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 II – Online Form #2

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 #2_Application to NCA

Start of Block: Default Question Block

HEU-EFS Form #2 - Application to NCA(s) This online form is designed to collect data from sponsors participating in the EFS pilot after the application is submitted to 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 10 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 APPLICATION & STUDY DETAILS

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

_____

Q2 Please select the option that describes the EFS based on the number of countries and clinical sites involved:

- ○ Single-country, single-centre (1)
- ○ Single-country, multi-centre (2)
- ○ Multiple-country, multi-centre (3)

X→

Q3 Which of the following EU/EEA NCAs was the EFS application submitted to? Please check all that apply. **If your answer is the same as in Form #1, please skip this question.**

- [ ] 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)

Q4 Which of the following non-EU/EEA NCAs was the EFS application submitted to? Please check all that apply. If none, please select "None of the above." **If your answer is the same as in Form #1, please skip this question.**

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

X→

Q5 For each EU/EEA country listed below, please indicate the number of clinical sites that participated in the EFS. If no clinical sites participated in a country, no input is required - the default '0' will remain."

	Austria (1)	Czech Republic (2)	Denmark (3)	France (4)	Germany (5)	Ireland (6)	Italy (7)	Netherlands (8)	Poland (9)	Spain (10)
Number of Clinical Sites (1)										

Display this question:

If Please select the option that describes the EFS based on the number of countries and clinical sit... = Multiple-country, multi-centre

Carry Forward Selected Choices from "Which of the following EU/EEA NCAs was the EFS application submitted to? Please check all that apply. If your answer is the same as in Form #1, please skip this question."

Q6 What was the leading NCA in the EFS assessment?

- 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)

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EARLY DIALOGUE - TO BE DISCUSSED

Q7
Did the sponsor participate in an Early Dialogue with the NCA?

- ○ Yes (1)
- ○ No (2)
- ○ I don't know / Not sure (3)

Display this question:
If Did the sponsor participate in an Early Dialogue with the NCA? = Yes

Q8 What was the modality of the Early Dialogue with the NCA? Please check all that apply.

- ☐ Email correspondence (1)
- ☐ Phone call(s) (2)
- ☐ Online video meeting(s) (3)
- ☐ In-person meeting(s) (4)
- ☐ Other (please specify): (5) _____
- ☐ I don't know / Not sure (6)

Display this question:
If Did the sponsor participate in an Early Dialogue with the NCA? = Yes

Q9 Which of the following topics were discussed during the Early Dialogue with the NCA? Please check all that apply.

- [ ] EFS eligibility criteria (1)
- [ ] Sponsor competencies (2)
- [ ] Technical documentation (3)
- [ ] Involvement of Ethics Committees (4)
- [ ] Need for experts at NCA level (5)
- [ ] Clinical site or investigator participation (6)
- [ ] Other (please specify): (7) _____
- [ ] I don't know / Not sure (8)

Display this question:
If Did the sponsor participate in an Early Dialogue with the NCA? = Yes

Q10 Was the Early Dialogue with the NCA helpful in streamlining the EFS application process?

- ○ Yes (1)
- ○ No (2)

Display this question:
If Was the Early Dialogue with the NCA helpful in streamlining the EFS application process? = Yes

Q12 In your opinion, what were the benefits of the Early Dialogue for the sponsor?

_____

_____

_____

_____

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DEVICE INFORMATION & PATIENT INVOLVEMENT

Q13

What is the risk classification of the device used in the EFS?

- ○ Class I (1)
- ○ Class IIA (2)
- ○ Class IIB (3)
- ○ Class III (4)

Q14 What is the therapeutic area that the EFS falls under?

- ○ Circulatory system (cardiovascular / lymphatic) (1)
- ○ Endocrinology and diabetes (2)
- ○ Gastroenterology and hepatology (3)
- ○ General and plastic surgery, dentistry (4)
- ○ Nephrology and urology (5)
- ○ Neurology (6)
- ○ Obstetrics and gynecology (including reproductive health) (7)
- ○ Ophthalmology (8)
- ○ Orthopedics, traumatology, rehabilitation (9)
- ○ Respiratory, anesthesiology, intensive care (10)
- ○ Other (11) _____

Q15 Did the EFS include the assessment of health-related quality of life through patient-reported outcome measures (PROMs), or not?

- ○ Yes (1)
- ○ No (2)

Q16 Did the EFS include the assessment of health-related quality of life through patient-reported experience measures (PREMs), or not?

- ○ Yes (1)
- ○ No (2)

End of Block: Default Question Block

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