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HEU EFS

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

The patient perspective: Involvement of patients in translational research and clinical investigations

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Who we are

- Independent, non-governmental **umbrella organisation of patient organisations**, founded in **2003**
- **Non-disease specific, chronic conditions**
- **82 members across 24 countries**: national coalitions & EU disease-specific organisations
- Mission: To **advance the collective voice of patients** through **advocacy, education, empowerment, partnership**

- First global non-profit **alliance of heart patient organisations**, established to provide a voice for those living with or affected by cardiovascular disease
- **147 patient organisation** affiliates across **45 countries** worldwide
- Mission: To create and **unite** a global cardiovascular patient community **to advocate for the best possible outcomes for people living with heart disease**.

Patient engagement in HEU-EFS

- Multi-stakeholder collaboration within the project is the key to success
- Three pillars to achieve this:

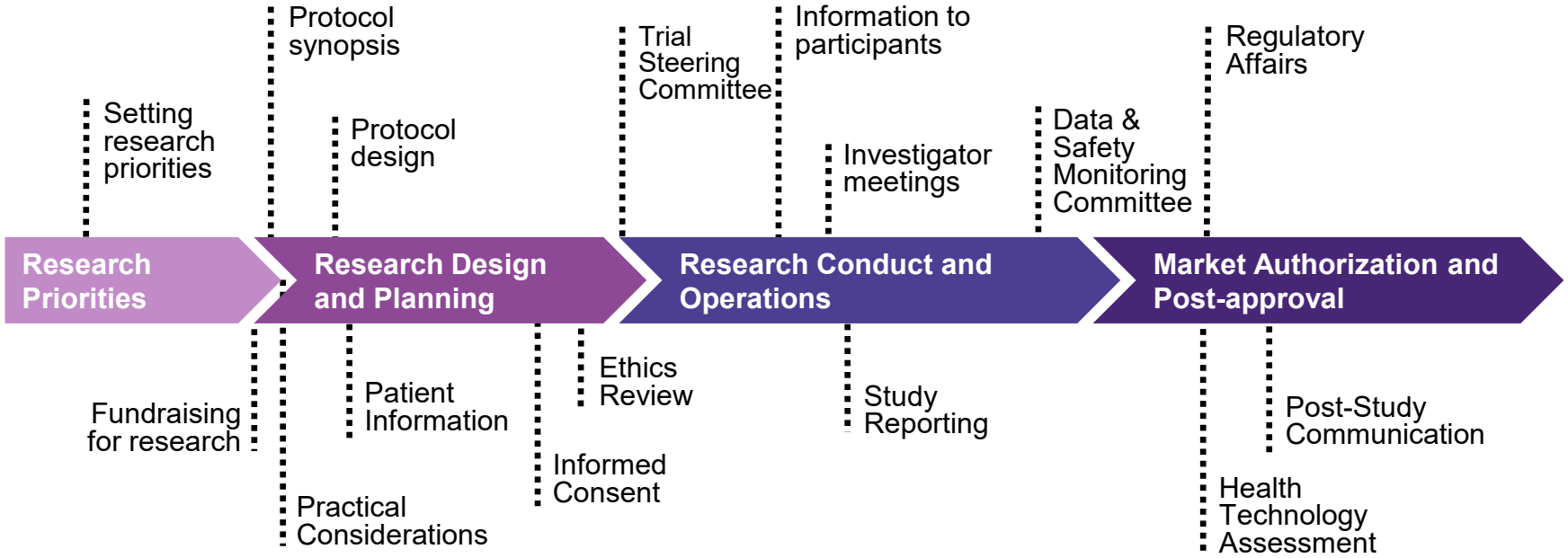
Umbrella patient organisations	Patient Advisory Group (PAG)	Patient Engagement Ambassadors (PEAs)
EPF and Global Heart Hub oversee and facilitate **patient engagement** throughout the project. We work in collaboration with PAG and PEAs. We provide input across the project, bringing **high-level and collective patient perspectives**.	A group of about 10 patients with different profiles (i.e., different geographies, disease areas, genders, ages, levels of health literacy) who will bring **patient perspectives** to the project through their **valuable, first-hand feedback and input.**	Working for organisations that are **consortium members**. They have the technical expertise on the project's subject matter and WP activities needed to adequately **help integrate patient perspectives** in the different workstreams.

How patients can be involved

Patient involvement in research

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

To promote good practice requires engagement with all actors… Impact of patient involvement is **greater the earlier patients are involved** – from priority setting stage to co-design & co-production of clinical research



Benefits of involving patients

Patients' unique experiences and insights can help make better devices (e.g. addressing (unmet) needs, more tailored functionalities, boosting acceptance on market, address safety and efficacy concerns among target patient groups, …)

Patient feedback can help us:

- understand the **benefits** most important to them,
- what **risks** they may or may not be willing to take, and
- what **improvements** could be made

Patient involvement supports meaningful innovation:

- Enhances **legitimacy**, **transparency**, and **accountability**
- Leads to better, more relevant **results**
- Challenges researchers' **assumptions**

This is true across the product's lifecycle

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Best Practices and Recommendations

Transparent & Accessible Communication

Clear, Lay Language	Comprehensive Information	Timely & Ongoing Updates	Accessibility to All	Empathy & Emotional Intelligence
Use non-technical terms, visuals, and diagrams in all patient-facing materials. • Explain technical procedures in accessible ways. • Adapt content for varying health literacy levels.	Share all relevant details: study objectives, expected outcomes, risks, benefits, trial type (EFS or other), available support, possible conflicts of interest, etc.	Keep patients informed about any changes, cancellations, or results after trial completion.	Ensure materials are available to underserved and under-represented groups and tailored to specific patient needs (e.g. persons with incapacity) • Monitor and leverage CTIS as a model for public access.	Respond to patient questions with patience and understanding. • Build trust through transparent, compassionate communication.

Comprehensive Patient Support Systems

Fair Reimbursement & Compensation	Logistical & Emotional Support	Facilitating Cross-Border Participation	Clarify Participation vs Treatment	Empathy in Support Delivery
Ensure transparent, equitable policies for all participants.	Provide assistance with travel, accommodation, and emergencies. • Designate clear points of contact for queries and urgent needs.	Address regulatory and practical barriers for patients from different regions, especially in rare disease contexts.	Clearly communicate that EFS participation is not equivalent to guaranteed treatment access. • Balance the promise of innovation with realistic expectations.	Recognize and respond to patient needs with understanding and respect.

Meaningful Patient Engagement

Active Co-Creation	Diverse PAG	Review & Feedback	Post Trial Follow-Up	Prioritize	Build Trust
Involve patients in designing study protocols, informed consent forms, and identifying unmet needs.	Establish Patient Advisory Groups (PAG) reflecting a range of patient experiences and backgrounds.	Enable patients to review study results and provide feedback on their experience.	Ensure patients have access to trial results and continued access to beneficial devices/treatments after the trial ends.	Prioritize **Safety, Transparency, and Inclusivity**: Integrate these principles into eligibility criteria and study design.	Build Trust **Through Ethical Practice**: Address health literacy, practical concerns, and communication to foster a truly patient-centred approach.

Disclaimer

The **HEU-EFS** project is funded by the European Union, the private members, and those contributing partners of the Innovative Health Initiative Joint Undertaking (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.

Adopted by the **European Patients' Forum (EPF)** Annual General Assembly in March 2009, the “Framework for Cooperation” outlines how EPF works with partners who provide unrestricted sustainable funding to contribute to EPF’s strategic plan and annual work programme, and why this is important. This partnership is not solely financial and focuses also on open and transparent dialogue and the exchange of independent views and positions between EPF and these partners. This framework document also describes how this is undertaken in practice, without comprising either party.
In keeping in line with our commitment to transparency, all **financials** pertaining to EPF are available on our **website.** Click here to view all our **accounts and balance sheets.** Click here to view all acknowledgements of **Financial Support.** Click here to view the current and past **Annual Reports** which outline the amounts of our funding and their sources.

Global Heart Hub receives both unrestricted funding and dedicated financial support for specific causes, enabling us to continue our vital work representing and defending the rights and interests of individuals living with or affected by cardiovascular diseases. All funding received is governed by individual contracts specifying the use of the funds and all reporting requirements are adhered to. As a patient organisation that prioritises health, we do not accept any funding from companies producing products deemed harmful to health. Global Heart Hub is committed to securing multi-industry support. A complete list of all our current funding partners can be found **here**. A breakdown of the latest financial statement can be found **here**.

Thank You

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