.e., different geographies, disease areas, genders, ages, levels of health literacy) who bring **patient perspectives** to the project through their **unique, valuable feedback and input.**



Patient Engagement Ambassadors

PEAs are individuals working for organisations which are **consortium members**. They have the technical expertise on the project's subject matter and Work Package activities needed to adequately help **integrate patient perspectives** in the different workstreams.

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Impact and benefits of EFS

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INDUSTRY

- Improve efficiency and effectiveness in technology development.
- Maximize the probability of market access.
- Maximize the probability of adequate remuneration for innovation.

COMPETENT AUTHORITIES

- Foster access to innovation while maintaining adherence to rigorous authorization process and preserving patient safety.
- Anticipate and smooth the decision-making processes thanks to early exchange of information.
- Increase the innovativeness and competitiveness of the sector.

PATIENTS

- Timely access to innovative medical technologies that can address unmet clinical needs with no alternative treatment option.
- Controlled and safe access to innovative medical technologies.

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Specific benefits and challenges of EFS for patients

- **A complex balance** of potential health benefits vs costs of uncertainty
  - **Earlier access** to new devices that may improve patients' health or advance the standard of care
    - …including support for better design of future clinical investigations in broader patient populations and improved data for HTA
    - Participation in the study may bring **limited personal benefit**
  - **Uncertainty of risks** when testing new concepts
    - Limited non-clinical data
- **Eligibility criteria**
  - Health status, risk tolerance, ability to use the existing standard of care
- **Utilisation of meaningful endpoints** and **outcomes that matter to patients**
- **Access** to EFS
  - Limited accessibility of investigation sites, small studies, complexities re identification of patients

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The importance of patients' involvement

				
From identifying unmet needs	…defining research priorities	...study design	to review of proposals, implementation and publication	and more
				

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Thank you

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