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

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

WP5 Program monitoring system

DELIVERABLE 5.1

Assessing the Performance of Early Feasibility Studies in the EU – Annex VI – Online Form #6

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe

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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.

HEU-EFS_WP5_Form #6_After CE Marking

Start of Block: Default Question Block

Form #6 - After CE Marking This online form is designed to collect data from sponsors participating in the EFS pilot after the CE marking. The data will be used to calculate performance metrics and generate a dashboard to monitor the performance of the EU EFS program. The form will take less than 15 minutes to complete. You can track your progress using the progress bar. Your responses will remain confidential, and no individual sponsors or medical device technologies will be identifiable. Should you have any questions or comments please contact Federico Facciolo (federico.facciolo@sdabocconi.it) or Francesco Malandrini (francesco.malandrini@sdabocconi.it).

Q0 Please enter the 8-digit code identifier you created and inserted in Form #1:

_____

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Q1 Please enter the exact date the medical device obtained the CE mark using the format DD-MM-YYYY (e.g., 01-01-2025)

_____

Q2 Which of the following EU/EEA countries is the medical device being adopted in clinical practice? Please check all that apply.

- [ ] Austria (Austrian Agency for Health and Food Safety (AGES) (1)
- [ ] Czech Republic (State Institute for Drug Control) (2)
- [ ] Denmark (Danish Health and Medicines Authority) (3)
- [ ] France (Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)) (4)
- [ ] Germany (Federal Institute for Drugs and Medical Devices (BfArM)) (5)
- [ ] Ireland (Health Products Regulatory Authority) (6)
- [ ] Italy (Ministero della Salute) (7)
- [ ] Netherlands (Health and Youth Care Inspectorate) (8)
- [ ] Poland (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) (9)
- [ ] Spain (Spanish Agency for Medicines and Medical Devices) (10)

Q3 Which of the following non-EU/EEA is the medical device being adopted in clinical practice? Please check all that apply.

- [ ] United States (FDA) (1)
- [ ] UK (MHRA) (2)
- [ ] Switzerland (Swissmedic) (3)
- [ ] New Zeland (MedSafe) (4)
- [ ] Georgia (RAMA) (5)
- [ ] Other (6)
- [ ] None of the above (7)

Q7 How many HTA recommendations has the medical device received since CE marking?”

_____

Q8 Please indicate the total number of HTA reports submitted or issued for this medical device:

_____

Q12 Were any cost-effectiveness studies conducted after CE marking for this medical device?

- O Yes (1)
- O No (2)

Q13 Please briefly describe any published economic evaluations and their outcomes:

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Q14 Has the medical device been included in a Coverage with Evidence Development scheme in any country?

O Yes (1)

O No (2)

Q15 Has the medical device received support from any special funding mechanisms after CE marking (e.g., innovation grants, hospital pilot budgets, national programs)?

O Yes (1)

O No (2)

Q16 How many Field Safety Notices (FSN) have been issued for this medical device?

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Q17 How many recalls from the market have been issued for this medical device?

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End of Block: Default Question Block

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