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 IV – Online Form #4

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 #4_EFS pilot

Start of Block: Default Question Block

Form #4 - EFS Pilot This online form is designed to collect data from sponsors participating in the EFS pilot after the start of the EFS pilot. 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:

_____

Page Break

Q1

What was the total number of patients enrolled in the EFS? Please report the number of all patients who were ever enrolled, regardless of duration or withdrawal status.

_____

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Q2 Please list all clinical sites in the EU involved in the EFS, along with the contractual signature date, the site initiation visit date, and the first patient enrollment date for each site. Use one line per clinical site entry. If you have more than one site to report, please click on "Add another site." Report your information using the following format: Clinical Site Name, Date of Contractual Signature (DD-MM-YYYY), Date of Site Initiation Visit (DD-MM-YYYY), Date of First Patient Enrolled (DD-MM-YYYY). For example: ABC Hospital, 01-01-2025, 15-01-2025, 30-01-2025

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Page Break

EFS STATUS

Q3 Did any patients withdraw from the EFS before completing the study protocol?

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

Q4 Was the EFS terminated, withdrawn, or suspended? If yes, why?

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

Display this question:
If Was the EFS terminated, withdrawn, or suspended? If yes, why? = Yes

Q5 Did the sponsor conduct additional pre-market clinical investigations after the EFS was terminated, withdrawn, or suspended? If yes, which ones?

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

Q6 Did the EFS transition to a subsequent pre-market clinical investigation?

- O Yes (please indicate what type of study, e.g., pivotal study) (1) _____
- O No (2)

End of Block: Default Question Block

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