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 III – Online Form #3

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.

HEU-EFS_WP5_Form #3_Validation by NCA

Start of Block: Default Question Block

Form #3 - Validation by NCA(s) This online form is designed to collect data from sponsors participating in the EFS pilot after the application is reviewed by the NCA. 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 5 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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EFS APPROVAL

Q1 Please enter the exact date the EFS was approved using the format DD-MM-YYYY (e.g., 01-01-2025)

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Q2 Which of the following EU/EEA NCAs approved the EFS? 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 NCAs approved the EFS? 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 Were there any comments required by the NCAs during the application assessment?

- ○ Yes (1)
- ○ No (2)

Q8 Was the EFS application rejected?

- ○ Yes (1)
- ○ No (2)

Display this question:

If Was the EFS application rejected? = Yes

Please describe the reasons or grounds provided by the NCA for rejecting the application:

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ETHICS COMMITTEES APPROVAL

JS

Q9 Please list all ethics committees in the EU involved in the EFS, along with the submission date and the approval date for each committee. Use one line per ethical committee entry. If you have more than committee to report, please click on "Add another committee." Report your information using the following format: Ethical Committee Name, Date of Submission (DD-MM-YYYY), Date of Approval (DD-MM-YYYY). For example: ABC Ethical Committee, 15-01-2025, 30-01-2025

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End of Block: Default Question Block

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