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 V – Online Form #5

COCIR Advancing Healthcare · efpia · EuropaBio · 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 #5_After subsequent pre-market study following the EFS pilot

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Form #5 - After subsequent pre-market study following the EFS pilot This online form is designed to collect data from sponsors participating in the EFS pilot that have conducted subsequent pre-market clinical investigations following 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:

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Q1 Please list all clinical sites in the EU involved in subsequent pre-market clinical investigations following the EFS pilot, 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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