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Press release

Improving patient access to innovative medical technologies in the European Union

European consortium to develop a "Harmonized Approach to Early Feasibility Studies for Medical Devices in the European Union" (HEU-EFS)

[30 January 2024, Milan] - The HEU-EFS Consortium has announced its creation. This four-year project, funded by the Innovative Health Initiative under the Horizon Europe Framework Programme and involving 22 public and private organisations across Europe (including EEA and Switzerland), aims to improve the early evidence generation pathway for medical device innovators. This will contribute to foster access to innovative technologies for patients with unmet needs, strengthen clinical development excellence, increase attractiveness of the EU, and support healthcare system' efficiencies.

Technological innovation in health care continues to expand to respond to increasing patient needs. However, the innovators' journey to bring such innovations to patients in a timely and harmonised manner has become long and complex. This is partly due to rising R&D costs, ever-stricter European regulations as well as a lack of harmonised approaches in Member States for early evidence generation.

This creates uncertainty for innovators and a decline in attractiveness of Europe, with delays in bringing these breakthrough technologies to the EU market. Ultimately patients in Europe are missing out on the latest medical technology innovations that could improve their prognosis and quality of life.

HEU-EFS aims to contribute to revering this trend. It will focus on the development of a **Harmonised Approach to EFS for Medical Devices in the European Union**. EFS are small clinical studies designed to gain early insights into an innovative medical technology early in the development process, before starting a larger clinical trial.

EFS represent a crucial first step in the evidence-generation pathway, allowing innovators to test their potentially breakthrough innovations and build a robust business case, and the healthcare systems

to better accompany the introduction of those new innovations that could bring value to patients in need.

Although the possibility to undertake EFS is formally recognized by the international standard, in the EU there is no procedure, standard or guideline dedicated to this type of study. This means that EFS are barely used in Europe, and early evidence generation is taking place elsewhere in the world.

HEU-EFS will develop and validate a robust, unified approach to allow early insights into technology evidence generation and to make the EU a conducive environment to undertake EFS. This will contribute to improving efficiency and effectiveness of product development, and ensure that the EU can attract investments into patient-centric, end-user efficient innovations, that bring value to the healthcare system.

"*The HEU-EFS program is a crucial step for positioning the EU as a worldwide epicenter for cutting-edge technologies. This strategic stance will draw investments in research and development, ideas, and expertise, thereby ensuring swift access to top-tier healthcare for patients*", says Rosanna Tarricone, Associate Professor at the Department of Social and Political Sciences and Associate Dean for Government, Health and Non-Profit Division SDA Bocconi, Bocconi University.

The consortium is funded by a €19 million grant from the Innovative Health Initiative (IHI), a public-private partnership between the European Commission and European life science industry associations. The project is coordinated by Bocconi University and the industry partners are led by Edwards Lifesciences. Engagement of wide range of stakeholders - universities, hospitals, contract research organizations, patient associations, health technology assessment agencies, MedTech companies and start-ups, regulatory authorities, notified bodies, professional associations and members of ethics committees – will drive a wide acceptability of the framework across countries and sectors.

According to Andrea Rappagliosi, Senior Vice President Public Affairs EMEA, Canada and LATAM at Edwards Lifesciences, "*The new HEU-EFS EU program will allow innovative MedTech companies to significantly contribute to improve access for patients in Europe. This will contribute to a triple win: a healthier population, a more efficient health and hospital system, and a more attractive and competitive EU*".

Notes to the editor

HEU-EFS consortium members

PUBLIC CONSORTIUM

PRIVATE CONSORTIUM

Supported by
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About HEU-EFS

EU Regulations on medical devices (MDs), in-vitro diagnostics, and Health Technology Assessment envisage a harmonised lifecycle approach for clinical evidence generation of MDs. To be effective this approach requires evidence generation plan to be developed since early stages of product development, by engaging all relevant stakeholders.

At present, in the EU there are no standardized procedural frameworks/guidelines/common reference standards for Early Feasibility Studies (EFS), clinical investigations allowed by ISO 14155:2020 conducted early in the development aiming to inform the product development. The ambition of the HEU-EFS project is to develop a harmonised framework for the EU EFS Program, as one integrated step of evidence generation cycle. Project objectives include: (1) conducting research/analysis on state of play (i.e., characteristics, challenges, impacts) of pre-market programs for MDs, including EFS; (2) building a sustainable network of stakeholders at EU/national level to promote/support EFS implementation; (3) developing a sound, widely applicable, harmonised EU methodology and formulating recommendations to uptake EFS; (4) undertaking pilots to test the proposed framework; (5) developing instruments to monitor the EFS performance; and (6) implementing a dedicated, sustainable, open access online portal dedicated to EFS methodological framework, best practices and network.

To achieve these goals, the **HEU-EFS** consortium has been designed including a wide range of relevant stakeholders: research organisations, HTA bodies, patient organizations, healthcare providers, SMEs (including health technology developers, legal experts, and a CRO), and 6 major private companies that are part of a pre-identified industry consortium. An Advisory Board made of competent authorities, notified bodies, medical and biomedical engineering professional associations, networks and industry trade association will collaborate to the success of the initiative.

This project has received funding from the European Union's Horizon Europe Research and Innovation programme under grant agreement No 101112185, project **HEU-EFS**.

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The project website: www.heuefs.eu.

Project duration: 1 October 2023 – 30 September 2027.